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Evidence for Better Lives Study: A comparative birth-cohort study on child exposure to violence and other adversities in eight low- and middle-income countries – Foundational Research.

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3 **Evidence for Better Lives Study: A comparative birth-cohort study on child exposure to**
4 **violence and other adversities in eight low- and middle-income countries – Foundational**
5 **Research.**
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ABSTRACT

Introduction. Violence against children is a health, human rights and social problem affecting approximately half of the world's children. Its effects begin at pre-natal stages with long-lasting impacts on later health and wellbeing. The *Evidence for Better Lives Study* (EBLS) aims to produce high-quality longitudinal data from cities in eight low- and middle- income countries (LMICs) – Ghana, Jamaica, Pakistan, the Philippines, Romania, South Africa, Sri Lanka, and Vietnam – to support effective intervention to reduce violence against children. EBLS-Foundational Research tests critical aspects of the planned EBLS, including participant recruitment and retention, data collection and analysis. Alongside epidemiological estimates of levels and predictors of exposure to violence and adversity during pregnancy, we explore mechanisms that may link exposure to violence to mother's biological stress markers and subjective well-being.

Methods and analyses. EBLS-FR is a short longitudinal study in a sample of 1,200 pregnant women. Data are collected during the last trimester of pregnancy and 2-6 months after birth. The questionnaire for participating women has been translated into nine different languages. Measures obtained from mothers include, among others, mental and physical health, attitudes to corporal punishment, adverse childhood experiences, pre-natal intimate partner violence (p-IPV), substance use, and social/community support. Hair and dry blood spot (DBS) samples are collected from the pregnant women to measure stress markers. To explore research participation among fathers, EBLS-FR recruits 300 fathers in Philippines and Sri Lanka.

Ethics and dissemination. Ethics approvals have been granted for this study by all recruiting sites and universities in the project. Results will be disseminated through journal publications, conferences and seminar presentations involving local communities, health services and other stakeholders. Findings from this work will help to adjust the subsequent stages of the EBLS project.

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3 **Key words:** Peri-natal intimate partner violence, low- and middle-income countries, child
4 development, violence exposure, cross-cultural violence research, children's rights, violence
5 against women and children, violence prevention, perinatal and childhood adversity.
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13 **STRENGTHS AND LIMITATIONS**

- 14 - Evidence for Better Lives-Foundational Research is designed to inform a large-scale,
15 birth cohort study in eight cities across the world.
 - 16 - Data collection instruments, recruitment strategies, and data management procedures
17 are implemented and tested to collect comparable data on exposure to violence.
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 - 19 - Participants have been selected using a non-probabilistic sampling strategy.
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- Generalisation to the broader underlying population is limited.

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3 Around half of children worldwide experience some form of interpersonal violence (1).
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5 Previous evidence suggests that exposure to violence interferes with children's neurological
6
7 and socio-emotional development, contributes to lasting behavioural problems and has lifelong
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9 effects on well-being, health, and productivity (2-6). While the negative impact of violence has
10
11 been extensively documented, less is known about the effect of prenatal exposure to prenatal
12
13 intimate partner violence (p-IPV) at early stages of child development. Recent research
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15 suggests that exposure to IPV during the prenatal period can be linked to a number of morbid
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17 conditions such as antepartum haemorrhage (11), low birth weight, preterm delivery (4) and
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19 other indices of poor foetal health (7-10). While the mechanism explaining these outcomes
20
21 remain unclear, multiple possible pathways linking p-IPV with child development outcomes
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23 have been suggested, such as via mental illness, substance use, healthcare underutilisation,
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25 poor emotional attachment to the foetus, maternal stress, systemic inflammation and the
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27 regulation of specific genes relevant to, for example, the functioning of the hypothalamic-
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29 pituitary-adrenal axis (12, 13). Research in humans and other mammals suggest that exposure
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31 to dangerous levels of cortisol can have long-lasting impact on multiples areas of the brain,
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33 affecting, for instance, memory, verbal IQ, and behaviour (10,14).
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42 The implementation of preventive policies informed by data has been proven to contribute to
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44 the reduction of violence against children (15). However, to date, most research into violence
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46 during the first years of children's lives has been conducted using cross-sectional, retrospective
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48 designs in affluent societies (16, 17). Little is known from low- and middle-income countries
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50 (LMICs), where most of the world's children live and where resources to address these
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52 problems are limited (18,19).
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3 In this context, the *Evidence for Better Lives Study* (EBLS) aims to produce high-quality
4 evidence from non-western societies to support effective strategies to reduce violence against
5 children from pregnancy onwards. It involves an interdisciplinary impact and capacity-building
6 programme of longitudinal research based in eight cities chosen to reflect the diversity of
7 cultural, social and economic conditions across the globe. EBLS is an ambitious research
8 programme developed in four main stages (see Figure 1), including an initial scoping exercise
9 (December 2015), a feasibility study (October 2016-March 2018), the current foundational
10 research (July 2018-December 2019) and a full study expected to start in 2020.
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28 *FIGURE 1 ABOUT HERE*

29 Four features make EBLS-Foundational Research (FR) a significant advance on previous
30 studies. First, it recruits pregnant women in the third trimester of pregnancy, measuring
31 prenatal exposures to violence and other adversities when they are happening and thereby
32 overcoming the limitations of using retrospective recall (20, 21).
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40 Second, the longitudinal design of the study allows researchers to collect information on the
41 same families over time, a method that is uniquely well placed to illuminate issues that affect
42 children's development, both in terms of individual and family-level factors, and also higher-
43 level influences, such as changing policies and social norms related to violence and abuse (22,
44 23). Longitudinal data collection yields important information on factors which may form part
45 of the causal chain leading to favourable/unfavourable outcomes. In doing so, they provide
46 essential evidence for prevention knowledge and policy-making (24-27).
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3 Thirdly, EBLS-FR intends to address the lack of longitudinal studies examining violence in
4 LMICs with analogous sampling and measurement to allow comparisons across locations (28).
5
6 Without the comparable methods used for longitudinal data collection in multiple settings, it is
7
8 difficult to make cross-cultural comparisons of associations between exposures and outcomes
9
10 (29). Furthermore, although it is widely accepted that a foetus is influenced by the environment
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12 from conception and that the period from conception to age 2-3 is critical for development (30),
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14 few cohort studies have started in pregnancy, particularly in LMICs (31).
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21 Fourthly, a distinctive component of EBLS-FR is to engage fathers and male partners of the
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23 participants and learn more about how they can be motivated to participate in research. Extant
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25 research has linked father involvement in parenting to a number of crucial child outcomes, such
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27 as better infant cognitive development, more positive relationships with peers, better
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29 psychosocial adjustment as well as greater academic achievement (32). Conversely, psychiatric
30
31 disorders and violent behaviour of fathers, both inside and outside the family, can increase the
32
33 risk of psychological and developmental difficulties in children (33, 34). Fathers' participation
34
35 rates in birth cohort studies have been reported as lower than mothers'; however, birth-cohort
36
37 studies have traditionally invested less in the recruitment and retention of fathers (31,35,36).
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39 Hence, EBLS-FR has recruited fathers in two sites, to gain further insight into engaging them
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41 in developmental research as well as to run an initial examination of the fathers' characteristics
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43 and their associations with maternal and child wellbeing.
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51 In sum, EBLS will have the potential to influence local and international policies to prevent
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53 exposure to violence. It can also promote cross-site and global learning about how families and
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55 communities in different societies support their children to achieve their full developmental
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57 potential. EBLS-FR serves as a critical step towards generating such evidence for violence
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3 prevention by testing rigorous and comparable ways to collect multi-country longitudinal data
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5 starting from pregnancy.
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10 **Study aims**

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12 This protocol outlines the motivation and methods for the EBLS-FR, developed as a pilot to
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14 inform EBLS and examine the key uncertainties in the project design (37, 38). The aims of the
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16 EBLS-FR are:
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19 1. To develop and test strategies of recruiting pregnant women and following them up
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21 during the perinatal period across eight EBLS-FR sites.
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24 2. To assess the feasibility of fathers' and male partners' participation in the study.
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27 3. To test the strategies to collect, manage and analyse comparable high-quality data
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29 across the eight EBLS sites, including questionnaires and biological samples.
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32 4. To produce initial sample prevalence estimates of key indicators, such as prenatal
33
34 exposure to violence, women's levels of well-being, stress, depressive symptoms, pre-
35
36 and peri-natal complications, and to describe the characteristics of their male partners.
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39 5. To explore associations of the key indicators reported by mothers and fathers with
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41 maternal and birth outcomes.
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44 6. To build and strengthen local research capacity for longitudinal research by
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46 coordinating skill development opportunities and establishing local and international
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48 collaborative networks that include early career researchers.
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51 7. To enhance engagement with policy makers, community members, and other
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53 stakeholders and ensure that future stages of EBLS are designed to produce relevant
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55 knowledge and strategies to support efforts to address violence against children in all
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57 study sites.
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DESIGN

EBLS-FR is a prospective birth cohort study that targets 1,200 pregnant women (150 in each of eight sites) and 300 fathers (150 in two sites) in different cultural contexts across the world. Measurements are carried out during the third trimester of pregnancy and when the child is aged two to six months. The EBLS-FR protocol for recruitment and collection of data has been approved by the Ethics Boards of all universities involved in the project (see section declarations for more detail).

Study settings

Participating sites were selected according to the following criteria: i) country status of a low- or middle-income economy, ii) representation of different regions of the world, iii) a political environment receptive to research-based evidence, iv) the presence of local research teams with the expertise and willingness to conduct comparative research and engage in advocacy based on the findings, and v) existing links of the research teams with local prenatal healthcare services to facilitate access to the target sample. In 2017, the participating sites and associated research teams were decided as follows (see Figure 2): Valenzuela (University of the Philippines, Philippines), Hue (Hue University, College of Medicine and Pharmacy, Vietnam), Ragama (University of Kelaniya, Sri Lanka), Tarlai Kalan (Health Services Academy, Pakistan), Cluj-Napoca (Babes-Bolyai University, Romania), Worcester (Universities of Cape Town and Stellenbosch, South Africa), Koforidua (University of Ghana, Ghana), and Kingston (University of the West Indies, Jamaica).

FIGURE 2 ABOUT HERE

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3 The sites were chosen to reflect the heterogeneity of social and cultural conditions across major
4 world regions: the Caribbean, Europe, Sub-Saharan Africa, the Indian Subcontinent and South-
5 East Asia. An overview of several international indices provides an account of such diversity
6 (See Table 1). For instance, a comparison of the homicide rates in each site (i.e., rate of
7 intentional homicide per year per 100,000 inhabitants), suggests that while Romania, Sri Lanka
8 and Vietnam report rates under the global average (6.4 per 100,000 population), Jamaica
9 displays a rate of violence almost seven times higher than the global average (39). The Gender
10 Inequality Index (GII) shows that Vietnam and Pakistan report the lowest and the higher rates
11 of inequalities respectively in reproductive health, education, political representation and
12 access to the labour market (40). Variation is also observed in other cross-comparative indexes
13 such as GDP, Crude Birth Rates and percentage of population aged 0-14 years.
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31 *TABLE 1 ABOUT HERE*
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34 Capturing this diversity across the sites is critical for establishing how similar (and therefore
35 generalisable and universal) the conditions are that lead to violence against women and
36 children in different countries, and for demonstrating the consistency of their impact on
37 children's long-term development. It is also crucial for understanding the cultural, contextual
38 and policy factors that may lead to differences in risk of violence, and its adverse effects on
39 child development. The diverse samples also offer opportunities to identify site-specific
40 features that may be protective (50).
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52 **Sampling strategy**
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54 Based on the time and resources allocated for this project, the decision was taken to use
55 convenience sampling of participants within sites – a non-probabilistic strategy that allows a
56 consecutive selection of participants in order of appearance (51). Since we aim to achieve a
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3 sample that involves diverse social backgrounds within the study area, each local team attempts
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5 to target a specific number of private and public prenatal medical services.
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10 **Study participants**

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12 *Pregnant women.* The EBLS-FR sample comprises 150 pregnant women recruited from health
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14 centres in each of the eight sites (N=1,200 total). All women attending check-ups in the selected
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16 clinics/hospitals are eligible if they satisfy the following three criteria: i) in the third trimester
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18 of their pregnancy (i.e., weeks 29-40), ii) aged over 18 when signing the informed consent
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20 form, and iii) having their main residence within the study's defined geographical area.
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27 *Fathers.* Due to resource constraints, a sample of 150 fathers is recruited in only two of the
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29 EBLS-FR sites, that is, Sri Lanka and the Philippines (N=300 total). All women who consent
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31 to participate in EBLS-FR in Sri Lanka and the Philippines are asked about the possibility of
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33 their husband or partner participating in the study. To be eligible, fathers need to meet the
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35 following three criteria: i) being the father figure to the baby, although not necessarily the
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37 biological father; ii) aged over 18 when signing the informed consent, and iii) having their
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39 main residence within the study's defined geographical area.
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44 **Recruitment, screening, consent and incentives**

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46 *Recruitment.* Trained female fieldworkers approach pregnant women directly at local health
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48 services during antenatal check-ups. When the direct approach is not feasible, potential
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50 participants are first approached by the treating clinician (e.g., nurse, midwife, obstetrician),
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52 who briefly presents the research project and asks the woman if she is willing to meet with
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54 EBLS-FR representatives. Fathers are invited to take part in the study only if the pregnant
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56 woman provides written consent to their inclusion.
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3 *Screening and consent.* Pregnant women and fathers expressing interest in the EBLS-FR are
4 invited to answer a brief screening questionnaire to establish their eligibility. If eligible, they
5 are invited to provide written informed consent. Information sheets, consent forms and
6 questionnaires are translated into the most common languages spoken by the participants. If
7 the participant cannot read, versions of the information sheet and consent forms are played by
8 audio recording or read out aloud. As suggested by the World Health Organization's (WHO)
9 Research Ethics Committee¹, the consent of participants who cannot write is obtained via
10 alternative means (e.g., audio recording or participant's thumbprint). The number of eligible
11 participants who are approached but do not show interest in the study is also recorded, along
12 with any reasons for non-participation, if provided.
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28 When both the woman and her husband/partner participate, they are interviewed separately to
29 ensure confidentiality (52).
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35 *Incentives.* All study participants are offered a token of appreciation. Each local team
36 determines the specific incentive in consideration of cultural and local expectations, as well as
37 the corresponding ethical rules. In all cases, the incentive is approximately equivalent to the
38 hours spent in the study, reimbursed at minimum wage in the site. In addition, participants are
39 offered a reimbursement of travel expenses to facilitate the access of participants who could be
40 underrepresented due to difficulties in paying for transport (53, 54).
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59 ¹ http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf
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Data collection

Data collection has been planned to be implemented from February to December 2019. To ensure comparability of measures across sites (55), the EBLS-FR team has developed a set of standardised questionnaires.

The EBLS questionnaires were first developed in English and then translated into nine different languages². With small modifications, the process of translation has followed the guidelines suggested by the WHO³. Only minor adjustments have been made to ensure that measures are relevant in each location (e.g., which ethnicities are recorded).

Data are collected by fieldworkers who have received standardised training covering topics such as recruitment, consent, data collection and storage procedures, principles of research ethics, referral procedures, and management of risk and difficult situations in the field (e.g., participant distress or unsafe situations). Special emphasis has been put on skills and strategies to collect data on violence against women in diverse cross-cultural settings (56). All these topics are also covered in a fieldworker handbook specifically developed for EBLS-FR.

Pregnant women: Questionnaires and instruments.

Questionnaire. The questionnaire completed by pregnant women is a mix of Computer-Aided Personal Interviews (CAPI), and Computer-Assisted Self-Interviewing (CASI) for the more sensitive items (i.e., intimate partner violence, adverse childhood experiences and substance use). To facilitate access for expectant mothers with low levels of literacy, Audio-Supported Self-Completion Interviewing (A-CASI) has been programmed.

² Urdu, Afrikaans, IsiXhosa, Romanian, Filipino (Tagalog), Sinhala, Tamil, Vietnamese and Twi

³ http://www.who.int/substance_abuse/research_tools/translation/en/

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3 In EBLS-FR, data from participating women are collected at two time points. The baseline
4 assessment is completed when the women are in the third trimester of their pregnancy. The
5 baseline assessment takes approximately 120 minutes, involving the completion of a 210-item
6 questionnaire and the collection of biological samples. Subsequently, a brief follow-up
7 assessment is conducted with the mother when the child is at least two months old. The follow-
8 up assessment takes approximately 20 minutes and involves the completion of a 22-item
9 questionnaire. It also helps to test the process of re-contacting participants and retaining them
10 post-birth.
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24 *Measures.* Measures for pregnant women include items on demographic factors,
25 socioeconomic status, prenatal health and reproductive history, adverse childhood experiences,
26 community and social support, mental health and other psychological traits, as well as prenatal
27 maternal attachment to the unborn child. The follow-up measures collect data on mothers'
28 mental health, child well-being and birth memories (see Table 2).
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38 Informed by a literature review developed by the EBLS consortium (13), we have identified
39 salient factors that may relate to the predictors and consequences of exposure to violence in the
40 perinatal period. For reasons of space, only the main measures used to capture these factors are
41 described in the following paragraphs.
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49 *Prenatal Intimate Partner Violence (p-IPV).* P-IPV is measured using a scale extracted from
50 the WHO's multi-country study on women's health and domestic violence against women (56).
51 We use six items to capture physical violence (e.g., I was hit with a fist or something else that
52 could hurt) four items to measure emotional abuse (e.g., I was insulted or made feel bad about
53 myself); and three items for sexually abusive behaviours (e.g., I was physically forced to have
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3 sexual intercourse when I did not want to). A four-point Likert scale (i.e., never, once, a few
4 times, many times) allows the participant to report the frequency of exposure to such
5 experiences over the last six months. Questions have been validated in multi-racial, ethnic
6 populations and in pregnant women and therefore have appropriate psychometric properties
7 (57, 58). Exposure to p-IPV is collected using A-CASI as this approach has been demonstrated
8 to facilitate the disclosure of IPV when compared with face-to-face interviews and self-
9 administered written screens (59,60).

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22 *The Perceived Stress Scale (PSS)*. The PSS, developed by Cohen and Williamson (61), was
23 designed to measure the degree to which respondents appraise aspects of their own life
24 experiences as unpredictable, uncontrollable and emotionally overwhelming. The scale
25 includes 10 items (e.g., feeling one could not cope with all the things that one had to do) and
26 responses are provided using a four-point Likert scale (i.e., *not at all, several days, more than*
27 *half the days, nearly every day*). The PSS has superior psychometric properties when used with
28 a normative population, when compared with alternative scales and also when administered to
29 pregnant mothers (62, 63).

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42 *Hair samples*. Each pregnant woman is asked to provide a sample of hair cut from the posterior
43 vertex area (where growth rates are least variable), as close as possible to the scalp. Hair
44 samples produce measures of cortisol concentrations, an index of accumulated stress exposure
45 validated for use in pregnant women (64). Since each centimetre of hair represents a month's
46 period of exposure, it is possible to quantify cumulative physiological stress during the second
47 trimester of pregnancy. Previous research has suggested the second trimester of pregnancy in
48 particular as a critical period for stress exposure (e.g., 10).

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3 *Blood samples.* Dried blood spots are collected by applying a few drops of blood, drawn by
4 lancet from a finger, onto medical-grade, absorbent filter paper. Blood samples are analysed
5 for a biomarker of inflammation (C-reactive protein, C-RP). We will relate these biomarkers
6 to information on violence exposure and maternal outcomes in order to illuminate the
7 biological mechanisms underpinning the effects of violence and adversity exposure on
8 maternal and birth outcomes (65-67).
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17 *TABLE 2 ABOUT HERE*
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22 *Father's questionnaires.* Data are collected using a paper and pencil questionnaire at two
23 different time points. As in the case of pregnant women, the baseline assessment is completed
24 during the third trimester of the woman's pregnancy. Interviews take approximately 40
25 minutes, involving the completion of a 90-item questionnaire. The follow-up assessment
26 encompasses 37 items to be completed in about 20 minutes.
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35 *Measures.* The *father's questionnaire* requests information on demographic factors,
36 socioeconomic status, adverse childhood experiences, partner support, mental health,
37 psychological traits and substance use. These items are similar to those used in the mother's
38 questionnaire. However, the questionnaire for fathers includes some specific items measuring
39 attitudes to fatherhood, participation in antenatal care visits, and the father's participation in
40 household activities (89-91). The follow-up assessment asks the participant to complete items
41 on paternal attitudes, paternal enjoyment and paternal confidence after birth (See Table 3).
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Data analysis

Descriptive statistics will include frequency of p-IPV, associations between exposure to violence and the putative outcomes (e.g. C-RP, childbirth weight, maternal mental health). At the same time, candidate mediators and moderators in exposure-outcome associations will be explored. We will conduct measurement invariance analysis and make comparisons on latent variables across the sites. Statistical techniques will thus include linear and generalised linear models, structural equation models and multi-group item response theory and/or factor models. If available, EBLS-FR data will be compared with prevalence in the population. For instance, frequencies of intimate partner violence, perinatal depression and levels of stress or substance use will be compared with the prevalence of the same risk factors in the city's population.

All primary analyses will be pre-registered using open-access resources, such the Open Science Framework (<https://osf.io/>). After a period of embargo, data will be available for the use of the international scientific community. Local stakeholders will be consulted to prioritise additional research questions to be answered with the data.

Confidentiality and data protection

In EBLS-FR all participants are assigned a numeric identification (ID) code. The personally identifiable data, including contact details, are kept separate from all data collected via questionnaires to ensure confidentiality. EBLS uses a number of technical and organisational measures to maintain security, confidentiality, completeness and integrity of the data associated with the study. This includes adherence to the requirements on collection and processing of personal identifiable data as stipulated by the General Data Protection Regulation (GDPR) EU 2016/679.

Data quality and data management

Multiple strategies are utilised to enhance the quality of data collection. They include training of project workers in the administration of questionnaires, training of clinical and project staff in the measurement of specific indices and validation checks for consistency and completeness of routinely collected data. Lab analyses will be subject to strict quality controls based on established protocols. Data will be screened for out-of-range or otherwise implausible values before finalising the dataset.

Organisational structure

EBLS comprises a consortium of 15 co-investigators who are collectively responsible for conducting the research. Given the multi-disciplinary nature of violence and its impacts on child development, the team includes expertise in disciplines such as developmental psychopathology, paediatrics, criminology, and public health. The organisational structure includes a coordinating team at the University of Cambridge. In each of the sites, a collaborative research team has been established to implement the EBLS-FR study.

DISCUSSION

Ending violence against children and dealing with its consequences requires that we develop a better understanding of the factors that foster child development in various societies and identify the risk factors that need to be addressed most urgently. EBLS is designed to make novel contributions to these key questions by drawing on parallel data collection in eight sites, thus enabling both within- and cross-country analyses. While the experience of conducting the EBLS-FR will illuminate the feasibility of procedures for the next stages, psychometric analyses will provide empirical information on the cross-cultural performance of the study's measures. Analyses of the EBLS-FR data will also provide initial estimates of the levels of

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3 exposure to adversity and the relationships between exposures and outcomes, as well as test
4 potential pathways and moderating factors.
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10 Conducting research in multiple regions will allow us to examine how findings generalise
11 across different socio-cultural and political contexts. To complement participants' reports of
12 their experiences and behaviours, the study will also include biological data collection to
13 examine biological pathways related to violence and health. This will allow us to test for the
14 first time the combined role of systemic inflammation and the HPA axis on mediating the links
15 between p-IPV and maternal and birth outcomes. It has been argued that highlighting the
16 biological effects of social issues (such as violence) can be particularly effective in motivating
17 policy change (e.g.,92). EBLS-FR data collection tools and datasets from eight countries can
18 also benefit the broader research community working on violence prevention.
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33 EBLS-FR has also been designed to foster strategic collaborations and knowledge exchange
34 and capacity building between researchers, communities and policy makers in order to link
35 research findings to policy actions. Future stages of EBLS will reveal the extent and
36 manifestations of exposure to violence in each site; they will identify the salience of risk and
37 protective factors for different groups and contexts; they will alert decision-makers to the short
38 and long-term consequences of violence against women and children that are not currently
39 addressed; and they will establish the essential basis for future actions. Such knowledge
40 exchange between researchers and governments is essential to establish and evaluate
41 prevention efforts and report on progress toward SDG violence reduction targets.
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56 Conducting a multi-site project poses both research design and management questions of how
57 to maintain comparability across countries, while also examining relevant issues that are only
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3 present in some of the contexts, such as child marriage. As reflected in the organisational
4 structure of the study, we believe that multi-country, multi-disciplinary projects require both a
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6 strong level of international coordination and collaborating local governance structures.
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For peer review only

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DECLARATIONS

Ethics approval and consent to participate

The EBLS protocol for recruitment and collection of data has been approved by the following ethics boards:

University of Cambridge, School of Social Sciences (18/180) and the Human Biology Research Ethics Committee (HBREC.2018.27)

University of the Philippines Manila – Research Ethics Board, UPMREB 2018-558-01

The Institutional Ethics Committee of Hue University of Medicine and Pharmacy, Vietnam, H2018/430

Faculty of Medicine, University of Kelaniya, Sri Lanka - Ethics Review Committee P/208/11/2018

National Bioethics Committee (NBC) Pakistan, 4-87/NBC-364/19/1487

Consiliul Stiintific – Universitatea Babes-Bolyai, Romania, 18.362/11.10.2018

University of Cape Town Department of Health, Western Cape Government, South Africa, WC_201911_009

Health Impact Assessment – Western Cape Government

Faculty of Health Sciences, University of Cape Town, South Africa. Human Research Ethics Committee, 057/2019.

Health Research Ethics Committee (HREC) at *Stellenbosch University, South Africa, N18/09/099*

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Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Competing interests

The authors have no financial interests related to the findings reported in this protocol.

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Authors' contributions

Sara Valdebenito helped to plan the methods for EBLS-FR, drafted the paper, and took the lead in revisions.

Aja Louise Murray, Claire Hughes, Adriana Baban, Asvini D. Fernando, Bernadette Madrid, Catherine L. Ward, Joseph Osafo, Michael P. Dunne, Siham Sikander, Susan Walker, Vo Van

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2
3 Thang, Mark Tomlinson, Pasco Fearon, Marguerite Marlow and Diana Taut helped to plan the
4 methods, reviewed multiple drafts of the paper, and approved the final version submitted.
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7
8 Deshanie Chathurika helped to develop the father questionnaire, reviewed multiple drafts of
9 the paper, and approved the final version submitted.
10
11

12 Yulia Shenderovich helped to draft some sections of the paper and contributed with the
13 revisions.
14
15

16
17 Manuel Eisner is the principal investigator, he articulated the scientific bases of the study,
18 reviewed multiple drafts of the paper, and approved the final version submitted.
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FIGURES

Figure 1. The four main stages of Evidence for Better Lives

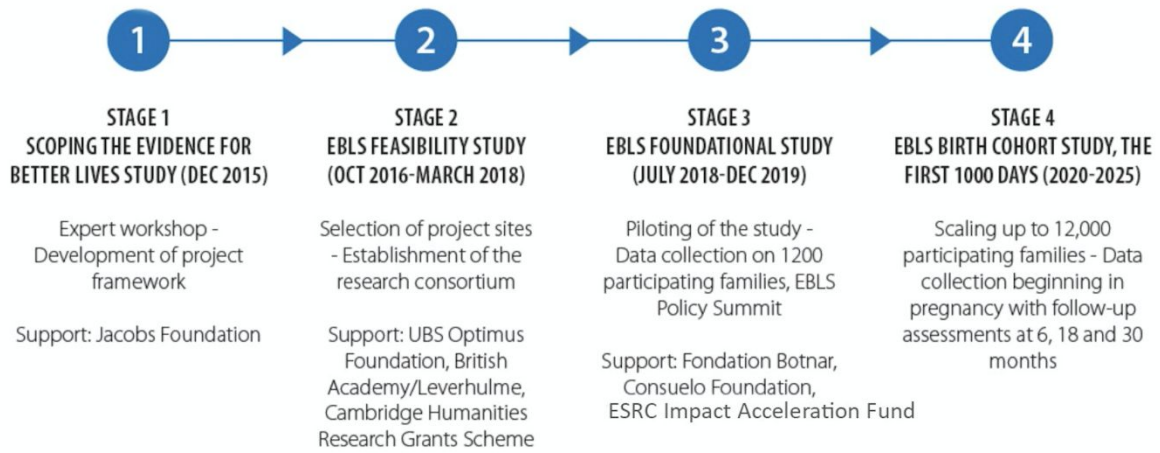


Figure 2. Evidence for Better Lives study sites



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TABLES

Table 1. EBLS sites: Selected country indicators

	Homicide rates ^a	Gender Inequality Index ^b	GDP in \$ (PPP) ^c	Crude birth rate ^d	% Population aged 0-14 ^e
Philippines	14.8	.427	8,935.3	23	32%
Vietnam	3.8	.304	7,434.77	17	23%
Sri Lanka	3.0	.354	13,449.99	15	24%
Pakistan	9.6	.541	5,543.99	28	35%
Romania	1.6	.311	26,595.44	10	15%
South Africa	33.1	.389	13,661.44	21	29%
Ghana	9.7	.538	4,738738.3	31	39%
Jamaica	39.1	.412	9,298.88	16	23%
Global	6.4	.441	17,971.072	19	26%

Sources: a. (41); b.(42); c. (43); d. (44); e. (45); f. (46); (47); (48); (49).

Table 2. EBLS-FR measures for mother's questionnaire

Measures	Sources	N° Items	Phase	Data collection strategy
Demographics	DHS (68) MacArthur Scale of subjective social status (69)	27	Baseline	CAPI
Prenatal health	Adapted from: The South Asian Birth Cohort (START) (70) Millennium Cohort Study (71)	20	Baseline	CAPI
Attitudes towards physical punishment	Attitudes towards spanking (72)	5	Baseline	CAPI
Community characteristics	Community characteristics scale – Adapted (73)	20	Baseline	CAPI
Adverse childhood experiences	WHO 2009, International ACE-IQ Questionnaire Adapted version (74)	19	Baseline	A-CASI
Intimate partner violence	WHO Multi-country Study on Women Health and Domestic Violence against Women (56)	13	Baseline	A-CASI
Partner supportiveness	Partner supportiveness/ relationship scale (75)	4	Baseline	CAPI
Social support	Social support scale (76)	13	Baseline	CAPI
Wellbeing	WHO-5 Well-Being Index (77)	5	Baseline	CAPI
Depression	PHQ9 (78)	9	Baseline and follow-up	CAPI
Suicidality	Suicidality item (79)	1	Baseline	CAPI

Stress	Perceived Stress Scale (80)	10	Baseline	CAPI
Aggression	The Brief Aggression Questionnaire (81)	12	Baseline	CAPI
ADHD symptoms	Adult ADHD symptoms -Adapted (82)	6	Baseline	CAPI
Self-control	Brief Self-Control Scale (83)	8	Baseline	CAPI
Substance use	Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) – Adapted version WHO ASSIST Working Group (84)	9	Baseline	A-CASI
Pregnancy related beliefs	Prenatal Attachment Inventory – Revised (85)	18	Baseline	CAPI
New-born health and well-being	Norwegian Mother and Child Cohort Study (MoBa) (86) Questionnaire for breastfeeding mothers (87)	8	Follow-up	CAPI
The mother's birth memories	The Birth Memories and Recall Questionnaire (88)	5	Follow-up	CAPI

Table 3. EBLs-FR measures for father's questionnaire

Measures	Sources	N° Items	Phase	Data collection strategy
Feelings about fatherhood (prenatal)	Adapted from the Avon Longitudinal Study of Parents and Children (89).	13	Baseline	Paper and pencil
Fathers' participation for antenatal care	(90,91)	7	Baseline Follow-up	Paper and pencil
Fathers' participation for household activities	Adapted from the Avon Longitudinal Study of Parents and Children (89).	8	Baseline Follow-up	Paper and pencil
Attitudes to fatherhood	Avon Longitudinal Study of Parents and Children and (89)	8	Follow-up	Paper and pencil
Paternal enjoyment	Avon Longitudinal Study of Parents and Children and Scourfield et al., (89)	5	Follow-up	Paper and pencil
Paternal confidence	Avon Longitudinal Study of Parents and Children and Scourfield et al., (89)	4	Follow-up	Paper and pencil
Activities with the new-born child	Avon Longitudinal Study of Parents and Children and Scourfield et al., (89)	6	Follow-up	Paper and pencil

BMJ Open

Evidence for Better Lives Study: A comparative birth-cohort study on child exposure to violence and other adversities in eight low- and middle-income countries – Foundational Research (Study Protocol).

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Keywords:	EPIDEMIOLOGY, MENTAL HEALTH, Prenatal diagnosis < OBSTETRICS, Child protection < PAEDIATRICS, Community child health < PAEDIATRICS

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3 **Evidence for Better Lives Study: A comparative birth-cohort study on child exposure to**
4 **violence and other adversities in eight low- and middle-income countries – Foundational**
5 **Research (Study Protocol).**
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ABSTRACT

Introduction. Violence against children is a health, human rights and social problem affecting approximately half of the world's children. Its effects begin at prenatal stages with long-lasting impacts on later health and well-being. The *Evidence for Better Lives Study* (EBLS) aims to produce high-quality longitudinal data from cities in eight low- and middle-income countries (LMICs) – Ghana, Jamaica, Pakistan, the Philippines, Romania, South Africa, Sri Lanka, and Vietnam – to support effective intervention to reduce violence against children. EBLS-Foundational Research tests critical aspects of the planned EBLS, including participant recruitment and retention, data collection and analysis. Alongside epidemiological estimates of levels and predictors of exposure to violence and adversity during pregnancy, we plan to explore mechanisms that may link exposure to violence to mothers' biological stress markers and subjective well-being.

Methods and analyses. EBLS-FR is a short longitudinal study with a sample of 1,200 pregnant women. Data are collected during the last trimester of pregnancy and 2-6 months after birth. The questionnaire for participating women has been translated into nine languages. Measures obtained from mothers will include, among others, mental and physical health, attitudes to corporal punishment, adverse childhood experiences, prenatal intimate partner violence (p-IPV), substance use, and social/community support. Hair and dry blood spot (DBS) samples are collected from the pregnant women to measure stress markers. To explore research participation among fathers, EBLS-FR is recruiting 300 fathers in the Philippines and Sri Lanka.

Ethics and dissemination. The study received ethical approvals at all recruiting sites and universities in the project. Results will be disseminated through journal publications,

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3 conferences and seminar presentations involving local communities, health services and other
4 stakeholders. Findings from this work will help to adjust the subsequent stages of the EBLS
5 project.
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12 **Key words:** Perinatal intimate partner violence, low- and middle-income countries, child
13 development, violence exposure, cross-cultural violence research, children's rights, violence
14 against women and children, violence prevention, perinatal and childhood adversity.
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20 21 22 **STRENGTHS AND LIMITATIONS**

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25 - The study is designed to inform a large-scale, birth cohort study in eight cities across
26 the world.
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29 - Evaluating training materials and tools developed will allow refinements and
30 improvements for the large scale study.
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33 - The study will enhance engagement with policymakers, community members, and
34 other stakeholders to support efforts to address violence against children in all study
35 sites
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38 - Data collection uses similar procedures to collect comparable data on exposure to
39 violence.
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42 - Participants are selected using a non-probabilistic sampling strategy. The
43 generalisation to the broader underlying population is limited.
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55 Around half of children worldwide experience some form of interpersonal violence (1).
56 Exposure to violence interferes with children's neurological and socio-emotional development,
57 contributes to lasting behavioural problems and has lifelong effects on well-being, health and
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3 productivity (1–4). While the negative impact of violence has been extensively documented,
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5 less is known about the effect of prenatal intimate partner violence (p-IPV) on early child
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7 development. Recent research suggests that exposure to IPV during the prenatal period is
8
9 linked to a number of morbidities such as low birth weight, preterm delivery (5) and other
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11 indices of poor foetal health (6–9). While the mechanisms explaining these outcomes remain
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13 unclear, multiple possible pathways linking p-IPV with child development outcomes have been
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15 suggested. These include mental illness, substance use, healthcare under-utilisation, poor
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17 emotional attachment to the foetus, maternal stress, systemic inflammation and the regulation
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19 of specific genes relevant to, for example, the functioning of the hypothalamic-pituitary-
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21 adrenal axis (10,11). Research in humans and other mammals suggests that exposure to
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23 dangerous levels of cortisol can have long-lasting impact on multiple areas of the brain,
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25 affecting, for instance, the child memory, verbal IQ and behaviour (9,12).
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33 Evidence-based preventive policies are known to contribute to the reduction of violence against
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35 children (13). However, to date, most research into violence during the first years of children's
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37 lives has been conducted using cross-sectional, retrospective designs in affluent societies
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39 (14,15). Little is known from low- and middle-income countries (LMICs), where most of the
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41 world's children live and where resources to address these problems are limited (1,16).
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47 In this context, the *Evidence for Better Lives Study* (EBLS) aims to produce high-quality
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49 evidence from non-western societies to support effective strategies to reduce violence against
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51 children from pregnancy onwards. It involves an interdisciplinary policy impact and capacity-
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53 building programme of longitudinal research based in eight cities chosen to reflect the diversity
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55 of cultural, social and economic conditions across the globe. EBLS is an ambitious research
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57 programme developed in four main stages (see Figure 1), including an initial scoping exercise
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3 (December 2015), a feasibility study (October 2016-March 2018), the current foundational
4 research (July 2018-December 2019) and a full study expected to start in 2020. While the first
5 two stages helped to articulate the aims of the project and to select the study sites, EBLS-FR
6 tests the main components for the full study (e.g., recruitment, data collection instruments,
7 translatis).

14
15 *FIGURE 1 ABOUT HERE*

16
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18 Four features make EBLS-Foundational Research (FR) a significant advance on previous
19 studies. First, it recruits pregnant women in the third trimester of pregnancy, measuring
20 prenatal exposures to violence and other adversities when they are happening and thereby
21 overcoming the limitations of using retrospective recall (17,18).

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Second, the longitudinal design of the study allows researchers to collect information on the
same families over time, a method that is uniquely well placed to illuminate issues that affect
children's development, both in terms of individual and family-level factors, and also higher-
level influences, such as changing policies and social norms related to violence and abuse
(19,20). Longitudinal data collection yields important information on factors which may form
part of the causal chain leading to favourable/unfavourable outcomes. Such studies provide
essential evidence for prevention knowledge and policy-making (21–23). For example,
longitudinal studies in Jamaica have found that limited stimulation of children in the home and
high levels of parental stress to be negatively related to child outcomes, including cognitive
function and behaviour (23). These findings guided the development of Jamaica's National
Parenting Policy, public messaging, and programmes for parents.

Third, EBLS-FR addresses the lack of longitudinal studies examining violence in LMICs with
analogous sampling and measurement to allow comparisons across locations (24). Without the
comparable methods used for longitudinal data collection in multiple settings, it is difficult to

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3 make cross-cultural comparisons of associations between exposures and outcomes (25).
4
5 Furthermore, although it is widely accepted that a foetus is influenced by the environment from
6
7 conception and that the period from conception to age 2-3 is critical for development (26), few
8
9 cohort studies in LMIC have started in pregnancy (27).
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14 Fourth, a distinctive component of EBLS-FR is to engage fathers and male partners of the
15
16 participants and learn more about how they can be motivated to participate in research. Extant
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18 research has linked father involvement in parenting to a number of crucial child outcomes, such
19
20 as better infant cognitive development, more positive relationships with peers, better
21
22 psychosocial adjustment as well as greater academic achievement (28). Conversely, psychiatric
23
24 disorders and violent behaviour of fathers, both inside and outside the family, can increase the
25
26 risk of psychological and developmental difficulties in children (29–31). While birth cohort
27
28 studies report lower participation rates in fathers than mothers, they have also traditionally
29
30 invested less in the recruitment and retention of fathers (27,32,33). Hence, EBLS-FR recruits
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32 fathers in two sites, to gain further insight into engaging them in developmental research as
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34 well as to run an initial examination of the fathers' characteristics and their associations with
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36 maternal and child well-being.
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45 In sum, a multi-country birth cohort study in LMICs, such as the planned EBLS, has major
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47 potential to influence local and international policies to prevent exposure to violence. It may
48
49 also provide invaluable opportunities for knowledge transfer by promoting inter-country and
50
51 global learning about how families and communities in different societies support their children
52
53 to achieve their full developmental potential. EBLS-FR serves as a critical step towards
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55 generating such evidence for violence prevention and the promotion of health early child
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3 development by testing rigorous and comparable ways to collect multi-country longitudinal
4 data starting from pregnancy.
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10 **Study aims**

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12 This protocol outlines the motivation and methods for the EBLS-FR, developed as a pilot to
13 inform EBLS, and examines the key uncertainties in the project design (34,35). The aims of
14 the EBLS-FR are:
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- 18
19 1. To develop and test strategies for recruiting pregnant women and following them up
20 during the perinatal period across eight EBLS-FR sites.
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24 2. To assess the feasibility of fathers' and male partners' participation in the study.
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28 3. To test the strategies to collect, manage and analyse comparable high-quality data
29 across the eight EBLS sites, including questionnaires and biological samples.
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33 4. To produce initial sample prevalence estimates of key indicators, such as prenatal
34 exposure to violence, women's levels of well-being, stress, depressive symptoms, pre-
35 and peri-natal complications, and to describe the characteristics of their male partners.
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39 5. To explore associations of the key indicators reported by mothers and fathers with
40 maternal and birth outcomes.
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- 43
44 6. To build and strengthen local capacity for longitudinal research by coordinating skill
45 development opportunities and establishing local and international collaborative
46 networks that include early career researchers.
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50 7. To enhance engagement with policy makers, community members, and other
51 stakeholders and ensure that future stages of EBLS produce relevant knowledge and
52 strategies to support efforts to address violence against children in all study sites.
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57 **DESIGN**

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3 EBLs-FR is a prospective birth cohort study that targets 1,200 pregnant women (150 in each
4 of eight sites) and 300 fathers (150 in each of two sites) in different cultural contexts across the
5 world. Measurements are carried out during the third trimester of pregnancy and when the child
6 is aged two to six months.
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14 **Study settings**

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18 Participating sites were selected according to the following criteria: i) country status of a Low-
19 Middle and Upper Middle income economy (36), ii) representation of different regions of the
20 world, iii) a political environment receptive to research-based evidence, iv) the presence of
21 local research teams with the expertise and willingness to conduct comparative research and
22 engage in advocacy based on the findings, and v) existing links of the research teams with local
23 prenatal healthcare services to facilitate access to the target sample. In 2017, the participating
24 sites and associated research teams were decided as follows (see Figure 2): Valenzuela
25 (University of the Philippines, Philippines), Hue (Hue University, College of Medicine and
26 Pharmacy, Vietnam), Ragama (University of Kelaniya, Sri Lanka), Tarlai Kalan (Health
27 Services Academy, Pakistan), Cluj-Napoca (Babes-Bolyai University, Romania), Worcester
28 (Universities of Cape Town and Stellenbosch, South Africa), Koforidua (University of Ghana,
29 Ghana), and Kingston (University of the West Indies, Jamaica).
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50 *FIGURE 2 ABOUT HERE*

51 The sites were chosen to reflect the heterogeneity of social and cultural conditions across major
52 world regions: the Caribbean, Europe, Sub-Saharan Africa, the Indian Subcontinent and South-
53 East Asia. An overview of several international indices provides an account of such diversity
54 (See Table 1). For instance, a comparison of the homicide rates in each site (i.e., rate of
55 intentional homicide per year per 100,000 inhabitants), suggests that while Romania, Sri Lanka
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3 and Vietnam report rates under the global average (6.4 per 100,000 population), Jamaica
4 displays a rate of violence almost seven times higher than the global average (37). The Gender
5 Inequality Index (GII) shows that Vietnam and Pakistan report the lowest and the highest rates
6 of inequalities respectively in reproductive health, education, political representation and
7 access to the labour market (38). Variation is also observed in other cross-comparative indexes
8 such as GDP, Crude Birth Rates and percentage of population aged 0-14 years.
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19 *TABLE 1 ABOUT HERE*
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22 Capturing this diversity across the sites is critical for establishing how similar (and therefore
23 generalisable and universal) the conditions are that lead to violence against women and
24 children in different countries, and for demonstrating the consistency of their impact on
25 children's long-term development. It is also crucial for understanding the cultural, contextual
26 and policy factors that may lead to differences in risk of violence, and its adverse effects on
27 child development. The diverse samples also offer opportunities to identify site-specific
28 features that may be protective (39).
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41 **Sampling strategy**

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43 Based on the time and resources allocated for this project, the decision was taken to use
44 convenience sampling of participants within sites – a non-probabilistic strategy that allows a
45 consecutive selection of participants in order of appearance (40). Since we aim to achieve a
46 sample that involves diverse social backgrounds within the study area, each local team attempts
47 to target a specific number of private and public prenatal medical services, when these exist.
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57 **Study participants**

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3 *Pregnant women.* The EBLS-FR sample comprises of 150 pregnant women recruited from
4 health centres in each of the eight sites (N=1,200 total). All women attending check-ups in the
5 selected clinics/hospitals are eligible if they satisfy the following three criteria: i) in the third
6 trimester of their pregnancy (i.e., weeks 29-40), ii) aged over 18 when signing the informed
7 consent form, and iii) having their main residence within the study's defined geographical area.
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17 *Fathers.* Due to resource constraints, only two sites have the capacity to test the father's
18 questionnaire. Sri Lanka and the Philippines plan to recruit a sample of 150 fathers each
19 (N=300 total). All women who consent to participate in EBLS-FR in Sri Lanka and the
20 Philippines are asked about the possibility of their husband or partner participating in the study.
21 To be eligible, fathers need to meet the following three criteria: i) being the father figure to the
22 baby, although not necessarily the biological father; ii) aged over 18 when signing the informed
23 consent, and iii) having their main residence within the study's defined geographical area.
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34 **Recruitment, screening, consent and incentives**

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37 *Recruitment.* Trained female fieldworkers approach pregnant women directly at local health
38 services during antenatal check-ups. When the direct approach is not feasible, potential
39 participants are first approached by the treating clinician (e.g., nurse, midwife, obstetrician),
40 who briefly presents the research project and asks the woman if she is willing to meet with
41 EBLS-FR representatives. Fathers are invited to take part in the study only if the pregnant
42 woman provides written consent to their inclusion. Note that as p-IPV is a risk factor for under-
43 utilisation of and delayed entry into antenatal care, our recruitment through antenatal clinics is
44 a limitation, in that it risks under-representing women experiencing abuse (41).
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57 *Screening and consent.* Pregnant women and fathers expressing interest in the EBLS-FR are
58 invited to answer a brief screening questionnaire to establish their eligibility. If eligible, they
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3 are invited to provide written informed consent. Information sheets, consent forms and
4
5 questionnaires have been translated into the languages spoken by the participants. If the
6
7 participant cannot read, versions of the information sheet and consent forms are played by
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9 audio recording or read out aloud. As suggested by the World Health Organization's (WHO)
10
11 Research Ethics Committee¹, the consent of participants who cannot write is obtained via
12
13 alternative means (e.g., audio recording or participant's thumbprint). The number of eligible
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15 participants who are approached but do not show interest in the study is also recorded, along
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17 with any reasons for non-participation, if provided.
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24 When both the woman and her husband/partner participate, they are interviewed separately to
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26 ensure confidentiality (42).
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31 *Incentives.* All study participants are offered a token of appreciation. Each local team
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33 determines the specific incentive in consideration of cultural and local expectations, as well as
34
35 the corresponding ethical rules (Table 2). In all cases, the incentive is approximately equivalent
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37 to the hours spent in the study, reimbursed at minimum wage in the site. In addition,
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39 participants are offered a reimbursement of travel expenses to facilitate the access of
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41 participants who could be underrepresented due to difficulties in paying for transport (43,44).
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45 *TABLE 2 ABOUT HERE*
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48 **Patient and public involvement**

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50 No patients will be involved. Study participants will be informed about study outcomes via
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52 websites of project partners and media reports. We are planning to produce a brief
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59 ¹ http://www.who.int/rpc/research_ethics/Process_seeking_IF_printing.pdf
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3 information sheet at the end of the foundational research for participants and a general
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5 audience.
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10 **Data collection**

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12 Data collection will be implemented from February to December 2019. To ensure
13 comparability of measures across the sites (45), the EBLS-FR team has developed a set of
14 standardised questionnaires.
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21 The EBLS questionnaires were first developed in English and then translated into nine different
22 languages². With small modifications, the process of translation has followed the guidelines
23 suggested by the WHO³. Only minor adjustments have been made to ensure that measures are
24 relevant in each location (e.g., which ethnicities are recorded).
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33 Data are collected by fieldworkers who have received standardised 40-hours of in-person
34 training covering topics such as recruitment, consent, data collection and storage procedures,
35 principles of research ethics, referral procedures, and management of risk and difficult
36 situations in the field (e.g., participant distress or unsafe situations). Special emphasis was
37 given to skills and strategies for addressing women experiencing violence (46–48). The
38 contents of the training were developed and approved by the EBLS consortium and they are
39 described in the fieldworker handbook specifically developed for EBLS-FR. Training at each
40 site was carried out by the local research coordinator who had been previously trained by the
41 Cambridge team.
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59 ² Urdu, Afrikaans, IsiXhosa, Romanian, Filipino (Tagalog), Sinhala, Tamil, Vietnamese and Twi

60 ³ http://www.who.int/substance_abuse/research_tools/translation/en/

Pregnant women: Questionnaires and instruments.

Questionnaire. The questionnaire completed by pregnant women is a mix of Computer-Aided Personal Interviews (CAPI), and Computer-Assisted Self-Interviewing (CASI) for the more sensitive items (i.e., intimate partner violence, adverse childhood experiences and substance use). To facilitate access for expectant mothers with low levels of literacy, Audio-Supported Self-Completion Interviewing (A-CASI) has been programmed.

In EBLS-FR, data from participating women are collected at two time points. The baseline assessment is completed when the women are in the third trimester of their pregnancy. The baseline assessment takes approximately 120 minutes, involving the completion of a 210-item questionnaire and the collection of biological samples. Subsequently, a brief follow-up assessment is conducted with the mother when the child is at least two months old. The follow-up assessment takes approximately 20 minutes and involves the completion of a 22-item questionnaire. The follow-up assessment re-measures key variables for the EBLS-FR such as mental health and mother-child attachment. It also helps to test the process of re-contacting participants and retaining them post-birth. The nature of a pilot study has restricted the follow-up to a maximum of six months after birth. However, the main study is expected to follow participants during the first five years of life.

Measures. Measures for pregnant women include items on demographic factors, socioeconomic status, prenatal health and reproductive history, adverse childhood experiences, community and social support, p-IPV, mental health and other psychological traits, as well as prenatal maternal attachment to the unborn child. The follow-up measures collect data on mothers' mental health, child well-being and birth memories (see Table 3).

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3 Informed by a literature review developed by the EBLS consortium (11), we have identified
4
5 salient factors that may relate to the predictors and consequences of exposure to violence in the
6
7 perinatal period. For reasons of space, we simply describe below the main measures used to
8
9 capture these factors.
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14 *Prenatal Intimate Partner Violence (p-IPV).* p-IPV is measured using a scale extracted from
15
16 the WHO's multi-country study on women's health and domestic violence against women (46).
17
18 It measures exposure to violence during the last six months (i.e., current pregnancy). We use
19
20 six items to capture physical violence (e.g., I was hit with a fist or something else that could
21
22 hurt); four items to measure emotional abuse (e.g., I was insulted or made to feel bad about
23
24 myself); and three items for sexually abusive behaviours (e.g., I was physically forced to have
25
26 sexual intercourse when I did not want to). A four-point Likert scale (i.e., *never, once, a few*
27
28 *times, many times*) allows the participant to report the frequency of exposure to such
29
30 experiences in her lifetime and over the last six months. Questions have been validated in multi-
31
32 racial, ethnic populations and in pregnant women and therefore have appropriate psychometric
33
34 properties (49,50). Exposure to p-IPV is collected using A-CASI as this approach has been
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36 demonstrated to facilitate the disclosure of IPV when compared with face-to-face interviews
37
38 and self-administered written screens (51,52).
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47 *The Perceived Stress Scale (PSS).* The PSS, developed by Cohen and Williamson (53), was
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49 designed to measure the degree to which respondents appraise aspects of their own life
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51 experiences as unpredictable, uncontrollable and emotionally overwhelming. The scale
52
53 includes 10 items (e.g., feeling one could not cope with all the things that one had to do) and
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55 responses are provided using a four-point Likert scale (i.e., *not at all, several days, more than*
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57 *half the days, nearly every day*). The PSS has superior psychometric properties when used with
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3 a normative population, when compared with alternative scales and also when administered to
4 pregnant mothers (54,55).
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10 *Hair samples.* Each pregnant woman is asked to provide a sample of hair cut from the posterior
11 vertex area (where growth rates are least variable), as close as possible to the scalp. Hair
12 samples produce measures of cortisol concentrations, an index of accumulated stress exposure
13 validated for use in pregnant women (56). Since each centimetre of hair represents a month's
14 period of exposure, it is possible to quantify cumulative physiological stress during the second
15 trimester of pregnancy. Previous research has suggested the second trimester of pregnancy in
16 particular as a critical period for stress exposure (9)
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28 *Blood samples.* Dried blood spots are collected by applying a few drops of blood, drawn by
29 lancet from a finger, onto medical-grade, absorbent filter paper. Blood samples are analysed
30 for C-reactive protein (C-RP), a biomarker of inflammation,. We will relate these biomarkers
31 to information on violence exposure and maternal outcomes in order to illuminate the
32 biological mechanisms underpinning the effects of violence and adversity exposure on
33 maternal and birth outcomes (57–59).
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45 *TABLE 3 ABOUT HERE*
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45 *Father questionnaires.* Data are collected using a paper and pencil questionnaire at two
46 different time points. As in the case of pregnant women, the baseline assessment is completed
47 during the third trimester of the woman's pregnancy. Interviews take approximately 40
48 minutes, involving the completion of a 90-item questionnaire. The follow-up assessment
49 encompasses 37 items to be completed in about 20 minutes.
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3 *Measures.* The father questionnaire requests information on demographic factors,
4 socioeconomic status, adverse childhood experiences, partner support, mental health,
5 psychological traits and substance use. These items are similar to those used in the mother's
6 questionnaire. However, the father questionnaire includes some specific items measuring
7 attitudes to fatherhood, participation in antenatal care visits, and the father's participation in
8 household activities (60–62). The follow-up assessment asks the participant to complete items
9 on paternal attitudes, paternal enjoyment and paternal confidence after birth (See Table 4).
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TABLE 4 ABOUT HERE

Data analysis

Descriptive statistics will include frequency of p-IPV, and associations between exposure to violence and the putative outcomes (e.g., C-RP, childbirth weight, maternal mental health). At the same time, candidate mediators and moderators in exposure-outcome associations will be explored. We will conduct measurement invariance analysis and make comparisons on latent variables across the sites. Statistical techniques will thus include linear and generalised linear models, structural equation models and multi-group item response theory and/or factor models. When data from multiple sites are used, multi-level models or multi-group models will be used to take account of the nested structure of the data. If available, EBLIS-FR data will be compared with prevalence in the population. For instance, frequencies of IPV, perinatal depression and levels of stress or substance use will be compared with the prevalence of the same risk factors in the city's population. For the sites that conduct father interviews, models such as actor-partner interdependence models will be used to illuminate the influences of partners on one another's mental health, well-being, and parental behaviour (63).

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3 All primary analyses will be pre-registered using open-access resources, such the Open Science
4 Framework (<https://osf.io/>). After a period of embargo, data will be available for the use of the
5
6 international scientific community. Local stakeholders will be consulted to prioritise additional
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8 research questions to be answered with the data.
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14 **Ethics and dissemination**

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16 The EBLS-FR protocol for recruitment and collection of data has been approved by the Ethics
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18 Boards of all universities involved in the project (see section declarations for more detail).
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20 Results will be disseminated through journal publications, conferences and seminar
21
22 presentations involving local communities, health services and other stakeholders.
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28 **Confidentiality and data protection**

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30 In EBLS-FR all participants are assigned a numeric identification (ID) code. The personally
31
32 identifiable data, including contact details, are kept separate from all data collected via
33
34 questionnaires to ensure confidentiality. EBLS uses a number of technical and organisational
35
36 measures to maintain security, confidentiality, completeness and integrity of the data
37
38 associated with the study. This includes adherence to the requirements on collection and
39
40 processing of personal identifiable data as stipulated by the General Data Protection Regulation
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42 (GDPR) EU 2016/679.
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49 **Data quality and data management**

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51 Multiple strategies are utilised to enhance the quality of data collection. These include training
52
53 of project workers in the administration of questionnaires, training of clinical and project staff
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55 in the measurement of specific indices, and validation checks for consistency and completeness
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57 of routinely collected data. Lab analyses will be subject to strict quality controls based on
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3 established protocols. Data will be screened for out-of-range or otherwise implausible values
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5 before finalising the dataset.
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10 **Organisational structure**

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12 EBLIS comprises a consortium of 15 co-investigators who are collectively responsible for
13
14 conducting the research. Given the multi-disciplinary nature of violence and its impacts on
15
16 child development, the team includes expertise in disciplines such as developmental
17
18 psychopathology, paediatrics, criminology, and public health. The organisational structure
19
20 includes a coordinating team at the University of Cambridge. In each of the sites, a
21
22 collaborative research team has been established to implement the EBLIS-FR study.
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28 **DISCUSSION**

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30 Ending violence against children, dealing with its consequences, and reducing children's
31
32 exposure to threats to their healthy development, requires a better understanding of the factors
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34 that foster child development in various societies and the identification of risk factors that need
35
36 to be addressed most urgently. EBLIS is designed to make novel contributions to these key
37
38 questions by drawing on parallel data collection in eight sites, thus enabling both within- and
39
40 cross-country analyses. While the experience of conducting the EBLIS-FR will illuminate the
41
42 feasibility of procedures for the next stages, psychometric analyses will provide empirical
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44 information on the cross-cultural performance of the study's measures. Analyses of the EBLIS-
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46 FR data will also provide initial estimates of the levels of exposure to adversity and the
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48 relationships between exposures and outcomes, as well as test potential pathways and
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50 moderating factors.
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3 Conducting research in multiple regions will allow us to examine how findings generalise
4 across different socio-cultural and political contexts. To complement participants' reports of
5 their experiences and behaviours, the study will also include biological data collection to
6 examine biological pathways related to violence and health. This will allow us to test for the
7 first time the combined role of systemic inflammation and the HPA axis on mediating links
8 between p-IPV and maternal and birth outcomes. It has been argued that highlighting the
9 biological effects of social issues (such as violence) can be particularly effective in motivating
10 policy change (64). EBLS-FR data collection tools and datasets from eight countries can also
11 benefit the broader research community working on violence prevention.
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26 EBLS-FR has also been designed to foster strategic collaborations, knowledge exchange and
27 capacity building between researchers, communities and policy makers in order to link research
28 findings to policy actions. Future stages of EBLS will reveal the extent and manifestations of
29 exposure to violence in each site; they will identify the salience of risk and protective factors
30 for different groups and contexts; they will alert decision-makers to the short and long-term
31 consequences of violence against women and children that are not currently addressed; and
32 they will establish the essential basis for future actions. Such knowledge exchange between
33 researchers and governments is essential to establish and evaluate prevention efforts and report
34 on progress toward SDG violence reduction targets (65).
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49 Conducting a multi-site project poses both research design and management questions of how
50 to maintain comparability across countries while also examining relevant issues that are only
51 present in some of the contexts, such as child marriage. As reflected in the organisational
52 structure of the study, we believe that multi-country, multi-disciplinary projects require both a
53 strong level of international coordination and collaboration with local governance structures.
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For peer review only

DECLARATIONS

Ethics approval and consent to participate

The EBLS protocol for recruitment and collection of data has been approved by the following ethics boards:

University of Cambridge, School of Social Sciences (18/180) and the Human Biology Research Ethics Committee, UK HBREC.2018.27

University of the Philippines Manila – Research Ethics Board, Philippines, UPMREB 2018-558-01

The Institutional Ethics Committee of Hue University of Medicine and Pharmacy, Vietnam, H2018/430

University of Kelaniya, Faculty of Medicine, Ethics Review Committee, Sri Lanka, P/208/11/2018

National Bioethics Committee (NBC), Pakistan, 4-87/NBC-364/19/1487

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Health Impact Assessment – Western Cape Government

University of Cape Town, Faculty of Health Sciences, Human Research Ethics Committee, South Africa, 057/2019.

Health Research Ethics Committee (HREC) at Stellenbosch University, South Africa, N18/09/099

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Consent for publication

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Availability of data and material

Not applicable.

Competing interests

The authors have no financial interests related to the findings reported in this protocol.

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Authors' contributions

Sara Valdebenito helped to plan the methods for EBL5-FR, drafted the paper, and took the lead in revisions.

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TABLES

Table 1. EBLS sites: Selected country indicators

	Homicide rates ^a	Gender Inequality Index ^b	GDP in \$ (PPP) ^c	Crude birth rate ^d	% Population aged 0-14 ^e
Philippines	14.8	.427	8,935.3	23	32%
Vietnam	3.8	.304	7,434.77	17	23%
Sri Lanka	3.0	.354	13,449.99	15	24%
Pakistan	9.6	.541	5,543.99	28	35%
Romania	1.6	.311	26,595.44	10	15%
South Africa	33.1	.389	13,661.44	21	29%
Ghana	9.7	.538	4,738738.3	31	39%
Jamaica	39.1	.412	9,298.88	16	23%
Global	6.4	.441	17,971.072	19	26%

Sources: a. (37); b.(38); c. (66); d. (67); e. (68).

Table 2. Incentives por participants

Sites	Incentive Baseline	Cost (£)	Incentive Follow-up	Cost (£)	Incentives for fathers	Cost (£)
Philippines	Groceries	2	Groceries	2	Groceries	2
Vietnam	Voucher	5	Voucher	5		
Sri Lanka	Grocery voucher	4.78	Bank deposit for the baby	4.56	Grocery voucher	4.78
Pakistan	Household items for the woman	2.5	Jumper suit for the baby	2.5	N/A	N/A
Romania	Grocery vouchers	27	Grocery vouchers	10	N/A	N/A
South Africa	Grocery voucher	9	Grocery voucher	9	N/A	N/A
Ghana	Money	2.78	Money	2.78	N/A	N/A
Jamaica	Phones Cards	4.26	Phones Cards	4.26	N/A	N/A

Note: Differences in cost are explained by their gross domestic product per capita at nominal values (66).

Table 3. EBLS-FR measures for mother's questionnaire

Measures	Sources	N° Items	Phase	Data collection strategy
Demographics	DHS (69) MacArthur Scale of subjective social status (70)	27	Baseline	CAPi

Prenatal health	Adapted from: The South Asian Birth Cohort (START) (71) Millennium Cohort Study (72)	20	Baseline	CAPI
Attitudes towards physical punishment	Attitudes towards spanking (73)	5	Baseline	CAPI
Community characteristics	Community characteristics scale – Adapted (74)	20	Baseline	CAPI
Adverse childhood experiences	WHO 2009, International ACE-IQ Questionnaire Adapted version (75)	19	Baseline	A-CASI
Intimate partner violence	WHO Multi-country Study on Women Health and Domestic Violence against Women (46)	13	Baseline	A-CASI
Partner supportiveness	Partner supportiveness/ relationship scale (76)	4	Baseline	CAPI
Social support	Social support scale (77)	13	Baseline	CAPI
Well-being	WHO-5 Well-Being Index (78)	5	Baseline	CAPI
Depression	PHQ9 (79)	9	Baseline and follow-up	CAPI
Suicidality	Suicidality item (80)	1	Baseline	CAPI
Stress	Perceived Stress Scale (81)	10	Baseline	CAPI
Aggression	The Brief Aggression Questionnaire (82)	12	Baseline	CAPI
ADHD symptoms	Adult ADHD symptoms -Adapted (83)	6	Baseline	CAPI
Self-control	Brief Self-Control Scale (84)	8	Baseline	CAPI
Substance use	Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) – Adapted version WHO ASSIST Working Group (85)	9	Baseline	A-CASI
Pregnancy related beliefs	Prenatal Attachment Inventory – Revised (86)	18	Baseline	CAPI
Newborn health and well-being	Norwegian Mother and Child Cohort Study (MoBa) (87) Questionnaire for breastfeeding mothers (88)	8	Follow-up	CAPI
The mother's birth memories	The Birth Memories and Recall Questionnaire (89)	5	Follow-up	CAPI

Table 4. EBLS-FR measures for father's questionnaire

Measures	Sources	N° Items	Phase	Data collection strategy
Feelings about fatherhood (prenatal)	Adapted from the Avon Longitudinal Study of Parents and Children (60)	13	Baseline	Paper and pencil
Fathers' participation for antenatal care	(61,62)	7	Baseline Follow-up	Paper and pencil
Fathers' participation for household activities	Adapted from the Avon Longitudinal Study of Parents and Children .	8	Baseline Follow-up	Paper and pencil

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3	Attitudes to	Avon Longitudinal Study of Parents and	8	Follow-up	Paper and
4	fatherhood	Children (60)			pencil
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6	Paternal enjoyment	Avon Longitudinal Study of Parents and	5	Follow-up	Paper and
7		Children (60)			pencil
8					
9	Paternal confidence	Avon Longitudinal Study of Parents and	4	Follow-up	Paper and
10		Children (60)			pencil
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12	Activities with the	Avon Longitudinal Study of Parents and	6	Follow-up	Paper and
13	newborn child	Children (60)			pencil
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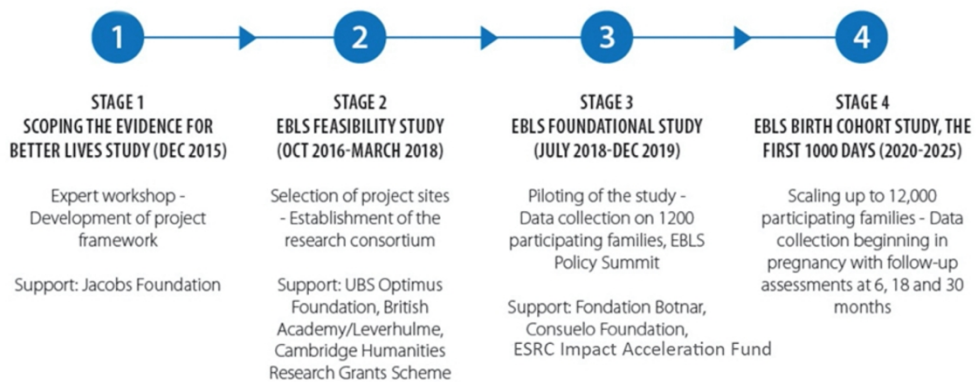


Figure 1. The four main stages of Evidence for Better Lives

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Figure 2. Evidence for Better Lives study sites