STOP

Intimate Partner Violence In Pregnancy

[redacted]

Deliverable 1.5

First Consortium Meeting

The STOP project has received funding from the European Union's Rights, Equality, and Citizenship Programme under Grant Agreement No 881648

Table of Contents

Contents

1. INTRODUCTION

1.1 Purpose of the document

This document contains the minutes from the STOP Kick Off meeting (the first Consortium meeting for the STOP project). It summarizes the presentations and discussions which took place among the attendants, which included representatives from all Consortium partners, including all local coordinators as well as the Project Coordinator.

1.2 Structure of the document

The document lists the attendants from each partner organization followed by a summary of each item on the agenda structured chronologically for each day of the meeting.

1.3 Glossary

AAS	Abuse Assessment Screening
D	Deliverable
CONSORT	Consolidated Standards of Reporting Trials
EPDS	Edinburgh Postnatal Depression Scale
GA	Gestational Age
IPV	Intimate Partner Violence
ISA	Index of Spouse Abuse
MAST	Model for Assessment of Telemedicine Applications
MBR	Danish Medical Birth Register
MOVERS	Measure of Victim Empowerment Related to Safety
PRO	Patient Reported Outcomes
RCT	Randomized Controlled Trial
RSD-CTP	Region of Southern Denmark – Centre for Telepsychiatry
RSD-OUH	Region of Southern Denmark – Odense University Hospital
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STOP	Stop Intimate Partner Violence in Pregnancy
UGR	University of Granada
WAST	Women Abuse Screening Tool
WP	Work Package

2. STOP Project Kick Off

The first of a total of four consortium meetings in the STOP project took place on September 28 and 29 2020. While originally planned as a physical meeting, the current COVID-19 situation caused a change in venue. The meeting was held virtually via GoToMeeting.

2.1 Attendants

[redacted] (UGR)
[redacted] (UGR)
[redacted] (RSD-OUH)
[redacted] (RSD-OUH)
[redacted] (RSD-OUH)
[redacted] (RSD-CTP)
[redacted] (RSD-OUH)
[redacted] (UGR)
[redacted] (OUH-RSD)
[redacted] (RSD-CTP)
[redacted] (RSD-OUH)
[redacted] (RSD-CTP)
[redacted] (UGR)
[redacted] (RSD-OUH)
[redacted] (UGR)
[redacted] (RSD-OUH, *Project Coordinator*)

3. DAY 1 – Monday 28 September

All participants introduced themselves and the local coordinators introduced each beneficiary. The Chair presented the agenda for the two-day Project Kick Off Meeting (the STOP project's first consortium meeting). As it was originally planned as a physical meeting, the program has been adjusted to reflect its new virtual nature. The participants expressed hope that the second consortium meeting (which will take place in December 2020) will allow for a physical meeting.

3.1 Overall introduction to the project

The Project Coordinator provided an overview of what the Consortium has committed itself to over the next two years, including the screening, video counseling, and safety plan tools to be developed and used throughout the project.

The overall objective of the STOP project is to empower European women exposed to IPV during pregnancy through a change in attitude and behavior via an eHealth intervention. This will be achieved through the implementation and evaluation of electronic screening tools (in WP2), video

[redacted]seling (in WP3 and WP4), a safety planning application (in WP3 and WP4), and the development of a protocol for a full-scale randomized controlled trial (in WP5).
The project's specific objectives are to:

- Develop a systematic risk screening program for identification of pregnant women exposed to IPV, using validated tools or questionnaires embedded electronically in antenatal care (WP 2);
- Develop a video counseling program delivered by staff specifically trained for guiding pregnant women exposed to IPV, using individually tailored video counseling improve safety planning coupled with a safety planning app (WP 3);
- Conduct risk screening and counseling in Denmark and Spain to improve support for pregnant women with IPV exposure for their empowerment and reduction in perinatal depression and repeated IPV episodes (WP 4);
- Prepare the basis for a large-scale future IPV interventions within antenatal care settings by conducting a pilot/feasibility randomized controlled trial (WP 5);
- Evaluate and disseminate via plain language reports in the media and scientific outputs increasing awareness about IPV during pregnancy among patients and public authorities (WP 1).

The project's anticipated outcome is:

- Improved knowledge and capacity of health care professional in assessing IPV risk among pregnant women (WP 2);
- Improved knowledge and capacity of health care professional in preventing IPV among pregnant women through workshop with at least 10 trained video counsellors in Denmark and Spain (WP 3);
- Identification of pregnant women exposed to IPV followed by prevention and protection
- 11,000 pregnant women in Denmark and 2,000 in Spain will be screened for IPV risk through an electronic screening tool, and an estimated approx.;
- 400-500 women screened positive for IPV exposure and offered video counseling;
- Decreased violence (ISA), decreased depression signs (EPDS), increased empowerment (MOVERS);
- A feasibility study and a pilot RCT and development of a rigorous protocol for an RCT and future upscaling across Europe (WP 5);
- Increased awareness of IPV in pregnancy with patient and public involvement and engagement including public authorities with incorporation of eHealth into a multiagency care pathway in a white paper for health and social care professionals for its long-term sustainability (WP 1).

[redacted]will be achieved through the following five work packages (WP), which, except for the management and coordination WP, were discussed in detail during this two-day kick off meeting.

WP1:

- Project management and coordination, and evaluation and dissemination of project results

WP2:

- Implementation of AAS in Denmark and Spain;
- In Denmark the AAS will be incorporated in patient reported information (PRO data), an electronically based questionnaire that pregnant women fill in routinely before 12 weeks of gestation;
- In Spain an app based on AAS will be developed. Women who attend routine antenatal care at a number of selected high load antenatal clinics will be screened utilizing tablets with the app installed. The screening will be performed in relation to their first antenatal care visit before 12 weeks of gestation;
- In both settings, women who are screened positive with the AAS will undergo confirmatory testing using the ISA.

WP3:

- Development of video counseling sessions;
- Development of a safety planning app with interactive modules designed to guide women through a process of self-reflection and self-management;
- Training of counsellors in assisting the women in developing safety plans tailored according to the safety planning app and input from the individual women a
- Joint training workshops relying on training resources from acknowledged and experienced IPV NGOs;
- 5 percent are estimated to be screened positive for IPV (combined AAS and ISA). These women will be contacted by telephone and invited to participate in the project. If the women consent, they will be offered video counseling coupled with the safety planning app;
- Video counseling will be provided by counsellors (at the hospital) with women at home.

WP4:

- Epidemiological and behavioral science approaches will be applied to analyze providers' and client's perceptions and response to the intervention;
- Structured questionnaire interviews will be performed in relation to the inclusion and six months after the intervention to assess the interventions impact on women's repeated violence (ISA) signs of depression (EPDS) and empowerment (MOVERS);

[redacted] Semi-structured individual interviews will be performed to explore whether the eHealth intervention helps to enhance client trust in the health care system;
- The MAST will be used to evaluate the intervention with reference to users' perspectives, safety (risk of harm, network problems, data safety), and ethical aspects (right to refuse mobile package, stigma and discrimination).

WP5:
- A pilot study will determine whether the eHealth intervention can be feasibly delivered within the context of a full-scale RCT;
- Data from the pilot study will provide information about;
- Based on the outcome of the pilot study a protocol for a full scale RCT will be drafted and published:
  a) Estimates for the variance of key clinical outcome measures, and the dropout rate;
  b) Recruitment duration;
  c) Patient adherence to eHealth intervention as an indirect measure of acceptability;
  d) Reasons for non-adherence;
  e) Obstacles to recruitment, randomization, and consent;
  f) Other feasibility measures.
- An amendment to the Grant Agreement is under way, awaiting the verification of the RSD bank account in the EU system.

3.2 Systematic Screening for IPV – W2

WP2 is linked to the project's objective 1 and aims to develop a systematic risk screening program ready to identify pregnant women exposed to IPV for recruitment into the project intervention. As such, the objective of WP2 is to develop a systematic risk screening program for identification of pregnant women exposed to IPV, using validated tools or questionnaires embedded electronically in antenatal care.

[redacted] explained how the applied screening tools WAST and AAS will be used during the project. WP2 will develop the eHealth tool using validated questionnaires for two different antenatal care settings, to be deployed in Danish and in Spanish. The initial screening will be assessed with a short AAS questionnaire, which if positive will be verified using the more detailed ISA with a cutoff set according to international recommendations. Screening outcomes will fall into two groups:

Option 1: Negative WAST and AAS
Option 2: Positive WAST and AAS - followed by ISA.

[redacted] explained that the best option is to screen using WAST in the first trimester and AAS in the third trimester. The added value of WAST is its sensitivity (92 percent) in screening not only for explicit violence but also for rising tensions and violence in less evident ways. WAST thus permits identification of more women exposed to IPV.

The attendees discussed the use of both WAST and AAS as well as the applicability of AAS, e.g. in relation to family structures and current vs. previous partners, or the effect of family structures, as the interpretation of how well screening tools predict violence depends on family structures and divorce structures within and between the partner countries. Therefore, safety measures need to take cultural contexts into account. The interpretation of the screening must consider timing, e.g. a woman screened at GA 12 for violence occurring within the last twelve months, she may no longer be with the perpetrating partner, thus having rid herself of danger. This necessitates analysis of the information provided by the woman, before determining her immediate need for the counseling intervention.

In Spain, the implementation of AAS and ISA will be facilitated for midwives and pregnant women via an electronic application for mobile phones and tablets. Each midwife in the participating antenatal care setting will be provided with the electronic device containing the app. Twenty midwives have been selected; they work in the primary healthcare sector in four different regions.

In Denmark, the AAS and ISA will be incorporated in the Region of Southern Denmark's official app *Mit Sygehus* (My Hospital) which includes electronic patient reported outcomes modules. The PRO data are collected routinely among all pregnant women in the Region during their antenatal care booking visit during their first trimester. Women who screen positive on AAS and ISA will be identified in the PRO data and contacted via telephone by trained midwives. AAS will screen for violence both within the last 12 months, and before.

In Denmark, an estimated 11,000 women will be screened, with an expected hit rate at 4 percent. In Spain, a rate of 8% is expected. With the more restrictive Danish approach, a wider inclusion in the beginning is suggested.

Based on the data, the Danish team will seek to determine the prevalence of IPV nationally by linking to the Danish National Registry. Further, a cohort study will determine the association between IPV exposure and adverse pregnancy outcomes. Information about the outcome of the index pregnancy will be retrieved from the MBR after the women have delivered. Finally, the WP will seek validation of the Danish version of the ISA by analyzing the validity and reliability of the Danish version. The original ISA has been translated into Danish by two independent, bilingual people and approved by experts. This will be inspired by the *Spanish Validation of the Spanish*

[redacted]*n of the Index of Spouse Abuse* study. The Danish cutoffs will be established with the assistance of the Spanish team. [redacted] will work on it as part of her tasks.

The timing of the training of midwives was discussed. The use of "Super Users" is suggested, that is a core group of midwives who received intensive training now with follow-up in January 2021. Despite a preference for delaying the training of the midwives to January 2021, our Grant Agreement stipulates that the training of the midwives is done in November 2020. However, re-training of the midwives will take place in January 2021 along with the training of the video counsellors. Virtual training of the midwives may be necessary due to the ongoing COVID-19 situation. If it is not possible to conduct training of the midwives before the end of November 2020, we would need to apply for an extension [the Coordination Team has since argued for and received permission to extent D2.3 and D2.4].

[redacted] emphasized that an early evaluation of the screening effort will be valuable to the project.

3.3 Video counseling and safety planning app – WP3

The objectives of WP3 are to:

- Improve support for women exposed to IPV through individually tailored video counseling;
- Improve knowledge of safety among women exposed to IPV.

WP3 investigates the needs, preferences, and concerns of pregnant women exposed to IPV as well as service providers' perspectives in routine antenatal care in Denmark and Spain. It develops the content of the video counseling intervention and taking into account the approach of selected IPV non-profit organizations, it develops a training protocol to assist antenatal care workers in providing the targeted counseling of women exposed to IPV. It organizes a training workshop for midwives and counsellors from Denmark and Spain, as well as key project members. Consortium partner RSD-CTP is responsible for setting up the technical infrastructure for conducting video counseling in collaboration with UGR. This includes choosing technical providers of secure video software, testing video counseling services in both countries, and adapting the technical setup to antenatal care units.)

The safety planning app, which is part of WP3, is being prepared. RSD-CTP conducts a market survey of available safety planning apps in order to identify evidence-based mHealth approaches for supporting women at risk of IPV. The app chosen will be adapted to the specifications outlined through conversations with relevant non-profits and the women they serve. RSD-CTP is responsible for the selection of a safe and evidence-based app, the training of antenatal care workers in introducing the app to women exposed to IPV and integrating the safety planning app

[redacted]ervice delivery. Workshop with two midwives and three non-profits provided input to the app and the video consultations. They provided ideas for features and functionality.

[redacted] presented an alpha version of the safety planning app tentatively called MyPlan; she requested other ideas for the name. My Pregnancy was suggested, but partners may want to see what it is about, in order to know about the progress of the pregnancy. Control Panel could be a delightfully anonymous name. Please sent any suggestions for a name to Kristine.

Selected functionalities of the app were discussed. Overall, it is important that the women know that they do not need to spend a lot of time on the app:

Help button:
It should include different emergency numbers to meet different needs, e.g. authorities, women's shelters, etc. It would be preferable to offer direct calling to friends or relatives. It should be customizable to each woman's own needs. During the video consultations, the counsellors should help the women add the numbers to the app, if they do not come pre-installed.

Warning signs and strategies:
May be one of the most important features of the app. It should be possible to categorize warning symptoms. During the video consultations, the counsellors should help write these, as it should not be a stand-alone tool.

Hope box:
This feature may make the app overly complex.

Mood ratings:
This may be a valuable feature if used during consultations, where the woman is asked to fill it out. However, it may be counterproductive to simplicity unless used right but is better for long-term counseling as it is difficult to use short-term especially if compliance is compromised. It is suggested to remove the feature.

Rant box:
Generally, the attendees fail to see the purpose.

Quick message:
Pre-produced messages. Without 24-hour coverage this feature is not applicable to emergencies. It may be outside the context of the STOP project. However, some see it as an important feature.

Nearest emergency rooms:

[redacted]mportant that the counsellors are skilled in filling out safety plans when they help the women write these.

Peer stories:
Personal messages:
It was suggested that the app contains information about violence and risk factors (for both woman and child) related to the pregnancy to inform and motivate the women.

The discussion continued on Day 2, as the attendees consider it key to the project. The features will also be discussed again at the next monthly meeting.

4. DAY 2 – Tuesday 29 September

The agenda for Day 2 was slightly changed, to reflect the continuation of the important and fruitful discussion of WP3 from Day 1.

4.1 Implementation and multidisciplinary assessment of the STOP intervention – WP4

The WP will improve support for women with IPV exposure for their empowerment and a reduction in perinatal depression and repeated IPV episodes. To guide the implementation of the WP, a protocol will be written according to the SPIRIT guidelines for clinical trials.

WP4 is a continuation of WP2 and WP3 and concentrates on implementing and evaluating the eHealth components that are developed. The approach will be multidisciplinary, relying on mixed methods methodologies. In evaluating the intervention, the acceptability, feasibility, and effect of the apps will be assessed. In both Denmark and Spain, data will be collected at study inclusion (pre-intervention) and six months post-eHealth interventions. The information collected is change in women's empowerment, assessed by ISA, EPDS and MOVERS. The WP will evaluate the effect of video counseling and the safety planning on IPV occurrence and signs of depression among pregnant women exposed to the IPV. The use of social science methods will allow us to also evaluate the participants' experience with the intervention, as well as the acceptability of the intervention setup.

The women will be invited to anonymous participation in the project at their first physical conversation with their midwife as an add-on to the routine antenatal care (GA 14-16), where they will be asked if they would like to participate in the intervention; all will be informed they should they decline, it will not affect the service they receive in any way. If a pregnant woman, as part of routine antenatal care is found to be in need of special support because of e.g. exposure to violence, she will be referred to department capable of tailoring individual programs for her.

[redacted]rent types of assessments and measures were discussed, including before/after the intervention, and support of family members. Early studies must be determined soon, if we want to be able to include this in what we ask the women during evaluation.
Intermediate measuring using small questionnaires may study the app and consultation's influence on women's ability to conduct safety planning. It should be evaluated as an outcome measure.

[redacted] presented her findings from a forthcoming systematic review of IPV and eHealth interventions and shared her thoughts for a multidisciplinary assessment of the STOP project and the importance of establishing core outcome measures for IPV.

The acceptability and feasibility of video counseling and the safety planning app will be evaluated by the MAST (Model for Assessment of Telemedicine Applications) model. [redacted] presented the model and its applicability in STOP:

Multidisciplinary assessment:

1. Health problem and characteristics of the application
2. Safety
3. Clinical effectiveness
4. Patient perspectives
5. Economic aspects
6. Organizational aspects
7. Socio-cultural, ethical, and legal aspects

The clinical effectiveness will be measured via objective 1: Effect of video counseling + safety app on reduction of IPV.
Outcome measurements: Questionnaire pre-post intervention

1. IPV: ISA scale
2. Depression: EPDS
3. Empowerment MOVERS

Health problem and characteristics of the application, safety, patient perspectives, organizational aspects, socio-cultural, ethical, and legal aspects will be measured via objective 2: Acceptability and feasibility of video counseling + safety app.
Outcome measurements: Individual qualitative interviews post-intervention

- Participants: Health personnel + pregnant IPV victims
- Tool: Semi-structured interview guide based on MAST topics
- Data: Audio records, transcripts, Nvivo
- Analysis: Content analysis (deductive - inductive)

[redacted]

Economic aspects will be measured via basic cost data that can be used to calculate the costs of upscaling the intervention to all hospitals and healthcare institutions in Denmark and Spain will also be collected.

The outcomes of the project were discussed. Inclusion and exclusion criteria for those who screen positive were discussed. We shouldn't exclude non-native language speaking women, as IPV may also be prevalent among immigrant partners. Many immigrants in Spain come from Latin America, and as such speak the local language, but immigrants from e.g. North Africa would otherwise be excluded, as would many immigrants in Denmark. Rather, it would be beneficial if the midwives determine the women's potential and thereby decide whom to exclude and whom to include.

Some women will need to consider their participation, and those who initially refuse may later reconsider. If so, we should make it clear to the women that the project is still open to them. If women who after one video counseling session are referred to shelters or other services that assume counseling are likely to exit the project. It will be beneficial to make a follow-up of those women, in order to gain insight into STOP's effect on these women as well.

A qualitative study should analyze the motives of both those women who accept and those who decline participation.

A separate meeting will be set up to discuss publication policies including co-authorships.

4.2 Video Counseling and Safety Planning App – WP3 (Continued from Day 1)

The attendees discussed the features of the app and agreed that the following features are:

Required:

- Contacts
- Warning signs
- Strategies
- Quick messages
- Nearest emergency rooms

Potential:

- Peer stories
- Mood ratings (Generally considered potential amongst the Danish attendees while dismissed by the Spanish attendees)

[redacted]*fluous or not relevant:*

- Personal messages
- Hope box
- Mood ratings
- Rant box
- Take a break

Except for peer stories, there was general consensus among the attendees about what to keep and what to scrap from the app. Peer stories may not help a woman in her acute situation, but it might inspire her. The possibility to include facts and risk factors about the consequences of IPV was again requested. It is helpful to women to know of other women's success stories, but the wording is very important and must be carefully considered in order to have the desired effect. Face-to-face communication is generally much more effective. Peer stories are a sympathetic idea, but the right phrasing is needed. Kristine will ask Danish and Spanish non-profits about relevant and effective peer stories, which will be included insofar as we can find them.

It is cardinal that the app is designed with usability in mind. The pregnant women must be able to easily find the right categories in the app, or its effectiveness plummets.

Strategies for danger situations should be arranged according to time, place, context, and other relevant factors. Danger assessment is a prerequisite for a safety plan. The ISA has an intensity score from which we can determine the risk level, which counselors must be aware of. We must be morally bound to inform the women when we are required to report IPV. It would be useful to develop a protocol for reporting cases of violence against the woman and a protocol for women who screen positive.

The need for risk scores to aid midwives was discussed, but no conclusion reached.
It was emphasized that with only a few (≈6) consultations (generally one per week), what we are able to achieve is limited. Especially if the woman only realizes the severity of the IPV after a while. As we offer counseling rather than psychological attention, we are unable to offer more than a few sessions. If women after the maximum number of sessions still shows a need for professional attention, we must refer them to other services. The midwives should follow-up with the women afterwards.

While the app is not a stand-alone tool, as midwives and counsellors will guide the women in its use, it should be considered the woman's own app - neither midwives, counsellors, nor anyone else will be able to access the data in it.

4.3 Feasibility of Continuation and Upscaling – WP5

WP5 is an exploratory WP intending to determine the feasibility of a large-scale RCT by designing and analyzing a pilot RCT. WP5 is an important part of the project, pointing forward to future projects and studies on IPV interventions. The feasibility of the project will be measured based on input from the previous parts. WP5 provides the basis for our claim that this project will help empower all women in Europe. The WP points to the future with ample opportunity to continue the collaboration of the Consortium.

WP5 studies women who are screened positive for IPV according to the thresholds of our screening tools.

The information to be obtained in WP5 is:

- How many pregnant women accept to fill in the IPV screening questions?
- Do the screening questions capture women exposed to physical IPV?
- How many women exposed to physical IPV accept to participate in the intervention?
- How many women are willing to participate in follow-up interviews after 3 and 6 months?
- What is the acceptability of the m-Health package for ongoing IPV prevention?
- What is the acceptability of video (and phone) counseling for IPV prevention in terms of compliance to the scheduled counseling sessions?

The objectives of WP5 are to determine estimates for the variance of key clinical outcome measures, and the drop-out rate, to be used for sample size calculation of the full-scale RCT which the Consortium contemplates in continuation of the STOP project. Further, it will estimate recruitment duration and determine adherence to an eHealth intervention for use as an indirect measure of acceptability. As part of that, it will obtain the reasons for non-adherence, identify obstacles to recruitment, and detect other feasible measures.

To determine whether the eHealth intervention can be feasibly delivered within the context of a full-scale RCT, the WP looks at the population (pregnant women screened positive according to the threshold/tool, the intervention (m-health, as defined according to WP3 and WP4), the comparison group (standard of care, without mHealth), the outcome (measurements of feasibility), and the design (pilot parallel RCT, co-designed by patient input using Zelen's design, if permitted by the ethics committee). Ditte shared the following two links about Zelen's design:
https://www.sciencedirect.com/science/article/pii/S089543561930602X?via%3Dihub
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1112637/

In preparing the RCT, it is important the women receive the same number of counseling sessions, with the same content. Video consultations should be structured accordingly.

[redacted]ty women in total (ten from Denmark and ten from Spain) will be randomized for the pilot RCT. The sample size is fairly small; Vibeke will discuss with Khalid Khan whether we are able to increase it.

In determination of feasibility, we will perform the analysis against established stop-go rules (response of the ethics committee, consent rate, dropout rate, adherence rate) for reporting to comply with the CONSORT statement for pilot and feasibility trials.

4.4 Social Activities

Following the scheduled presentations and discussions, the Kick-Off was closed with a quiz about the STOP project and the sites.

5. Appendices

Appendix 1: Attendance list
Appendix 2: Agenda

5.1 Attendance lists