STOP

Intimate Partner Violence In Pregnancy

Second Consortium Meeting

Minutes

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Report on the second consortium meeting

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V0.1	1/6/2021	First draft	Ivar Benjamin Horte, RSD(OUH)
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Executive Summary

The second consortium meeting of the STOP project was a virtual meeting and took place on December 17 and 18, 2020. During the meeting, the progress of each work package was discussed. The project's Advisory Board attended the meeting and provided feedback and suggestions to the consortium.

1. Introduction

1.1 Purpose of the document

The purpose of this report is to document the presentations and discussions from the second consortium meeting of the STOP project.

1.2 Structure of the document

The report follows the agenda for the two-day meeting, beginning with WP1 and ending with WP5. For coherence, discussions on WP4, which took place over both days are combined under Day 1.

1.3 Glossary

AAS	Abuse assessment screening
AOB	Any other business
D	Deliverable
DA	Danger Assessment
EPDS	Edinburgh Postnatal Depression Scale
EHR	Electronic health record
GA	Gestational age
IPV	Intimate partner violence
ISA	Index of spouse abuse
MOVERS	Measure of Victim Empowerment Related to Safety Scale
NP-ISA	Non-physical index of spouse abuse
P-ISA	Physical index of spouse abuse
RSD	Region of Southern Denmark
RSD(CTP)	Center for Telepsychiatry
RSD(OUH)	Odense University Hospital
STOP	Stop intimate partner violence in pregnancy *(the title of the project)*
T	Task
UGR	University of Granada
WAST	Women Abuse Screening Tool
WP	Work package

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2. STOP - Second Consortium Meeting

Date: December 17, 2020 (9 AM – 1 PM)
December 18, 2020 (9 AM – 1:30 PM)

Venue: GoToMeeting

Attendants:
Antonella L. Zapata Calvente (UGR)
Berit Schei (RSD)
Bjarne Rønde Kristensen (RSD)
Ditte Linde Søndergaard (RSD)
Emilie Nielsen (RSD)
Ivar Benjamin Horte (RSD)
Jesús Lopez Megias (UGR)
Juan Carlos Torres (UGR)
Karen Andreassen (RSD)
Kristine Falk Pedersen (RSD)
Lea Bo Sønderlund Ankerstjerne (RSD)
Rodrigo Fernández López (UGR)
Sabina de León (UGR)
Sandra Martin Pelaez (UGR)
Stella Martin de las Heras (UGR)
Vibeke Rasch (RSD) *(Project Coordinator)*

STOP Advisory Board:
Carmen Vives
Emma Bergman
Mirjam Lukasse *(Leader of the advisory board)*
Tine Gammeltoft

3. Day 1 - December 17, 2020

3.1 Welcome

Welcome to the second consortium meeting of the STOP project, and especially welcome to members of our Advisory Board. The board will meet directly following the program on Day 1 and they will present their feedback and advice on Day 2.

We had hoped finally to be able to meet in person but with the current COVID-19 situation in both Denmark and Spain, this was not possible. We hope to be able to meet physically sometime in 2021.

3.2 Overall Status of the Project

We are only four months into the project and already ten deliverables have been completed and eight milestones reached. These are deliverables 1.1, 1.3, 1.5, 2.1, 2.2, 2.5, 3.5, 3.6, 4.1, 4.2. and milestones 1,

2, 6, 7, 9, 10, 13, 14. Deliverables 2.3 and 2.4 were supposed to have been completed in November 2020, but because of the ongoing COVID-19 restrictions we received permission from the Project Officer to postpone them until the end of January 2021.

A number of deliverables will be completed over the next few months, preparing the screening and the counseling intervention for inclusion of pregnant women. In January 1.5, 2.3, and 2.4 are due, and in February all remaining deliverables in WP3 must be finished: 3.1, 3.2, 3.3, 3.4, and 3.7. These will complete RSD(CTP)'s primary tasks in STOP.

While it is still a long time from now, we would like to remind everyone that a progress report is due in September 2021 (month 13). The purpose of this report is to document the progress of the project to the EU. Also, please remember that financial reporting will be at the end of the project, so please keep track of any time sheets, expenses, etc., that you might have – note that person months have been allocated across WPs. Please, keep in mind that only expenses from September 2020 and onwards may be reimbursed by the STOP budget.

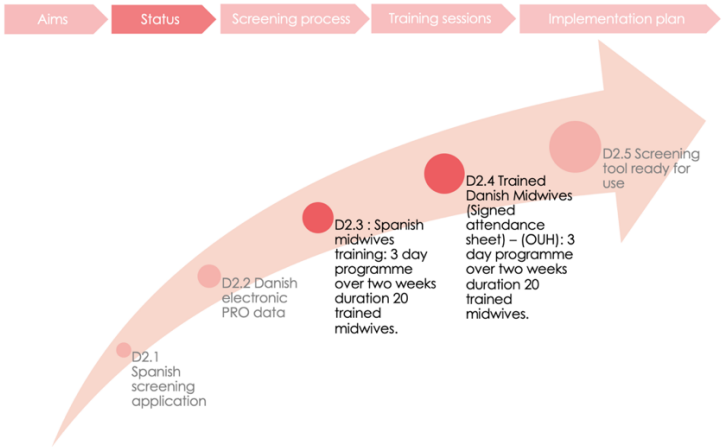
When earlier this year Odense University Hospital merged its EU participant identification code with the Region of Southern Denmark, an amendment became necessary. This has now been prepared and is only awaiting submission. However, technical issues with the EU's Funding & Tenders Portal prevents us from submitting the amendment at this time. The Project Officer has repeatedly asked their IT Helpdesk for a solution, which we are still waiting for. Once this is resolved, we will directly contact those at RSD and UGR who needs to act on it.

3.3 WP2: Systematic Screening for IPV

The purpose of WP2 is to develop a systematic risk screening program in Denmark and Spain. Using AAS, ISA, and WAST-Short (the latter in Spain only) pregnant women exposed to IPV will be identified. This subgroup will be offered a video counseling intervention, which is being prepared in WP3. The program features will ensure that women and midwives are protected during the data collection process so as to avoid risk to their safety. The feature to detect IPV exposure will ensure anonymity and confidentiality in compliance with both Danish and Spanish law. Each pregnant woman will be assigned an identification code for anonymity. The Danish eHealth tool and the Spanish application will both provide for informed consent.

Antonella presents the status of WP2 on the part of UGR.

2.1, 2.2, and 2.4 have been completed while 2.3 is awaiting completion.



2.1. ISA cut-off scores have been established:

SPAIN: NP-ISA: ≥ 14; P-ISA: ≥ 6
DENMARK: NP-ISA: ≥ 25; P-ISA: ≥ 10

UGR is using a cut-off validated in Spain by, among others, members of the STOP consortium. RSD is using the original cut-off set from when the ISA tool was first developed. It is the intention of STOP to validate ISA in Denmark with the assistance of UGR.

2.2 The development of an ICT application for the detection of IPV in Denmark and Spain has been completed.

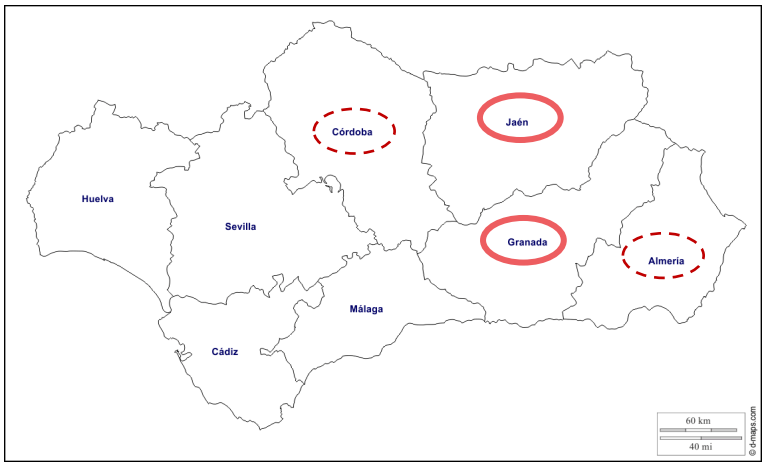
In Denmark, an electronic PRO data system is used to conduct the screening. This system is used by all women who attend antenatal care and first trimester ultra-sound screening in RSD, an offer more than 90 percent of pregnant women accepts. The PRO data tool, called My Hospital, is an app for smartphones and tablets, allowing the women to fill it out remotely. The women fill in the survey prior to their first appointment at the antenatal care clinics.

In Spain, the screening application will be facilitated by midwives via tablets and the women will answer the survey during their appointment. The screening process is as follows: Pregnant women (n=2000) will be screened at their first antenatal care visit by primary health service midwives (n=20). The midwives explain the objectives of STOP and stresses confidentiality after which they provide the women with a tablet with the screening application installed. The women answer the questionnaire and return the tablet. No partners will be present during this process. Should the COVID-19 situation worsen, preventing face-to-face contact with the women, midwives may conduct a telephone consultation; a contingency plan is place for telephone conducted consultation. Checkboxes have been included in the app to check if IPV screening is assessed over the phone.

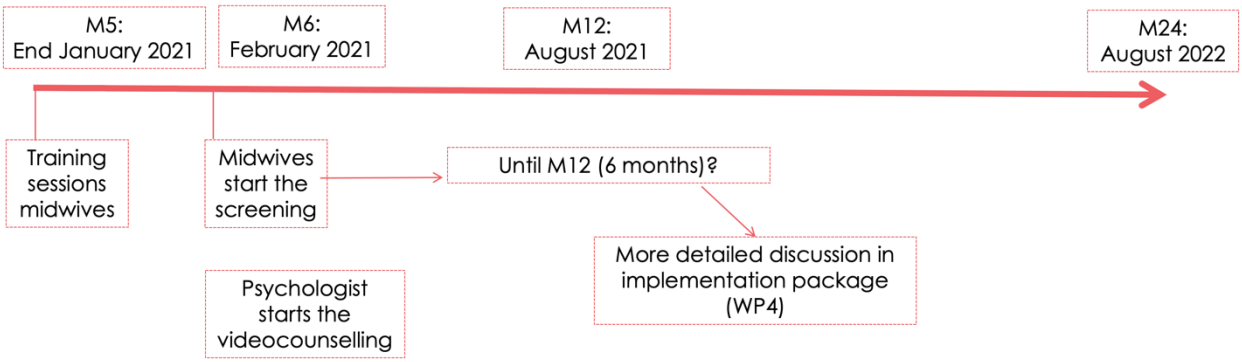
The screening process in Spain is facilitated by a dedicated app developed for STOP and installed on tablets to be used in the consultation with midwives. The app is prepared to be used both online and offline. The data collected will be stored on protected and secure servers and each midwife will have personal login credentials for the upload of data. When in consultation with the pregnant women, the midwives will provide a brief summary of STOP and ensure the women that anonymity and confidentiality are guaranteed. They will then obtain informed consent from the women. Should a woman reject participation, the midwife will ask her about her reasons for not participating and provide the woman with a leaflet about alternative resources. Participating women will be presented with a number of demographic questions prior to the actual IPV screening questions from the AAS. Those women who screen positive on AAS will be directed to the ISA. When using both AAS and ISA on the same population, ISA detects more cases than AAS; this discrepancy is confusing the researchers at UGR. To study it, a randomly selected 20 percent of the women who screen negative will be directed to ISA as well. Following the screening, the midwife will motivate the woman's participation in the video counseling intervention (UGR estimates an eight percent prevalence). If the woman accepts participation (estimated n=130), she will provide personal contact information, such as her e-mail address or her telephone number as well those timeslots when she prefers to be contacted (i.e., those times when it will be safest for her). Women who reject the intervention are asked as to their reasons why and are provided with a phone number to the counseling service, in case they later change their mind. The midwife will assure each woman that is welcome to do so.

The Advisory Board asked whether we have a protocol for directing those women who screen positive to other relevant services. Based on the severity of violence, we will refer to necessary resources in the community, such as social workers, as well as following all legal guidelines mandated by law. Should the midwives become aware of any serious risk to the wellbeing of a women, she may break her confidentiality.

2.3. The selection and training of midwives in Spain has been postponed and will take place in January 2021. To ensure a representative sample of women and reliability of the collected data, we will train at least twenty midwives in each of the two settings. Midwives are to be based in settings that offer antenatal care visits and they will have some experience with research in women health topics. The feedback from midwives about the systematic screening will be obtained and the impact on their work evaluated. In Spain, twenty midwives from Granada and Jaén (and possibly Córdoba and Almeria) will receive online training conducted by Jesús Lopez Megias and Stella Martin de las Heras during the month of January 2021. The duration of the training sessions will be two to four hours and the training sessions will be evaluated using a seven-point Likert scale (1-7).



The contents of the training sessions are: General aspects of IPV, a general introduction to the STOP project, contents of the screening app (rationale of and explanation of the screening tools), managing of the screening app, the role of the midwives, and communication (how to approach women about this sensitive topic, communication techniques, etc.). The screening phase lasts twelve months (not six months as shown below).



2.4 Lea and Karen reported the progress of WP2 at RSD(OUH). The selection and training of midwives in Denmark has been postponed and will take place in January 2021. Practical issues relating to the COVID-19 situation and ethical considerations have proved it difficult to find women for the pilot testing of ISA, RSD(OUH) has therefore decided to do the pilot testing on people who have expertise in the field of IPV, e.g., our Advisory Board, staff from charity helplines, and staff at women's shelters. The AAS questions have been approved and ISA questions will be mandatory in the screening process. In January 2021, the My Hospital PRO questionnaire will include AAS and ISA at all hospitals in RSD;

completing the survey will require answering of all AAS and ISA questions. The questionnaire is a part of the electronic health record.

The aims of the training of midwives in RSD are to introduce them to the concept of IPV as well as to the STOP project. The training sessions are a two-and-a-half-hour course taking place between November 2020 and January 2021. Besides IPV and STOP, the topics of the training sessions are the PRO questionnaire (AAS and ISA), an introduction to the intervention, and introduction to communication tools for the structure, and strategy for talking about IPV during consultations. The session will include virtual presentations and discussions.

At RSD, training of IPV-counsellors will happen at a three-day workshop on January 11-13. The screening begins on January 25, 2021.

3.4 WP3: Video Counseling and Safety Planning App

Kristine reports the progress of WP3. Focus group interviews and workshops have been conducted to collect data from both countries, explore similarities and differences, identify pregnant women's support needs and existing ways of handling risks of IPV, gain insight into the perspectives and needs of women at risk of IPV and antenatal care workers, desired features of a video counseling service, app-based support for self-management, empowerment and safety planning, and ways of implementing the eHealth intervention in existing support frameworks.

3.5 Focus group interviews have been conducted at all sites:

- One focus group interview with Danish NGO's
- Three individual interviews with Danish NGO's and midwives
- One interview with a Danish woman who have experienced IPV
- One focus group interview/workshop with Spanish NGO's and midwives
- One focus group interview with Spanish women who have experienced IPV

3.6 Workshops have been conducted at both sites:

- One participatory workshop with Danish NGO's and midwives
- One focus group workshop/interview with Spanish NGO's and midwives

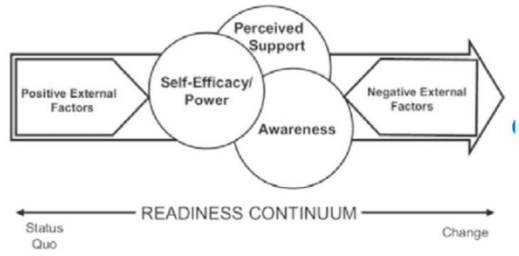
During the focus group interviews and workshops, a number of concerns arose that we need to take into consideration:

Concerns	Prevention/solution
6 video counselling sessions is not enough for treatment of violence	Expectations alignment is important in the beginning, this is counselling
Women who don't have Wi-Fi or enough data to conduct a video counselling	Phone call as an alternative?
Women who are together with their children and partner all the time	Exclusion?
Is it possible to gain the necessary trust in a video counselling, or will it create a distance and coldness between the counsellor and the woman?	Research with other target groups e.g. people with mental illness shows that it is possible to obtain therapeutic alliance on video.
Call will get interrupted, or unexpectedly finished, for instance if the partner is or comes home.	Code word and Plan B.
The women will feel watched and insecure about the safety of the applications.	Safety reassurance is important in the beginning

3.2. Kristine sums up the development of the content of the video counselling solution. The purpose of the counseling is to clarify and assess the situation of the pregnant woman subjected to IPV and to help her acknowledge that she is in a violent relationship. Ultimately, the counseling will guide her and encourage her to seek further treatment and help. The format of the counseling will be up to six video consultations of sixty minutes each. They will take place weekly or once a fortnight. The initial idea is that contents of the sessions will be customized for the individual needs of each woman, and while following scheduled themes they will come in no specific order. In Spain, the Amazon Chime communication service will be used; it has been tested and approved by RSD(CTP) and UGR. In Denmark, the app My Hospital (Mit Sygehus) will be used and the technical set up at all hospitals has been completed.

The suggested content of the video counseling sessions:

Framework:
Dutton's Empowerment Model: **increasing women's safety and enhancing choice-making and problem solving.**
Psychosocial Readiness Model (Cluss et al., 2006): **three internal factors (awareness, self-efficacy and perceived support) + external factors.**



Awareness	Session 1. - Danger Assessment and the evaluation of the abusive behaviour (psychological, physical…) Session 2-3. - Psycho-education: healthy relationships, the cycles of violence, consequence of violence…
Perceived Support	Session 2-3. - Safety Planning (app) - Network and resources
Self-efficacy	Session 4-6: - Self-esteem (empowerment) - Fears - Choice making and problem solving

The feasibility of scheduled themes is discussed. It is difficult to settle such themes for each session as it depends on the needs and circumstances of each woman. Also discussed are the value of linking to external resources, such as relevant WHO websites, etc. and brief descriptions of the themes and contents of the session.

3.3 A market survey of available safety planning apps has identified evidence-based mHealth approaches for supporting women at risk of IPV. Based on input from 3.1 as well as data security assessment requirements, CTP has chosen myPlan as the safety plan for STOP. A Danish version has been developed and it is now being translated into Spanish. As soon as the translation is finished, coding of the Spanish version will begin. At this point in time, data processing agreements are in process in both Denmark and Spain, the features have been chosen (based on our discussions at the STOP Kick Off Meeting in September 2020), and the programing is underway with a deadline of January 11, 2021. Flow testing remains to be done.

The app is called "Pregnant – Week by Week" ("Gravid – uge for uge" in Danish and "Embarazo – semana a semana" in Spanish). It is our intention that the women will customize the app and make it their own, suiting their individual needs. The app will be launched early/mid-February in Denmark and as soon as possible in Spain, aiming for early February.

The features of the app are:

- Contacts
- Warning Signs
- Strategies
- Quick Message
- Nearest Emergency Room
- Share My Location
- Knowledge About Violence
- Quick Exit

The inclusion of infographics is discussed. General infographics might be useful, but we should be wary of overloading the app with information. The approaching deadlines limit our ability to include these.

Jesús adds that the use of *some* graphic elements and other resources is valuable for the counseling. Likewise, it may be valuable to add or link to some online materials for the women to revise once they have worked with the counselors or for the counselors to suggest as useful resources for the women to consult. This should be general information relevant for most or all of the women, e.g., information about the cycle of violence. The nature of virtual counseling means that the women will benefit from additional resources which are not needed with face-to-face counseling.

Stella notes that we do not have to decide the use of infographics at this time, but to wait and see how they turn out. We should decide after the meeting with Jacquelyn C. Campbell on January 14, 2021. However, we cannot wait for too long, as the training of the counselors is coming up and they will need to know about all aspects of the safety app in order best help the women use it. If the app is not ready in time, Kristine offers to conduct further sessions for the Danish midwives.

Berit nots that high quality resources during counseling are important but the overarching purpose of the safety app is to support women who are in danger. The simpler a safety app is, the more useful it is.

Vibeke suggests a WP3 meeting to focus on relevant resources which may be added to the app. Antonella notes that some content may need to be developed first, and that this may be possible for mid-January.

Kristine reminds us that at this point, we may add any resources and materials that we see fit, but once the app has been finished by the programmers, any additional content must be paid for separately.

The women must learn about the safety app during their very first counseling session. Introducing the app is very important. Vibeke notes that introducing the app in Spain may be easier as it is introduced by a single person who is familiar with IPV counseling, whereas it in Denmark will be introduced by midwives (n=10) who are newly trained as IPV counselors.

3.4 The training of the counselors will take place on January 11-13, 2021 in Denmark and on January 21-22, 2021 in Spain. In Denmark seventeen midwives will participate for three days of case-based training, followed by an additional individual technical test of the video systems at the different sites (hospitals). In Spain, participants are Sabina and Jesús for two two-hour sessions followed by an additional technical test of the video counseling system.

The contents of the training sessions are:

- Framework for the video counseling sessions (Dutton)
- Knowledge about violence
- Danger assessment
- Process of self-recognition
- Resources and network
- Empowerment, self-esteem
- The difficult conversation
- Supervision
- Safety planning app
- Video counseling – best practice

3.7 A joint training workshop will be organized with participation of midwives/counselors from Denmark and Spain, as well as key project members. The purpose of this is to provide training and inspirational sessions to the personnel responsible for carrying out the counseling sessions. It will take place on February 1, 2021 as a two-and-a-half-hour webinar on GoToMeeting. Speakers are Jacquelyn C. Campbell from DOVE and Nancy E. Glass from myPlan US.

Berit inquires as to procedures for emergency situations. Vibeke replies that it is crucial that women are guaranteed confidentiality but in emergencies we may have to break it and that our safety policy allows for this. Regardless of this, national legislation may require that we break confidentiality if we suspect that the woman is in imminent danger.

It is agreed that the training manual should include a paragraph about what to do should the need for breaking confidentiality arise.

3.5 WP4: Implementation of the STOP Intervention

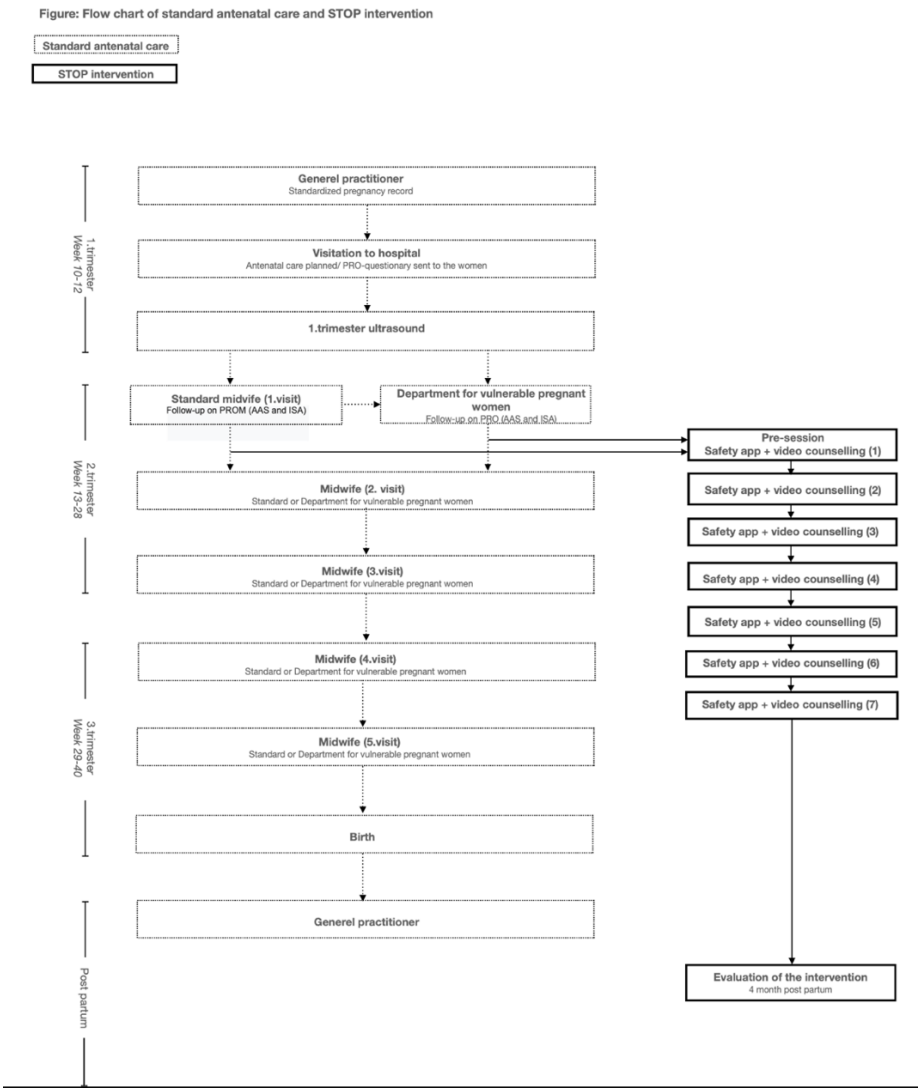
Presentations and discussion on WP4 take place over both days. For comprehension, they are combined here.

3.5.1 WP4 in Denmark

Karen reports on the implementation of the STOP intervention in Denmark, as demonstrated via this flowchart:

[see next page]

Figure: Flow chart of standard antenatal care and STOP intervention



All pregnant women in Denmark are invited to a first trimester ultrasound scan at an antenatal care clinic; 99 percent of them accept. In preparation for this, they fill out a PRO survey answering various lifestyle related questions and it is part of the women's EHR. The survey now includes the AAS. Women who screen positive for IPV exposure undergo repeated screening via ISA from which two scores are computed: P-ISA (severity of physical abuse) and NP-ISA (severity of non-physical abuse). The cut-off scores are ten for P-ISA and twenty-five for NP-ISA. All pregnant women in RSD are included, though women who cannot be informed about the study without their partners' or other relatives knowing about it are excluded, as are women who do have the mental or physical capacity to participate, women who do not understand Danish, and women who do not have a smartphone.

Women who are screened positive for IPV exposure will be invited to anonymous participation in the project at their first physical conversation with their midwife (GA 14-16). Midwife consultation is differentiated in order to ensure the necessary support and care in in relation to both obstetric and social and psychological risk factors. Women can be included to the intervention from both standard care consultation and from RSD(OUH)'s Department for Vulnerable Pregnant Women.

It is important to stress that the intervention is an add-on to the routine antenatal care, not a replacement.

Follow-up on IPV-exposure happens during consultation only if the partner does not participate. If the partner does, the midwife will call the woman afterwards to arrange an additional consultation. Some pregnant women may need time to acknowledge that they are exposed to violence, meaning that inclusion to the project will happen later in pregnancy. If a pregnant woman is suitable for the project and has given her consent, the midwife sends an e-mail to the IPV counsellor with the woman's phone number. The pregnant woman is contacted by the IPV counsellor and booked for a pre-session:

Pre-session with the IPV-counsellor:

- Follow-up on the answer from PRO
- Provide information about the project
- Get informed consent from the pregnant woman if she wants to attend
- Fill out a questionary with EPDS and Safety check list as well as background characteristic
- Introduce the Safety app

The following video counseling:

- Counselling held every second week
- The video counselling will be provided by the same IPV-midwife

After the video counseling:

- Women will be invited to an interview regarding the feasibility of video counselling and the smartphone safety app

Four months postpartum:

- Fill out a questionary with ISA, EPDS, and Safety check list

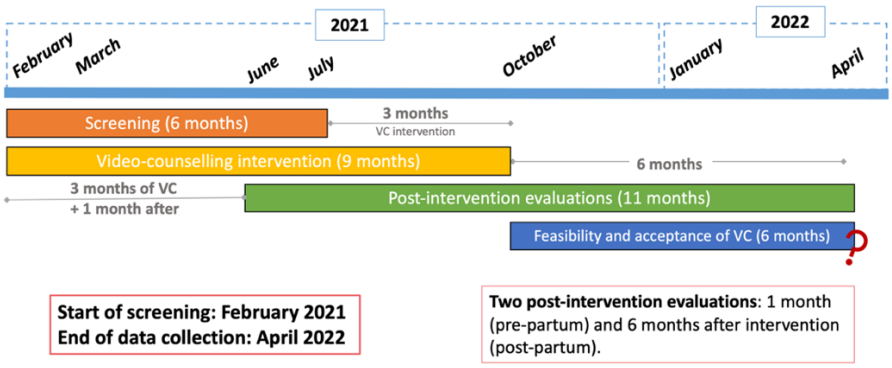
The follow-up data collection will compare before/after scores (ISA etc.). There will not be any control groups.

3.5.2 The Danish Version of ISA

Lea reports on the validation of the Danish version of ISA. The setup is in the making and the protocol is being prepared. The aim is to investigate the reliability and validity of the ISA and to establish a clinical cutting score for the physical and non-physical abuse subscales. The premature plan is that women who screen positive for IPV and answer the ISA will be part of the validation project. The women will be re-tested as part of the intervention. The validation is scheduled for the Spring of 2021.

3.5.3 WP4 in Spain

In Spain, the implementation is as follows.



Pregnant women are screened at the antenatal care setting using AAS and WAST-short, those who screen positive for IPV exposure were then screened using ISA. Those who screen negative are not eligible for participation. Eligible participants are invited to the project at their first physical conversation with the midwife and are offered six specially targeted consultations via video and get access to the safety planning app. UGR has developed a contingency plan for two scenarios: if not enough women are screened positive more midwives will be involved to screen a larger number of women (from the regions of Almería and Córdoba) and due to the risk of COVID-19 inhibiting the project start, phone consultations will be conducted or a postponement will be sought.

Participation in both screening and intervention is voluntary. If the woman accepts to participate, she will provide her contact information at the end of the questionnaire along with her preferred time of contact. A few days after the screening session, the counselor then contacts her for a pre-session by phone to obtain her informed consent, help her download the required apps (safety planning and Amazon Chime – for the video counseling), conduct a pre-intervention evaluation, and to schedule the first of the video consultations.

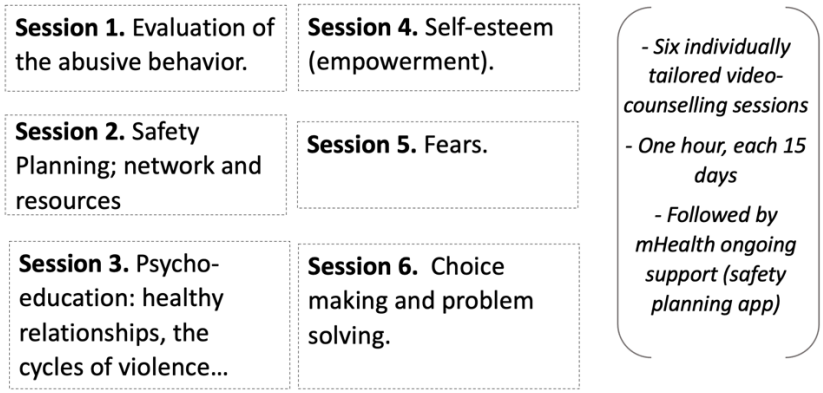
The leader of the Advisory Board inquires as to whether the intervention will be offered women whose pregnancies are terminated. Vibeke notes that this has not yet been determined, but we hope to be able to offer them some solution as they, too, are in need of an intervention.

In Spain, the intervention is planned to last from February 2021 to April 2022 and it will be conducted by Sabina (the psychologist). It will have four phases:

1. Pre-session (pre-intervention evaluation)
2. Video counseling sessions
3. Post-intervention evaluation (after 1 and 6 months)
4. Evaluation of the acceptability and feasibility of the intervention.

The pre-intervention evaluation will include MOVERS, EPDS, Safety Action Check List, and DA.

The video counseling sessions are structured as follows:



The post-intervention evaluations will include MOVERS, EPDS, Safety Action Check List, ISA, and DA leading to an evaluation of acceptability and feasibility of video counseling and app through semi-structured and in-depth individual interviews with five women and the psychologist.

3.5.5 Discussions on the implementation of WP4 in both countries

We will begin screening pregnant women by the end of January 2021 and the following month we will start the intervention. Vibeke notes that the Danish and Spanish teams should set up a meeting to look at whether the workflows are fully developed.

The timeframe of the follow-up in both countries is discussed. At this time, it is planned at four months post-intervention in Denmark (not four months postpartum as shown on the flowchart) and six months post-intervention in Spain. Jesús notes that we should have the same timeframe for the follow-up in both countries. Ditte notes that one or two months postpartum may be needed for measuring. Stella suggests that the first evaluation is before delivery and the second after delivery. The issue will be resolved at future WP4 meetings.

Vibeke is concerned that the number of women we can include within the project duration if we extend the screening period in time for the postpartum evaluation may compromise the sample size. She would prefer a larger sample size than follow through to postpartum for all. n≈440 in Denmark would be difficult to gather follow-up data from once postpartum.

Should the setup be different in Denmark and Spain? Vibeke suggests that those included in the qualitative study could perhaps be interviewed more than once? Jesús is in doubt about it, and whether we are allowed to change it in concern to the proposal.

A discussion of the pros and cons of changing the post-intervention evaluation follows. Berit states that a postpartum evaluation is very important, particularly given the short duration of STOP.

Six months post-intervention would likely clash with delivery; four months post-intervention would be preferable or an additional assessment after delivery. We could also do the second postpartum evaluation qualitatively. Asking women to answer a survey soon after delivery seems to be a bad idea.

Jesús notes that as this is a pilot study and not a randomized controlled trial, we can choose to do what we consider better. The postpartum evaluation is easier in Spain due to the lower number of women. In Denmark we could choose the qualitative assessment. The Danish team should discuss the setup internally.

Jesús suggests Spain waits and sees the progress of the project, expecting one-month post-intervention evaluation and see what is feasible. Try to have the six months post-intervention evaluation, if by June 2021 we don't have large enough sample size, we need to continue screening but if we have enough, we can do the six months evaluation. Ditte proposes a meeting in Denmark to decide there.

The only outcome short-term predelivery is regarding safety actions. Longer term outcomes postpartum will require postpartum evaluation. The Danish and Spanish teams will need to discuss and align this at a meeting, preferably early to mid-January.

The use of DA in Spain is discussed. DA is an objective in WP3 but not an evaluation measure. DA will be used to identify those women who need referral to further services, which is the reason it was included in WP3. Jesús explains that DA may be used in both Denmark and Spain.

The issue of women who don't have access to WIFI or data-plans was discussed. While it is the purpose of STOP to offer a *video* counseling intervention, the severity of IPV dictates that in those –

expectedly – rare cases when a woman who has screened positive has no Internet access, we will offer the counseling via telephone as we do not want to leave them behind. We will reevaluate this once the intervention has been in effect for a few months. We do not expect to see very many cases.

The issue of women who are with a partner or children at all times was discussed. In Denmark, these women are excluded whereas in Spain, we will try to offer them a room within the university where they may attend their counseling. We do not expect this to happen often.

The issue of informed consent was discussed. In Denmark, we will develop a form to be filled out during a pre-session with the midwife. This pre-session is expected to take place physically. The Danish team expect to have a meeting about collecting consent for the video counseling during the first week of January 2021. In Spain, we will use the electronic screening platform as an automatic consent vehicle collecting their consent for the video counseling when women proceed from the app's page one to page two. If the COVID-19 situation mandates screening via phone, the counselor will send the women a text message or an e-mail to a consent form.

End of Day 1.

4. DAY 2 - December 18, 2020

Day 2 begins with feedback from the Advisory Board, based on their observations on Day 1.

4.1 Feedback from the Advisory Board

The Advisory Board is impressed with the progress of STOP. The project consortium has enormous courage and has come a long way.

The Board provides their feedback to the screening tool, intervention, and safety app. Concerning the safety app, the Board thinks a diary function will serve as an important therapeutic tool for women's own insight. The app should be able to access the phone's camera and to store photos and conversations directly within the app. Eventually it may be important to the women to have an account of what they are going through, and the women may forget important details if they don't write them down. It may also allow them to identify patterns and provide a sense of security. The app may help empower the women, not only during pregnancy but also in the long-term. The Board thinks the emergency features are important but only relevant for a very limited number of people. The Board also thinks the women will answer the screening surveys accurately and truthfully.

The Board agrees that it will be valuable for the women if the app contains additional information to remind them of what they have learned during the sessions. The women may not need to consult it, but it will be there for those who do.

The Board suggests that different kinds of violence will be useful as many women are not aware that there are other kinds of violence than physical violence.

The Board inquires as to where the video counseling sessions are intended to take place, as some women may find it difficult to attend these in private. Kristine and Vibeke reply that we have considered it and will leave it up to the women to find a solution that suits them; we have considered providing a

room at the hospital but do not think this is a feasible solution. We will, however, do what we can to help the women find a suitable place. The Board notes that IPV is not an issue that women tend to talk about openly, so using for example a friend's house is not a useful solution and having the sessions at their jobsite is likewise not feasible.

The Board notes that it is not a good idea to have male video counselors. While it could work, women counselors are definitely preferable.

The Board suggests "testing" the midwives on changed attitudes, etc. following their training as those midwives who sign up for this job may have a special interest in the issue and thus have special knowledge or insight into the issue. The Board is keen on the teaching plan for the midwives, with case-based learning and practical training. They suggest having some people – former IPV victims – who have personal experience with IPV evaluate the cases and scenarios to be used in the training sessions. The Board emphasizes that the midwives must care but not care so much that, for instance, they offer to give their private contact information to the pregnant women. It is important to include this facet in the training. Vibeke replies that we are planning supervision and other measures for the midwives. The Board suggests having a follow-up training session as it would be valuable for the midwives.

The Board asks how we decided on six counseling sessions. Emile and Jesús reply that the STOP is a counseling intervention and not a psychological intervention. Revision of the literature on similar issues advises six sessions. With six sessions, the women will be ready for other public services which they may afterwards attend.

Stella notes that we must be flexible with the counseling timing, also for women who need to change their appointments with short notice. We should not have wall-to-wall sessions booked, as there need to be some time for flexibility, delays, etc.

The Board notes that the counseling in Denmark is handled by specially trained midwives while in Spain it is handled by a psychologist. It is common for pregnant women to see midwives and they may therefore easily tell their partners that they are seeing a midwife, whereas seeing a psychologist is not something they should tell their partner. How will we see to that? The Spanish team will discuss what the women can tell their partners they were doing while they're attending the counseling. The counseling will also contain debriefing elements, about what the women should do after a session.

The Board notes that some women are still completely honest to their partners and may tell them what is going on. Counselors should be prepared to read the women. Jesús replies that this is standard business for psychologists and Mirjam replies that midwives are also used to this.

The Board notes that some women are in denial and may not know why they need counseling and thus choose not to continue with it. Women who don't want to realize what is going on believe things are good as they are or that they will improve on their own once the child is born. Berit notes the women love their husbands and want the violence to end. Jesús notes that it is important that during the first session the counselors evaluate the stage the women are at, i.e., via the model of the stage of change. Ditte notes that we have discussed the need of a practical pre-session where we may see if the woman acknowledges that IPV is an issue. This could be linked to the model Jesús mentions.

Berit notes that counselors should ask the women what their goals are, what they hope to achieve. Women subjected to IPV are at different stages of comprehension; this is important to consider, also for our own analysis of the intervention.

The Board notes that sustainability is a concern in that STOP is a short project. They ask how we will ensure that the intervention does not disappear afterwards. Ivar replies that twenty-four months is the maximum length the project could have under its funding program, and that sustainability and continuation were written into the proposal; WP5 in part concerns continuation and funding for this. Stella notes that we will also seek national public funding for the continuation of the intervention. Emilie notes that the app is now paid for allowing us to use it in perpetuity, although some licensing restrictions may need to be maintained.

Emilie and Vibeke thanks the Advisory Board for their feedback. If during our recuring monthly meetings any issues arise, we will consult the Advisory Board. They may also be invited to future consortium meetings.

4.2 WP4 - Implementation of the STOP Intervention

Presentations and discussions of WP4 from both Day 1 and Day 2 are combined above.

4.3 WP5 – Feasibility of Continuation and Upscaling

The tasks of WP5 are still some time from now, but the team is working on preparing the basis for it. Sandra presents an update on WP5, which will determine whether the e-health intervention can be feasibly delivered within the context of a full-scale randomized controlled trial using this set up:

P	I	C	O	D
pregnant women screened positive according to the tool/threshold (WP2)	m-health (as defined according to WP3 and WP4)	standard of care (without m-health)	measurements of feasibility	pilot parallel RCT, co-designed by patient input (using Zelen's design, if permitted by ethics committee)

The objectives of WP5 are to:

- Determine the estimates for the variance of key clinical outcome measures and the dropout rate to be used for sample size calculates of the full-scale randomized trial
- Estimate recruitment duration
- Determine patient adherence to the e-health intervention for use as an indirect measure of acceptability
- Obtain the reasons for non-adherence
- Identify obstacles to recruitment, randomization, and consent
- Detect other feasibility measures

WP5 will seek input from focal groups in Denmark and Spain with victims of IPV. We are looking for their input regarding participation in the pilot randomized controlled trial

1. IPV victims state that they would have participated in that trial during their pregnancy. However, they believe that the main obstacles for participation would be:
   - to not consider herself as a victim
   - to feel ashamed
   - to be afraid of the partner learning about her participation
   - to believe that intervention will not help her

2. IPV victims express that in order to address those obtacles, is very important the way women should be approached. In this sense, they agree on the fundamental rol of the psychologist.

3. IPV victims also suggest that a "global intervention", including IPV plus other outcomes (postpartum depression, or others) would increase participation.

4. Spanish victims demand for the control group some kind of IPV support, either during the trial or afterwards. If this is not possible, they suggest to not inform to the control group about the existance of an intervention group.
   Danish IPV victim understands how RCT's works, that this kind of studies need a control group without IPV support.

WP5 relies heavily on input from the previous WPs in order to submit a proposal for ethical clearance for the trial.

4.4 AOB

The Project Coordinator suggests a physical meeting sometime in the spring of 2021 if at all possible, as it will be highly beneficial for all project members to meet in person and our next scheduled Consortium Meeting is not until the end of 2021. If it is not possible to meet in person before then, we should have an additional virtual Consortium Meeting in the late spring. Emilie will suggest possible dates before our calendars get to be too crowded. Jesús requests a list of meeting dates, including any additional meetings in 2021. Emilie will provide this.

The second STOP Consortium Meeting concludes with online social activities.

5. Appendices

5.1 Appendix A – Agenda

[Not included in this version]

5.2 Appendix B – Attendance List

[Not included in this version]