STOP – Third Consortium Meeting

June 23, 2021 (9:00 a.m. to 1:10 p.m.)
and June 24, 2021 (9:00 a.m. to 11:30 a.m.)

Venue: GoToMeeting.com

Attendees: [redacted] (Project Coordinator).

Day 1 – June 23

Welcome to the third consortium meeting in the STOP project. This meeting was decided in December as an unofficial, additional consortium meeting. The spring and summer of 2021 is a key period in the project and with our next consortium meeting scheduled for late November, the project group wanted this opportunity to check in on the progress of STOP and help keep momentum.

Overall Status of the Project (WP1)
The project has now entered its core phase with women being included into the intervention at both sites. Considering the circumstances, this is a great achievement.

Since spring, we have discussed the need for an extension of STOP. On May 21, we asked the project officer about the possibility of a ten-month extension. When by June 8 we had not heard from her, we sent her a reminder. As of June 23, we are still waiting for her response. We see from Horizon 2020 projects that, due to Covid-19, a six-month extension *should* be possible. Emilie and Ivar will follow up on this shortly *[a second reminder was sent on July 7, 2021]*.

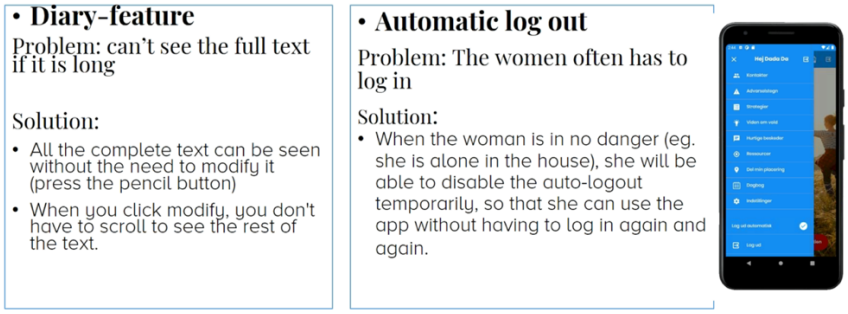
As previously mentioned, administrative issues within RSD requires an amendment to our Grant Agreement. We have been working on this since early June 2020, and now the financial unit in the European Commission's DG Justice have found a way to resolve the issue. This amendment will also address minor changes to the project, including the extension of the training deliverables 2.2. and 2.3, which were pushed from November to January.

Throughout the rest of 2021, three more deliverables are due: D1.4 – Progress Repirt in September and D5.1 – Protocol for Pilot RCT and D5.3 – Pilot RCT study + feasibility analysis in December.

As we will soon be halfway through STOP, Emilie and Ivar will prepare a draft of *Deliverable 1.4 - Progress Report*. It is a mandatory mid-term report required for projects with a duration of more than twelve months. It is due in September 2021 (month 13). All key members of the consortium

will be asked for input to the draft (UGR in July followed by RSD in August). Input should be limited to brief explanations of what was done and by which partner, as well as any deviations from the Grant Agreement and measures to prevent similar problems in the future.

Video Counseling and Safety Planning App (WP3)
The Safety Planning App has been updated with a diary feature and changes to the automatic log out function allowing the users to return to the app without the need of logging in again. These have been no-cost updates, as they improve on existing features. New features, however, must be paid for separately.



We are now paying €740 per month for the use of the app. Of the €10,000 set aside for subcontracting for the app, €7,354 have been spent on development. This leaves enough funding to last through September 2021. [redacted] and [redacted] are looking into how to finance licenses through the remainder of the project (estimated at €5,550). [redacted] expects that OUH and RSD will finance this. As soon as we hear from the project officer about an extension of STOP, we will need to consider how to finance any additional months of licensing.

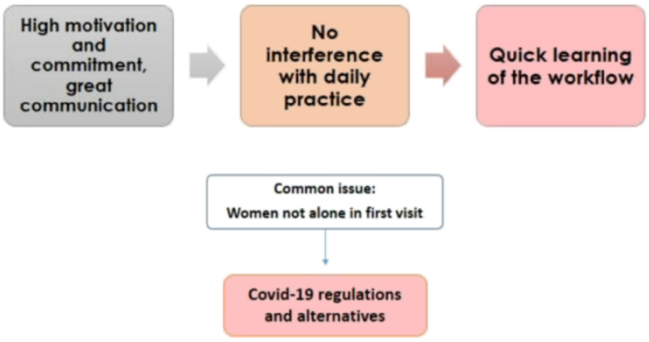
RSD-CTP continues to support both the midwives and [redacted] with whom they will have continuous follow-up meetings. [redacted] goes on maternity leave from September, at which time there will be a temporary replacement for her.

Two women have experienced issues with storage on their phones, preventing them from downloading the app. [redacted] will contact the developer about this. Jesús asks if the size of the app can be compressed. [On Day 2, Kristine reports that the developer agrees that the Android version is large compared with the iOS version. They will try to limit its size by the next update.]

It is important to look at the midwives' experiences with the counseling, but at this point it is likely too soon to do so, as the number of women whom they have been in touch with is still very low. We will consider this at a future monthly meeting.

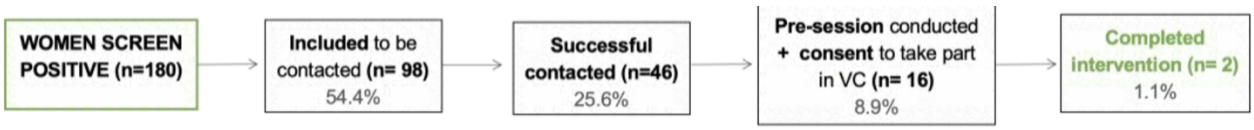
Implementation of the STOP Intervention (WP4)
Spain
UGR has experienced some challenges in the beginning with midwives relocating or dropping from the project. Additional midwives have been hired and the situation has been stabilized; there is a continuous flow of women. However, there is a decrease in the number of women, due, in

part, to a lower number of pregnancies as well as many midwives going on leave. By now, there are a total of 28 midwives across four primary care centers. Some midwives work in multiple centers, located in both urban and rural areas.

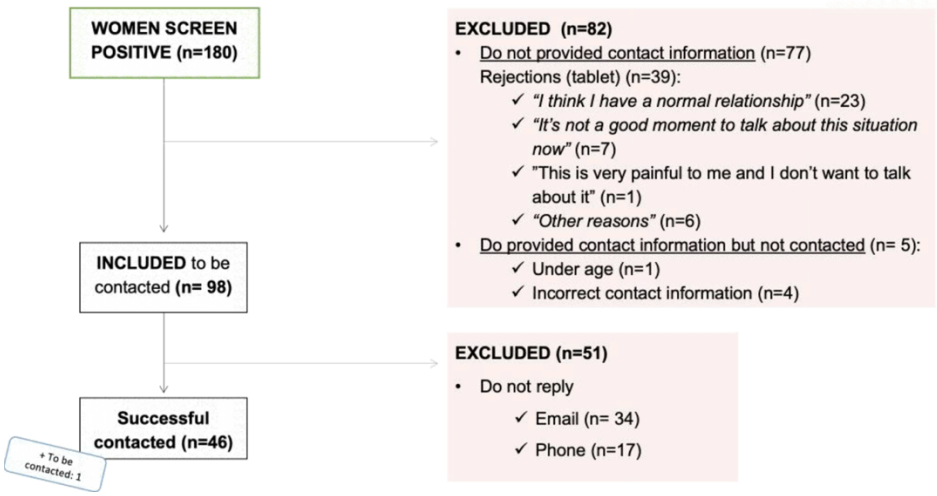


All midwives are highly motivated and committed to STOP and consider STOP a good way of addressing IPV. Most midwives have had no issues, however, often women are not alone at their first visit (where screening takes place) but bring their partners or family along. The midwives are developing strategies for having five to ten minutes alone with the woman. There have been no complaints about the screening process from the women and no issues with the user interface or the contents of the screening. However, language is sometimes a barrier in areas with high numbers of immigrants. The project is highly regarded across different populations, even by women who reject participation.

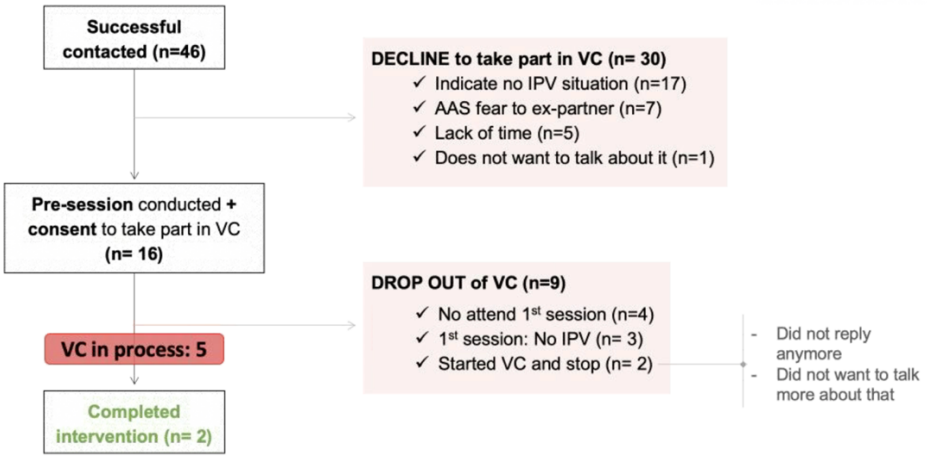
The WAST cutoff has been changed as there were too many false positive women; now two or more are needed to screen positive.



- 970 women screened in total in Spain and it is expected that 2,000 women have been screened by mid-November
- 180 positives (18.6 percent of invited women)
- 16 consented to video counseling
- 2 women have completed the intervention.



Reasons for rejecting participation:



Screening app and safety planning app:
UGR is continuously developing the screening tool. New QOL features and bugs are being addressed. New visual clarity as too many neglected to press the finish button in the app. Now midwives are automatically reminded to ask women to submit it (needed for acceptance of participation). A reject loop has been added for users to avoid missing data.

Safety APP downloaded

Woman	Nº sessions	APP*	No downloading reason
1	6	✓	
2	6	✓	
3	2	✗	Storage problem
4	2	✓	
5	3	✗	Storage problem
6	1	-	
7	1	-	

* Download planned for the 2nd session

Some women have experienced problems with the downloading of the app. Kristine is looking into this. Of its features, the most valued are resources and the diary function.

The quantitative evaluation is planned as:
Quantitative evaluations:
Measure of victim empowerment related to safety scale (MOVERS)
Edinburgh Post Natal Depression Scale (EDPS)
Safety Action Check List
Index of Spouse Abuse (ISA)

Lime survey (Link)
One and six months after finished the video counseling.

Qualitative evaluation:
Semi-structured and in-depth individual interviews:
Five women and the psychologist

Low e-mail response rates will be addressed by having the women double check contact information during the screening. Also, email text will be improved to be more personalized and pointing out the benefits for their babies.

The women feel the sessions are useful, supportive, and an opportunity to think about certain issues. Counselors feel the women are more empowered, more self-centered, and more informed (about opportunities and resources).

Berit very much appreciates the transparency and thoroughness of the process. She believes that those who decline or do not provide contact information – the majority of those would need it and appreciate it. Those who change their minds about not participating are given contact information to participate later or they may contact their midwife to be included. A card with contact information was considered, but they decided not to give out these.

Communication to the women and the text of the screening app have been adjusted during the last few months to better reach the women. Initial worries about preference of phone counseling vs video counseling have not been an issue.

Denmark

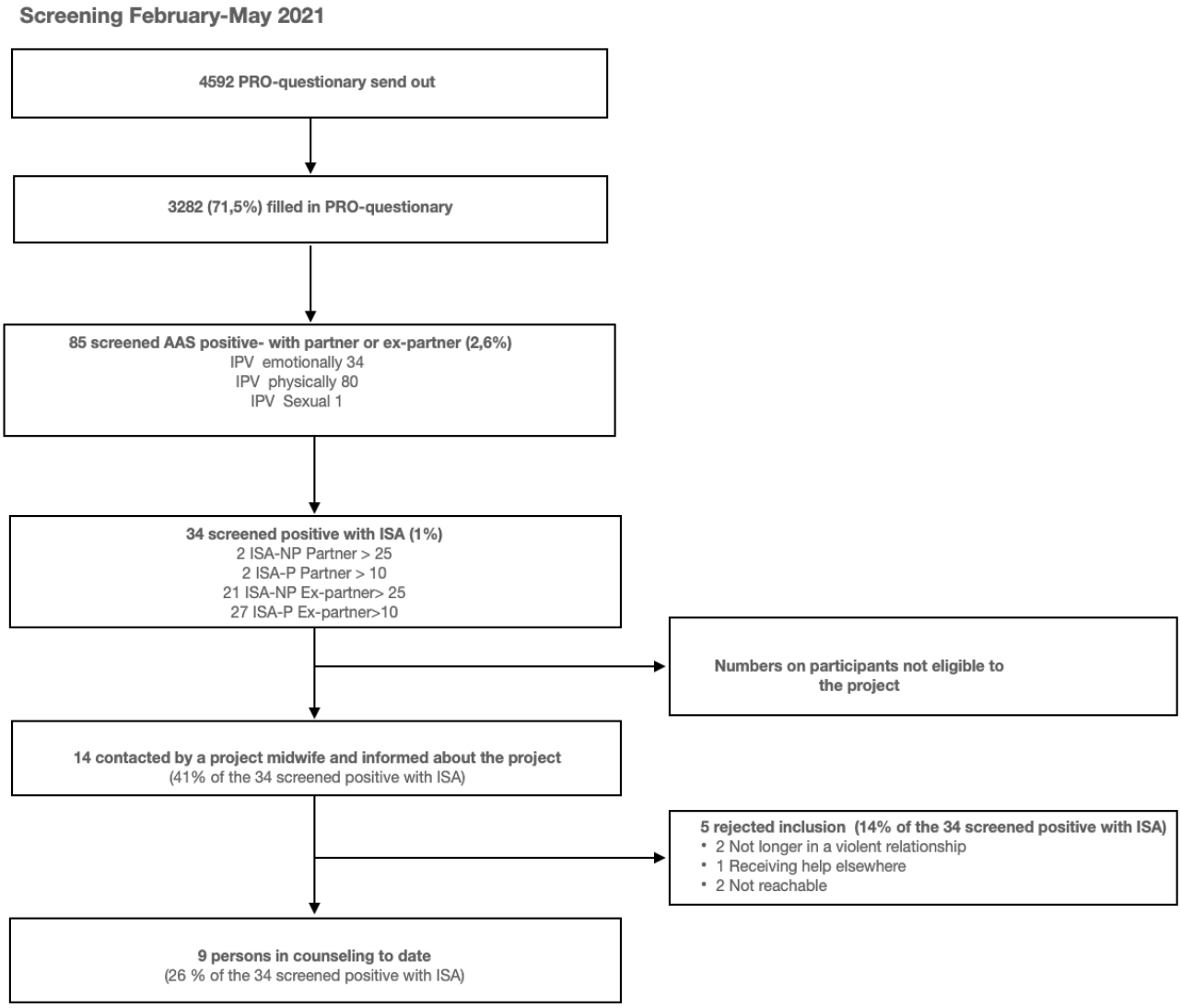
Denmark is a little delayed, as the initial screening takes place up to six weeks prior to their first midwife appointment. The intervention has started, and the first women are getting to their third or fourth video counseling session.

Response rate is 71.5 percent, although one site has a much lower response rate. The Danish team has met with them, and they are trying to address the issue and improve response rates. In May, there were technical issues with the PRO-data app *My Hospital*, which hosts the screening questionnaire. These have now been resolved. Two WAST questions were added in June.

Inclusion criteria were changed in early June:

- Women screened positive for IPV by either AAS or WAST are eligible for inclusion
- Women screened positive by AAS/WAST will still undergo repeated screenings by ISA in the PRO questionnaire, but their score is not important for inclusion

Flowchart and table illustrating screenings at RSD since February:



Screenings in Denmark between February and June 2021:

	February	March	April	Maj	June	Total
	n	n	n	n	n	n
Number of women screened	740	1264	739	539		3282
Number of women screened positive	16 (2,2%)	32 (2,5%)	27 (3,7 %)	10 (1,9%)		85 (2,6%)
AAS	16	35	32	7		85
WAST	N/A					
Positive in only AAS	16	32	27	10		85
Positive in AAS and ISA	6 (0,8%)	13 (1,0%)	10 (1,4%)	5 (0,9%)		34 (1,0%)
Positive in WAST	N/A					
Positive in WAST and ISA	N/A					
Number of women included		1	1	6	2	10
Number of women refused	0	0	2	1	2	5
Number of women new in counsseling	0	0	1	4	4	9

As part of an awareness campaign, posters informing about IPV and the screenings were distributed to the Danish clinics. These have been well received and response from women suggest that they have helped improve accuracy of the screenings.

Rescreening by midwives is an important part of the screening process in Denmark. The Danish team is working on helping the midwives conduct them.

As in Spain, in Denmark it is common for the women to bring their partners to their midwife appointments. During the visit, the midwives will attempt to talk to the women alone. If this is not possible, they will contact the women at some later point.

Status on AAS

2.6 percent have screeded AAS positive

- The majority exposed by ex-partners
- The majority indicates to be exposed to physical violence ever and emotional violence within the last year.
- More exposed to both physical and emotional IPV.

Type of IPV exposure (AAS)

- Emotional IPV: 34/3282 (1.03 percent)
    - Emotional within the last year (25) and fear of partner (9)
- Physical IPV: 80/3282 (2.43 percent)
    - Physical ever (72) and within the last year (8)
- Sexual IPV: 1/3282 (0.03 percent)

Status on ISA

- One percent screened ISA positive
- The majority screened positive for ISA-NP or ISA-P with ex-partner
- The majority screened positive for both ISA-NP and ISA-P
- Minor differences in the proportion of women screened ISA-P positive as compared to the proportion screened ISA-NP positive.

Day 2 – June 24

Joint Data Comparison

During Day 1, it was decided that we should compare the results from both sites. There is a noticeable difference between the percentages in Denmark and Spain. Spanish positives mainly come from WAST, while AAS provides only three percent. Denmark has only just begun to screen using WAST, which may account for part of the difference. Changes to the Spanish WAST criteria has since led to a decrease in positives.

	February-9th April (Spanish)	February-April (Danish)	7th May (Spanish)	May (Danish)	2nd June (Spanish)	June (Danish)	Total (Spanish)	Total (Danish)
Invited	-	2743	609	539	210	-	970	3282
Completed Screening	296		226		190	-	886	
Positives	98 (26,42%)	75 (2.73%)	32 (5.25%)	10 (1.9%)	32 (15.24%)	-	180 (18.6%)	85 (2.6%)
Intervention completed	-	-	0	-	1	-	2	-

	February (Spanish)	February (Danish)	March (Spanish)	March (Danish)	April (Spanish)	April (Danish)	May (Spanish)	May (Danish)	June (Spanish)	June (Danish)	Total (Spanish)	Total (Danish)
Total Positives		16 (2,2%)	10	32 (2,5%)	88	27 (3,7 %)	32	10 (1,9%)	32		180 (18.6%)	85 (2,6%)
Positive in only AAS	-	16	1	32	11	27	9	10	6	-	29 (2.99%)	85 (2.59%)
Positive in AAS and ISA	-	6 (0,8%)	0	13 (1,0%)	2	10 (1,4%)	2	5 (0,9%)	1	-	5 (0.52%)	34 (1,0%)
Positive in WAST	-		6	-	50		14		20	-	103 (10.62 %)	-
Positive in WAST and ISA	-		2	-	3		0		2	-	8 (0.82%)	-

The statistics have been reported differently between our two countries – in future, we should use the circulated template to ensure comparability. The Spanish team finds the template useful. For presentation of the findings for our monthly meetings, Karen and Rodrigo should prepare a joint slide to ease comparability.

We should analyze sensibility of indicators at both sites and identify reasons for differences.

[redacted] comments on the importance of retrospective analysis – to study the characteristics of those who accept counseling compared to those who don't.

[redacted] and [redacted] will check which permissions we need in order to share patient data between the project partners.

Implementation and Multidisciplinary Assessment of the STOP Intervention (WP4)
As stated in the Grant Agreement, MAST will be used as the framework for the assessment of the STOP intervention. MAST is a European framework for assessment of telemedical interventions across the following seven domains. The specific elements used depend on the project it is used for.

1. Health problem and characteristics of the problem
Assessment of the application in order to:

- Refine the research questions, e.g. choosing relevant outcome measures
- Formulate the methodological approaches to be taken in other domains of the assessment

A description of the technical solution in order to provide stakeholders with:

- Description of the application
- The features available
- Needs for training resources
- Division of responsibility between organization for the technical solution and support systems, etc.

2. Safety

- Identification and assessment of harms. For STOP, this mainly concerns the technical safety of the applications, such as downtime, etc.

3. Clinical effectiveness
The following topics can be included in the assessment of the clinical effectiveness:

- Effects on mortality
- Effects on morbidity (both physical and mental health)
- Quality of life
- Behavioral outcomes (such as empowerment)
- Utilization of women's shelters/networks

4. Patient perspectives
The following topics can be included in the assessment of patient perspectives on telemedicine applications:

- Satisfaction and acceptance (preference between face-to-face and telemedicine, privacy, and confidentiality)
- Understanding of information
- Confidence in the treatment

- Informativeness
- Ability to use the application
- Access
- Empowerment, self-efficacy
- Potential for future use

Qualitative interview guidelines are being drafted in Denmark and should be ready in about a month, after when the Spanish team will comment on them. The guidelines for interviewing the women should be prioritized over those for the counselors following. The project group agrees that the core of the interview guidelines needs to be the same between both countries.

[redacted] asks if the women have already accepted to be contacted by researchers? Vibeke will check if this is part of the informed consent which the women already signed. Stella confirms that this is the case in Spain.

5. Economic aspects
Economic evaluation (societal perspective) based on the number of resources when delivering the assessed telemedicine application in the health care sector and other sectors. The different types of resources are:

- Investment in equipment, etc.
- Maintenance
- Training of staff
- Use of staff
- Patients' use of time
- Relatives' use of time
- Transportation
- Unit costs or prices for each resource used

The economic domain may be the one that we are least prepared for. We should focus on this at a future meeting – estimating what the costs of the intervention are expected to be. We may invite Professor [redacted] (who was part of the team that developed the MAST) at Odense University Hospital/University of Southern Denmark.

6. Organizational aspects
The following topics can be used in the assessment of the organizational aspects of telemedicine applications:

- Process
- Workflow
- Staff, training, and resources
- Interaction and communication
- Structure
- Spread of technology, centralization, or decentralization
- Economy (see section on economic aspects)
- Attitude and culture

- Management

7. Socio-cultural, ethical, and legal aspects

- Changes in the patient's role in major life areas (e.g., social life, working life)
- Patients' relatives and others' understanding of the telemedicine application
- Societal, political context, and changes. Will the application influence the general model for the delivery of healthcare services if deployed?
- Changes in responsibility. Are the patients and/or relatives capable of handling the responsibility?
- Gender issues. Has the service any consequences on the position of gender?

Assessment of transferability

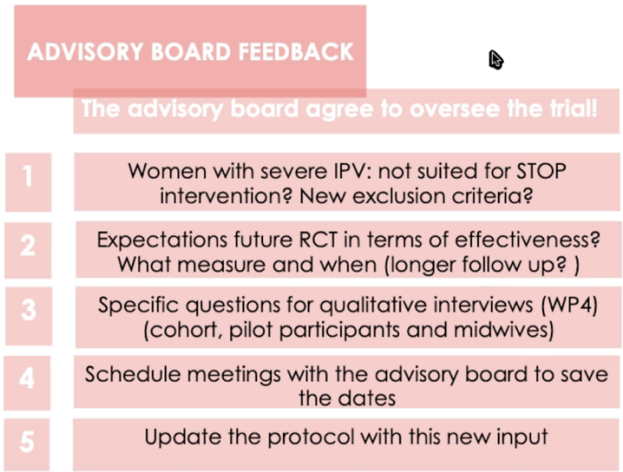
The assessment may also include considerations of whether the results can be generalized across settings. This consideration should be made within each of the seven domains.

Feasibility of Continuation and Upscaling (WP5)

The ethical application has been approved in Spain. In Denmark, the ethical board stated that clearance is not required.

We should start randomization at the same time in both countries, as the protocol covers both Denmark and Spain. At this point in time, we do not have enough women to carry out the RCT. Due to staffing issues, Vibeke hopes to postpone it until January; she will discuss it with the Danish team as soon as possible. In the meantime, there should be a WP5 meeting to decide on the starting date as soon as possible.

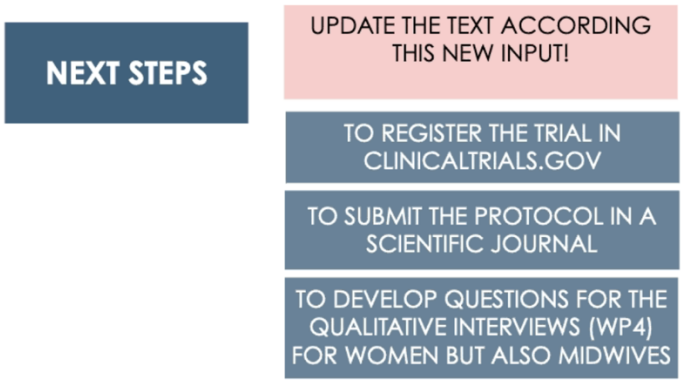
The advisory board has agreed to oversee the trial. They provided the following feedback:



We expect the number of women exposed to severe IPV to be very low, if any at all. However, for ethical reasons we need to measure the severity of IPV to protect women in the control group as delaying treatment for those suffering severe IPV cannot be justified (the control group is delayed by eight weeks). We could use a predetermined cut-off for ISA where those women who meet it

are excluded. We will determine if there are any individual reasons to exclude the woman. This should be added to our RCT flowchart. The discussion does not arrive at a final decision, and it will continue among project members. The coordination team reminds everyone that we need to adhere to the Grant Agreement.

The next steps of WP5 are:



We need to catch up on this at our monthly meeting in July.

AOB

Our next Consortium Meeting is November 23-24, 2021, but [redacted] suggests moving the dates to accommodate a longer stay and social activities *[the dates have since been pushed to November 25-26, 2021]*.

At the next consortium meeting, we should discuss what publications we contemplate. Before the meeting, each site should consider potential publications – based on our data sets – that they foresee.

This concludes the third – unofficial – STOP consortium meeting.

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