STOP

Intimate Partner Violence In Pregnancy

Deliverable 4.2

Protocol for data collection

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Executive Summary

This delivery describes the data collection for WP4. Women who screen positive for IPV (WP 2) are eligible to be included in the WP4 study and will be offered a technological intervention in the form of a safety planning app and telemedical counselling provided by midwives and psychologists, who have been trained in IPV counselling. Women will be included over the course of 12 months, and an estimated 520 women will screen positive and receive the intervention. In order to measure the impact of the intervention on IPV, questionnaire data will be collected pre- and post the intervention period. Further, qualitative interviews will be conducted with midwives, psychologists and women enrolled into the study, in order to get in-depth knowledge of the users' perspectives of the intervention, how it influences their safety as well as elucidate the ethical and organisational aspects related to implementing the intervention.

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1. INTRODUCTION

1.1 Purpose of the document

The aim of this document is to give an overview of the data collection for WP4 in Denmark and Spain.

1.2 Structure of the document

Firstly, this document will provide a background for the project. Secondly, an overview will be given of the study population followed by a short description of the STOP intervention and training of midwives and psychologist for the data collection. Thirdly, collection of quantitative data – in the form of questionnaire data – is outlined followed by a description of the qualitative data collection, in the form of interviews. Fourthly, the management of the data and monitoring of the intervention is described. Finally, ethical considerations and informed consent in relation to the data collection is outlined.

1.3 Glossary

AAS	Abuse Assessment Screen
CEA	Cost-Effectiveness Analysis
CTP	Center for Telepsychiatry
EPDS	Edinburgh Postnatal Depression Scale
ICER	Incremental Cost-Effectiveness Ratios
IPV	Intimate Partner Violence
ISA	Index of Spouse Abuse
MAST	Model for Assessment of Telemedicine Applications
MOVERS	Measure of Victim Empowerment Related to Safety
OUH	Odense University Hospital
PRO	Patient Reported Outcome
REDCap	Research Electronic Data Capture
RSD	Region of Southern Denmark
SD	Standard Deviation
STOP	Stop Intimate Partner Violence in Pregnancy
UGR	University of Granada
WAST	Women Abuse Screening Tool
WP	Work Package

2. STUDY PROTOCOL

2.1 Background and rationale

IPV is the most common form of violence against women worldwide (Sanz-Barbero et al., 2018). The term *intimate partner violence* describes physical, sexual, or psychological harm by a current or former partner or spouse. Estimates of the prevalence of physical violence during pregnancy vary globally. In Denmark and Spain, 1.8% and 3.6 % of pregnant women have reportedly been pushed, hit, slapped, kicked, choked, or physically hurt in some way during their most recent pregnancy (Lukasse et al., 2014). In addition to the adverse consequences of the physical harm, pregnant women exposed to IPV also suffer from an increase in mental health problems with 33-46% reporting signs of depression (Tho Tran et al., 2018). IPV also poses a risk to the offspring with an increased risk for preterm birth and low birthweight (Sigalla et al., 2017). Trials from various settings have found that IPV exposed women who receive telephone counselling combined with other forms of support or a web-based safety planning tool are more likely to adopt safety behaviours than women not offered such a solution (Tarzia et al., 2016). A safety planning tool combines 3 preventive strategies: (1) cognitive, problem-solving, and personalised safety planning; (2) encouragement to contact peers and professionals; and (3) encouragement to limit access to lethal means. In Australia and Denmark, the safety planning tool has been modelled into a smartphone app – called 'My Plan' – that target individuals at risk of or in a crisis.

2.2 Objectives

The project's overall objective is to reduce IPV among Danish and Spanish pregnant women through change in attitude and behaviour via focused video consultations supported by a smartphone safety planning app.

The specific objectives are:

1. To identify pregnant women exposed to IPV in Denmark and Spain
2. To describe the effect of video counselling coupled with a smartphone safety app on reduction of IPV among Danish and Spanish pregnant women exposed to IPV
3. To describe the acceptability and feasibility of video counselling coupled with a smartphone safety app

2.3 Study design

Prospective cohort study.

2.4 Study setting and participants

The study will take place in Region of Southern Denmark and in Andalusia, Spain.

2.4.1 Denmark

Women attending antenatal care at Esbjerg Hospital, Aabenraa Hospital, Kolding Hospital and Odense University Hospital in the Region of Southern Denmark will be invited to participate in the project.

During the autumn of 2020, screening for IPV will become part of routine antenatal care in the Region of Southern Denmark, where pregnant women are asked to fill in an electronical questionnaire on pregnancy related life-style measures and quality of life (PRO data). The obtained information will be used to help guide the routine midwifery consultation. The PRO data questionnaire includes a screening for IPV exposure based on the AAS, a 5-item screening questionnaire including physical, emotional, and sexual violence as well as threats/fear of violence during pregnancy.

2.4.2 Spain

The study will take place in routine antenatal care centres of Granada and Jaén (Andalusia). Pregnant women will in relation to their first antenatal care visit be asked by the midwife to fill in an electronical questionnaire in a tablet app with questions related to the relationship with the partner during pregnancy. The screening instruments for IPV exposure include AAS and a short version of the WAST-short, which is a 2-item tool that measures conflict and tension with the partner.

2.4.3 Eligibility Criteria (Denmark and Spain)

Women who screen positive for IPV exposure by AAS/WAST will undergo repeated screening by use of the ISA questionnaire, which is a 30-item scale designed to measure the physical and non-physical violence inflicted on women by their current or most recent male partners. The items are rated on a scale from 1 (never) to 5 (very frequently). Two different scores are computed: ISA-P (severity of physical abuse) and ISA-NP (severity of non-physical abuse), and an ISA global score. The scores range from 0 to 100. In Denmark, the cut-off scores of 10 for ISA-P, and 25 for ISA-NP developed by Hudson and McIntosh will be used (Hudson & McIntosh, 1981). In Spain, cut-off scores of 6 for ISA-P and 14 for ISA-NP will be applied based on the Spanish validation of the ISA tool (Plazaola Castaño, Ruiz Pérez, Escribá Agüir & Jiménez Martín, 2006).

Pregnant women in first trimester, who screen positive for IPV will be eligible for inclusion into the WP4 study. Women will be excluded if they (1) cannot be informed about the study without their partners or other family members knowing; (2) do not have the mental or physical capacity to participate in the study; (3) do not understand Danish/Spanish, or (4) do not have a smartphone.

2.5 Intervention, outcome, participant timeline and sample size

2.5.1 Intervention

The women will be invited to participate in the project at the first physical conversation with the midwife. They will be offered 3-6 specially targeted consultations via video and get access to a safety planning app.

The video counselling will be provided by midwives/psychologists, who have been trained in discussing and addressing IPV. The counselling will focus on conflict management, strategy planning in case of crisis situations and general information on partner violence. As part of the counselling, the women will receive help in developing a safety plan, which will be supported by the smartphone safety app that will help protect the women from ongoing violence. As part of the counselling, women will receive detailed information about options in their community regarding violence.

In Denmark, the app 'My Hospital' – which is widely implemented in the Region of Southern Denmark – will be used to organise and host the video consultations. In Spain, the platform 'Amazon Chime' – will be used. In both Denmark and Spain, an adapted version of the smartphone safety planning app 'My Plan' will be used as the safety planning app and support the video counselling. In 'My Plan', the pregnant woman can outline her network and write down the strategies and options she will use when the situations of violence arise. Further, the women will get access to a list of phone numbers and websites to governmental and local resources that provide counselling and care for women exposed to violence.

In Denmark, 10 midwives and will be trained as IPV counsellors in Nov-Dec 2020 and Jan 2021. In Spain, the counselling will be performed by a psychologist with experience in counselling IPV-exposed women. The counsellors will be invited to a webinar about violence during the time of pregnancy, before the project starts and during the project period. Further, the counsellors will attend a 3-day workshop that will include presentations, participatory activities and reflections regarding violence against

pregnant women and the project. Finally, project meetings will be conducted throughout the study period and contain a mix of presentations and reflexions from different resources within the field.

2.5.2 Outcome (impact, acceptability and feasibility of intervention)

In order to assess the impact of the intervention on a number of factors, quantitative questionnaire data will be collected at study inclusion (pre intervention) and when the study finishes (post intervention). Exposure to IPV will be assessed by use of the ISA tool, and pre/post-natal depression will be assessed by use of EPDS, which is a 10-item validated questionnaire designed to detect postnatal depression (Eberhard-Gran et al., 2001). Further, participants will be asked to conduct a danger assessment. In Spain, a Spanish version of the revised 20-item danger assessment scale (Campbell et al., 2009) will be used, and in Denmark a Danish version of the Swedish tool *FREDA* will be used, which is a cultural adaption the danger assessment scale. In order to measure the women's ability to carry out safety behaviour actions, a revised version of the 22-item safety action checklist (Ford-Gilboe et al., 2020) will be used in Denmark, whilst the MOVERS scale will be used in Spain (Goodman, Cattaneo, Thomas, Woulfe, Kwan Chong & Smyth, 2014). Further at study inclusion, participants will be asked to fill in an electronic questionnaire concerning background characteristics. Information about the outcome of the index pregnancy, delivery method and the child weight and length will be retrieved from the patient files after the women have delivered. Permission to do this will be obtained from the woman and from the National Data Protection Agencies.

In order to assess the acceptability and feasibility of video counselling and the smartphone safety app, a qualitative study will be conducted by individual in-depth interviews with participants (15 in Denmark and 5 in Spain) and interviews with the IPV counsellors conducting the video counselling sessions (6 in Denmark and 1 in Spain). The participants will be recruited through the video counselling sessions where they will be asked about their interest and willingness to participate in in-depth interviews. If they agree, an interview will be arranged according to the women's preference regarding time and place. IPV counsellors will also be recruited for interviews and interviewed at their convenience. A semi-structured interview guide will be developed for the interviews using the MAST as theoretical framework (Kidholm et al., 2012) with focus on the following domains: users' perspectives, their safety, ethical and organisational aspects, health problems and technology. The interview guide will be pilot tested on an IPV counsellor and a participant from the study prior to data collection starting. All

participants will give written consent prior to the interviews starting and data collection will stop once data is saturated. The interviews will be conducted in Danish/Spanish and audio recorded, and will be transcribed and analysed by use of a thematic content analysis using a combined inductive-deductive approach (Schreier, 2013). A coding frame will be developed, and themes will deductively be derived from the MAST model and supplemented with categories that inductively arise from the data.

2.5.3 Participant timeline

The participant timeline is illustrated in two separate flow charts, one for Denmark and one for Spain.

Figure 1. Flow chart of data collection in Denmark (WP4)

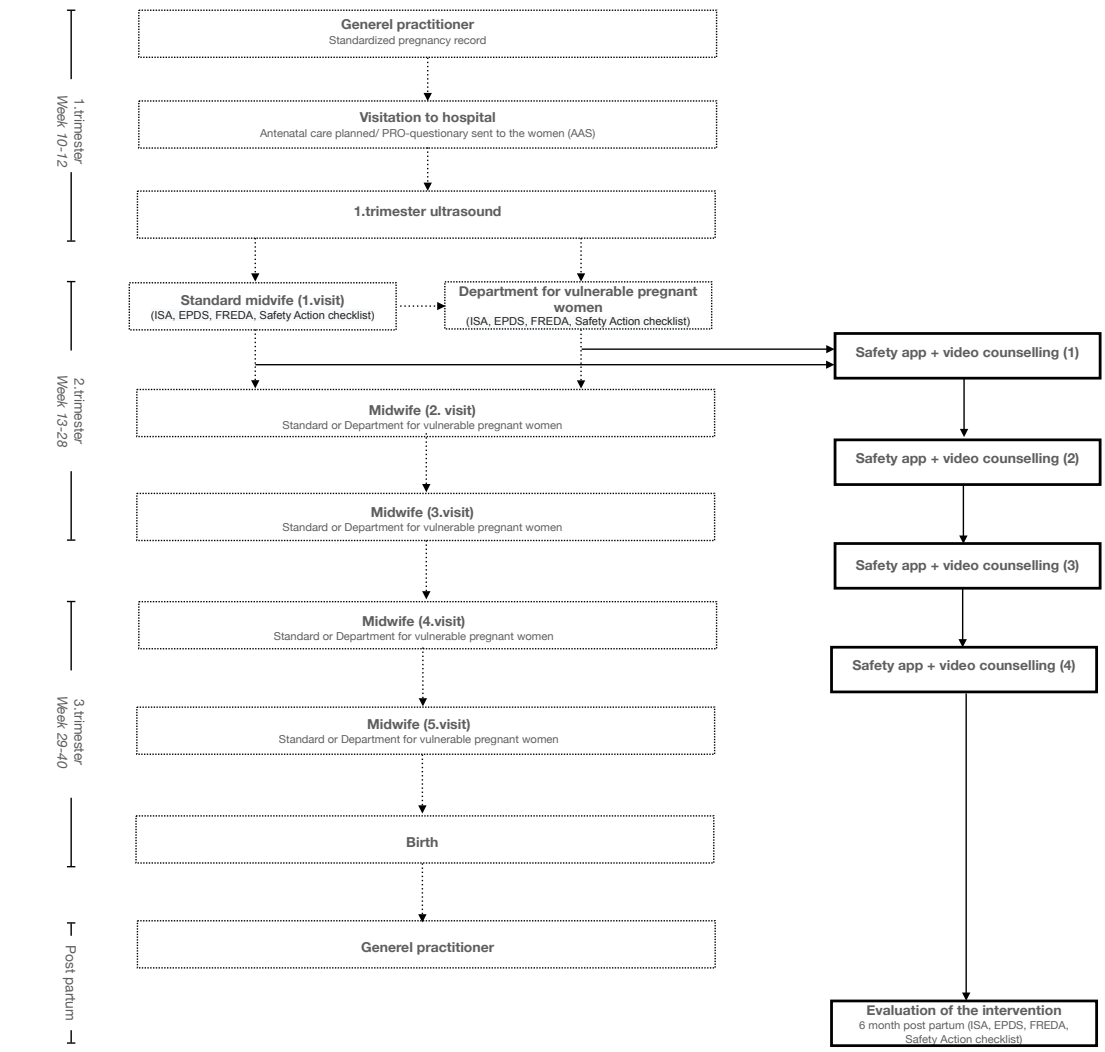
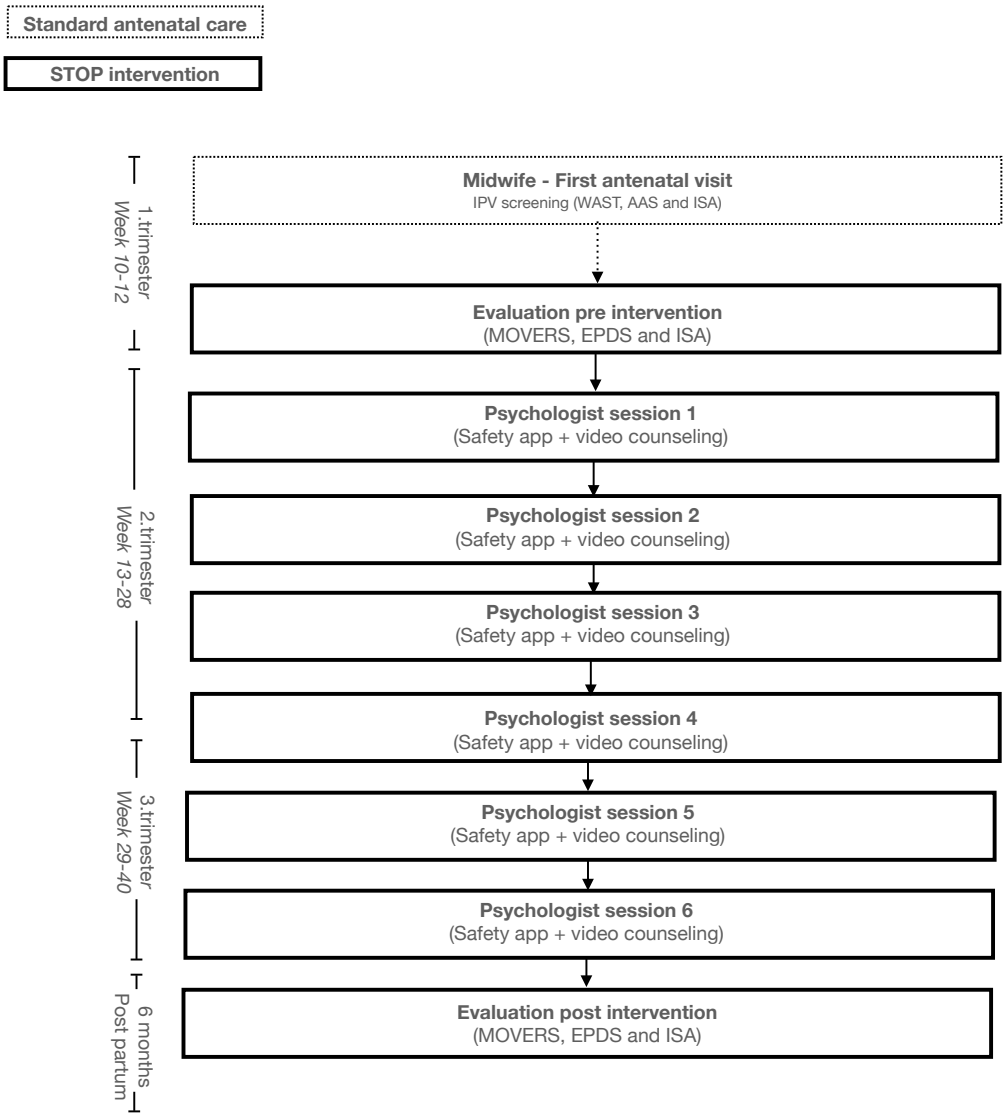


Figure 2. Flow chart of data collection in Spain (WP4)



2.5.4 Sample size

Women will be included over a 12 months period.

In Denmark, based on the annual number of deliveries in Region of Southern Denmark, an estimated 11.000 women will fill in the PRO data questionnaire and an estimated 440 women will screen positive for IPV and 390 will be included in the study. This estimation is based on an EU project in which 4% of the interviewed Danish women stated they had been exposed to IPV within the past 12 months (EU, 2015).

In Spain, 2000 women will fill in the screening app and an estimated, 160 women will screen positive for IPV and 130 women will accept participation in the study. This

estimation is based on the most recent available Spanish data on IPV exposure (Velasco et al 2014; Ministry of Equality 2019).

Little is known about our study population regarding the use of safety behaviours and there is a lack of information in the literature about anticipated mean values and SD for the measurements before and after the intervention. Thus, it is difficult to estimate an exact sample size to document a significant difference before and after the intervention. However, the estimated sample size of in all 520 women is considered sufficiently large to document a clinical meaningful effect of the intervention.

2.6 Data collection, management, and analysis

2.6.1 Data collection and management

Study data are collected and managed using REDCap electronic data capture tools. REDCap is a secure, web-based application designed to support data capture for research studies (www.project-redcap.org).

2.6.2 Data analysis

Baseline characteristics according to IPV exposure will be analysed using descriptive statistics and presented as numbers and frequencies.

To investigate the impact of the intervention on the women's exposure to IPV and their signs of depression, a relative risk regression will be performed with estimates reported as RRs with 95% CI. Further, the total ISA score and EPDS score will be calculated before and after the intervention and a linear regression will performed with results presented as regression coefficients (β) with 95% CI. In the adjusted analysis, we will controll for potential confounders selected a priori based on existing literature. Directed acyclic graphs will be generated for each outcome variable (IPV and depression) using DAGitty v2.3 as graphical tool for analyzing the causal diagrams (Textor el al 2011).

In order to estimate the cost-effectiveness of the intervention, a conventional CEA is carried out (Fesenfeld et al 2012). The effect measure is decrease in ISA score (measured pre and post intervention). The costs of the intervention will be estimated in Euro and include training costs, resource-use related to the technical development of the intervention (the safety planning app) and salaries to personnel. ICERs will be calculated (Drummond et al 2005):

$$ICER = \frac{\Delta\, Cost}{\Delta\, Effect} = \frac{Cost\ of\ intervention\ -cost\ of\ standard\ of\ care\ (0)}{ISA\ score\ pre\ intervention - ISA\ score\ post\ intervention}$$

All analyses will be carried out using STATA statistical software version 15.0.

2.7 Monitoring

The national responsible parties for WP4 (RSD-OUH and UGR) will be responsible for the overall monitoring of the intervention, for the realisation of outputs and for the establishment of appropriate reporting procedures. To facilitate and ensure coordination and communication between the involved institutions, a series of different activities will be undertaken: i) Monthly meetings will be organised at health facility level in Denmark and Spain. In these meetings, participant recruitment and experiences with the intervention will be discussed; ii) Quarterly coordination meetings will be arranged in each country with participation of a local project coordinator from each health facility and the national responsible coordinator; iii) Quarterly inter-institutional webinars will be held with participants from RSD-OUH, RSD-CTP and UGR.

2.8 Ethics

The STOP intervention will be implemented through midwifery consultations and will be an add-on to the routine antenatal care. Women who consent to participate will be given a unique study id and be asked to sign a consent form, which gives the researcher permission to contact them by telephone. A list of participants with their study ids will be safely stored by the researchers.

The project will follow the Helsinki Protocol (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects) and the WHO guidelines for researching violence against women: Putting women's safety first: Ethical and Safety Recommendations for Research on Domestic Violence against women (WHO, 2001).

As part of routine antenatal care, the midwives will follow the guidelines regarding routine enquiry about violence and referral as usual. The study group will ensure that all midwives in the antenatal care settings where women are recruited from have an overview of standard procedures and referrals in relation to vulnerable women. Women who accept to participate in the study will be offered video counselling sessions that will

take place at a time and place where the women feel safe. In relation to the video counselling, the women will be forewarned that if someone enters the room, the counsellor will change the topic of conversation by switching to counselling on pregnancy-related health problems. The woman will further be asked whether or not she would prefer to be called back another time and she will be provided with a number to call. The women will be informed that they can withdraw from the study at any time without it affecting their routine care.

3. REFERENCES

Campbell J, Webster DW, Glass N, 2009. The Danger Assessment - Validation of a Lethality Risk Assessment Instrument for Intimate Partner Femicide. *Journal of Interpersonal Violence*, 24;4: 653-674.

Drummond MF, Sculper MJ, Torrance GW et al. *Methods for the Economic Evaluation of Health Care Programmes*. New York: Oxford University Press; 2005.

Eberhard-gran M, Eskild A, Tambs K, Schei B, Opjordsmoen S, 2001. The Edinburgh Postnatal Depression Scale: validation in a Norwegian community sample. *Nord J Psychiatry,* 55**:** 113-7.

Ford-Gilboe M, Varcoe C, Scott-Storey K et al., 2020. Longitudinal impacts of an online safety and health intervention for women experiencing intimate partner violence: randomized controlled trial. BMC Public Health 20, 260. DOI: https://doi.org/10.1186/s12889-020-8152-8

Fesenfeld M, Hutubessy R, Jit M. Cost-effectiveness of human papillomavirus vaccination in low and middle income countries: A systematic review. *Elsevier Vaccine*. 2012; 31: 3786-3804.

Goodman, Lisa & Cattaneo, Lauren & Thomas, Kristie & Woulfe, Julie & Kwan Chong, Siu & Fels Smyth, Katya. (2014). Advancing Domestic Violence Program Evaluation: Development and Validation of the Measure of Victim Empowerment Related to Safety (MOVERS). Psychology of Violence. 5.

Hudson W & McIntosh SR, 1981. The Assessment of Spouse Abuse: Two Quantifiable Dimensions. *Journal of Marriage and Family,* 43**:** 873-888.

Kidholm K, Ekeland AG, Jensen lK, et al., 2012 A model for assessment of telemedicine applications: MAST. *Int J Technol Assess Health Care*, 28: 44-51.

Lukasse M, Schroll AM, Ryding EL et al. 2014. Prevalence of emotional, physical and sexual abuse among pregnant women in six European countries. *Acta Obstet Gynecol Scand*, 93, 669-77.

Plazaola Castaño, J., Ruiz Pérez, I., Escribá Agüir, V., & Jiménez Martín, J. M. (2006). Adaptación española de un instrumento de diagnóstico y otro de cribado para detectar la violencia contra la mujer en la pareja desde el ámbito sanitario. Madrid: Observatorio de Salud de la Mujer; 2006.

Ministry of Equality. Government Delegation for Gender-based Violence. Macro-survey on Violence against Women 2019.

Sanz-Barbero B, Lopez Pereira P, Barrio G. et al. 2018. Intimate partner violence against young women: prevalence and associated factors in Europe. *J Epidemiol Community Health*, 72, 611-616.

Schreier M. 2013. *Qualitative content analysis in practice,* London, Sage.

Sigalla GN, Mushi D, Meyrowitsch DW et al. 2017. Intimate partner violence during pregnancy and its association with preterm birth and low birth weight in Tanzania: a prospective cohort study. *Plos One*, 12, e0172540.

Tarzia L, Murray E, Humphreys C, et al. 2016. i-decide: An online intervention drawing on the psychosocial readiness model for women experiencing domestic violence. *Women's Health Issues*, 26, 208–16.

Tho Tran N, Nguyen HTT, Nguyen, HD et al. 2018. Emotional violence exerted by intimate partners and postnatal depressive symptoms among women in Vietnam: a prospective cohort study. *Plos One*, 13, e0207108.

Textor J, Hardt J, Knuppel S. DAGitty: a graphical tool for analyzing causal diagrams. *Epidemiology (Cambridge, Mass).* 2011;22(5):745.

Velasco C, Luna JD, Martin A, Caño A, Martin-de-las-Heras S. Intimate partner violence against Spanish pregnant women: application of two screening instruments to assess prevalence and associated factors. Acta Obstetricia et Gynecologica Scandinavica. 2014;93(10):1050–8.

WHO, 2001. *Putting Women's safety first: ethical and safety recommendations for research on domestic violence against women*. WHO: Geneva.