STOP

Intimate Partner Violence In Pregnancy

Deliverable 5.2

Strengths and Limitations of the Pilot RCT and future alternatives

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

Project Acronym	STOP
Contract Number	881648
Dissemination Level	Public
Nature of Document	Report

Title of Document	Strengths and Limitations of the Pilot RCT and future alternatives
Reference Number	D5.2
Work package contributing to the document	WP5
Version	V1
Expected Delivery Date	January 30 2023
Date	
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This document contains a description of the Strengths and Limitations of the Pilot RCT and future alternatives

Revision History			
Revision	Date	Comments	Author (name and organisation)
V1			

File name: STOP D5.2 Strengths and Limitations of the Pilot RCT and future alternatives.

Statement of originality: This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Executive Summary

This document describes a summary of the results of a pilot randomised controlled trial (RCT) conducted in Denmark and Spain and its strengths and limitations (deliverable D5.3. describes in more detail the results of the pilot RCT). It also contains propositions for future study designs based on a review of the relevant literature as the pilot RCT demonstrated that a future full-scale randomised study was unfeasible. In our pilot study, a subset of women from the STOP cohort study who screened positive for IPV during their first antenatal visit were invited to participate in pilot randomised controlled trial of psychological counselling by video conference. The objective was to randomise a total number of 20 participants to either the intervention or the control group. The intervention group received the e-health package (six video counselling sessions combined with the use of a safety planning app), while the control group would receive the same intervention yet with a delay of 8 weeks permitting collection of control outcome data. This document will interpret the pilot findings and the existing literature to come up with possible solutions to address the difficulties in the feasibility of a future full-scale randomised study observed in the pilot study.

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1. INTRODUCTION

1.1 Purpose of the document

This document contains the strengths and limitations of the findings of the pilot RCT study and propose options for future study designs considering other published studies in this field.

1.2 Structure of the document

Firstly, the document provides a summary of the of IPV in pregnancy and its consequences, e-health interventions and the rationale of the pilot RCT as well as its methodology. Secondly, we briefly explain the main results of the trial and analyse the strengths and limitations found during the implementation and development of the pilot trial in both countries. Lastly, other study design options for future studies that aim to address IPV among pregnant women are discussed according to the existing evidence about IPV and e-health interventions.

1.3 Glossary

APP	Application
D	Deliverable
IPV	Intimate Partner Violence
EU	European Union
eIPV	E-health psychological intervention in pregnant women exposed to intimate partner violence
EPV-R	Severe Intimate Partner Violence Risk Prediction Scale-Revised
MOVERS	Measure of Victim Empowerment Related to Safety
RCT	Randomised Control Trial
UGR	University of Granada
WP	Work Package

2. A SUMMARY OF THE PROTOCOL FOR PILOT RCT

Intimate partner violence (IPV) during pregnancy is a condition that is as common as obstetrics conditions such as gestational diabetes, and it is associated with maternal and neonatal complications. Yet systematic detection of IPV is not well-established in antenatal screening, which could be due to the effectiveness of protective interventions not having been evaluated so far. E-health interventions may be beneficial among mothers exposed to IPV. Prior to performing a full-scale effectiveness trial for such an intervention, a pilot study is required to assess the feasibility of randomising a sufficiently large number of women exposed to IPV during pregnancy.

We conducted a pilot randomised controlled trial (RCT), co-designed by participants using Zelen's design with additional qualitative evaluation and nested within a cohort study. We have used a modified Zelen's design with a double consent process[1–3] and a delayed intervention for the control group. In the first stage, informed consent was sought from all pregnant women to enter a cohort study. A predetermined small number of the cohort were then randomised, without their knowledge, to intervention or control. The intervention group received the e-health package as part of the cohort.

In the second stage, participants who have been assigned to the control, were re-approached, and given information about their participation in the control group. At this stage, they were invited to accept a delay in the intervention (e-health package eight weeks later) and were asked to give the second informed consent for a delayed intervention. Those who declined remained in the cohort study. Those in the cohort only group were not informed about the randomisation, as their subsequent follow up in the study remained part of the cohort study to which they would already have consented in the first stage. We have substituted the women who did not consent to being part of the control until we reached the sample required (5 women in each country).

2.1. Study setting

Participants were recruited at twenty-nine urban public primary health antenatal care centres within Andalusia (Spain) and at five regional hospitals in the Region of Southern Denmark.

2.2. Eligibility criteria

All women who fulfil the inclusion criteria were screened and invited to receive an e-health package. Of those who accepted the e-health intervention, 20 women would be randomised – 10 women in each country – and 5 women would be allocated to the intervention group and 5 would be asked to consent to be in the control group, in each country. However, we ended up randomising more women because of women rejected to be part of the trial, as we explain in section 3.

Inclusion criteria: pregnant women at <12 weeks gestation, who screen positive in IPV at the first antenatal visit and accept the e-health package. However, in Denmark the screening was performed in week 8-12 and the women were invited to participate in the pilot RCT at first midwifery consultation in week 14-16.

Exclusion criteria: (1) women who cannot be informed about the study without their partners or other family members knowing; (2) mentally or physically incapacity to participate in the study; (3) women below 16 years in Spain or below 18 years in Denmark; (4) inability to understand Danish/Spanish, (5) lack of internet and electronic device and (6) women with extreme severity of IPV. Women selected to participate in the trial in this situation have received an evaluation of danger before randomisation. If the severity of IPV was confirmed to be at high level of danger, they were routinely treated and supported according to the standard protocol in each country.

2.3. Intervention and control groups

In the intervention group, women who screened positive for IPV who accepted the e-Health intervention and who have been randomly allocated in the intervention group have received the e-health package as the rest of the cohort, as well as the baseline and outcome measurements. The e-health package included six video counselling sessions by trained providers - a psychologist in Spain and trained midwives in Denmark - and access to a mobile application for designing security plans, which was an adapted version of the mobile application "My Plan". The content of the six individually tailored sessions were based on the Dutton's Empowerment Model[4] and the Psychosocial Readiness Model[5]. Specifically, the contents included the evaluation of abusive behaviour; safety planning, network and resources; psychoeducation (healthy relationships, cycle of violence, etc.); self-esteem and empowerment; fears; choice making and problem solving. In the control group, IPV positive women who accepted the e-Health intervention package were asked for a second consent to receive a delayed intervention (8 weeks later) and to complete the baseline and outcome measurements. Women could request to leave the control group at any time and receive the intervention immediately (in which case the data were part of the cohort study).

2.4. Assessments and data collection

Data on socio-demographic characteristics and partner violence were collected during the screening process. The validated screening questionnaires to detect IPV were the short form of the Women Abuse Screening tool (WAST-Short)[6] and the Abuse Assessment Screen (AAS)[7]. Data from previous studies support the reliability and validity of the WAST[8] and the AAS[7]. If the women initially were screened positive, the screening questionnaires were followed by the Index of Spouse Abuse (ISA) questionnaire[9]. The ISA questionnaire is a detailed 30-item questionnaire about IPV (emotional, physical and sexual) in order to confirm the IPV and evaluate the severity of the violence. In the assessment IPV exposure, two different scores are computed: ISA-P (physical abuse) and ISA-NP (non-physical abuse).

The following quantitative questionnaire data were collected before and after the e-health intervention: exposure to IPV (assessed by use of the ISA tool), post-natal depression (assessed by The Edinburgh Postnatal Depression Scale[10]), their ability to carry out safety behaviour actions (measured by the safety action checklist[29]) and their empowerment (evaluated through Measure of Victim Empowerment Related to Safety, MOVERS[11]).

Qualitative data were collected through individual in-depth interviews with a sub-group of women at any point of the cohort and pilot study to explore their opinion and experiences of the study procedures and intervention. Additionally, we conducted interviews with the IPV

counsellors to explore their experiences with the delivery of the intervention and their opinion about a future full-randomised controlled trial.

The Deliverable 5.1. contains a more detailed description of the protocol of the pilot RCT, including the screening procedure, randomisation process, intervention, main objectives, data analysis.

3. SUMMARY OF MAIN PILOT RESULTS, STRENGHS AND LIMITATIONS

3.1. Summary of main results of the pilot RCT in Denmark and Spain

Table 1 outlines the main criteria that were considered to assess the feasibility of a full-scale RCT. In addition, we also include qualitative findings that support the decision-making around the feasibility of progressing to a full-scale trial.

Table 1. Suggested progression criteria in eIPV trial and main results

Feasibility objectives and related data to be collected	Go criteria to proceed to full trial	Criteria to reassess and adjust full trial protocol	Stop criteria	Data from our pilot RCT
Study population				
1. Consent rate of eligible women	Rate >25% of eligible women agreeing to participate.	Rate between 11% and 24% women agreeing to participate	Rate <10% of eligible women agreeing to participate	Rate of 13%: **Reassess and adjust full trial study protocol**
Study outcomes				
2. Proportion of women in either intervention or control group for whom the allocated treatment is adhered to.	Adherence to allocated treatment in >80% of study sample.	Adherence to allocated treatment in between 51% and 79% of study sample.	Adherence to allocated treatment in <50% of study sample.	Overall Rate of 31% Rate of 41% for the intervention group and rate of 16% for the control group **Stop criteria**
RCT process				
3. Collection of data on clinical outcomes	Complete data available of >80% of study sample.	Missing data between 21% and 49% of study sample.	Data missing of >50% of study sample.	Rate of 41% for the intervention group and rate of 16% for the control group: **Stop criteria**

The results showed that none of the progression criteria to assess the feasibility of conducting a full-scale RCT multi-centre were met. In other words, a future full-scale trial was not demonstrated to be feasible.

Specifically, the consent rate of eligible women was around 13%, which suggested that we should reassess and adjust the full trial protocol. In addition, the proportion of women in either intervention or control group for whom the allocated treatment is adhered to was only of 31%; if this rate was below 50%, the stop criteria was met. Finally, the analysis of the rate of the collection of data on clinical outcomes showed that we obtained a rate of 41% for the intervention group and rate of 16% for the control group. If this rate was below 50%, it also indicated that the full trial is not feasible.

These rates were based on the following information. We spend 267 days (more than eight months) to obtain full data of just 7 women in the intervention group (3 from Spain and 4 from Denmark) of the 10 women that we targeted. To get that, we randomised 17 women to that group, and more than the half (10 women) dropped out.

The case of the control is even worse in terms of numbers. Following the input from focus-group discussions with IPV survivors and ethical considerations, we did not choose to have a control group who did not receive the intervention. Instead, we offered a delayed intervention (eight weeks later), following the Zelen's design explained above. This may be the reason why all women randomised to the control group in Denmark rejected to be part of the group, because they did not want to delay the intervention. In Spain, of the women randomised to the control group (n=10), three were excluded for showing a potentially high severity of violence (exclusion criteria to be part of this group because of the possible danger of the delay). Among the remaining seven women, four dropped out at the time video counselling was supposed to start and thus did not answer the baseline questionnaires. Finally, three women started the intervention in the control group, but only two women provided complete outcome measures one-month postintervention. In the following section we analyse the strengths and limitations of the design and the input from the women, the midwives and the psychologist who conducted the video-counselling.

3.2. Strenghts of the pilot RCT

We undertook a pilot RCT, co-designed by participants and with independent input from advisory and ethics committee using Zelen's design with an additional qualitative evaluation. We considered that this pilot RCT has three main strengths: (1) It had tried to improve the satisfaction of the participants who are assigned to the control group conditions through different studies; (2) It had the support from the Patient and Public Involvement perspective in health and social care research, and (3) It has responded to the ethical requirements of institutions and the own research team involved in the project.

3.2.1 Research projects focused on the opinions of participants in the control conditions: they are unsatisfied with no receiving interventions.

Prior to performing a large interventional trial, a pilot study is needed to identify barriers to recruitment, assess feasibility and acceptability of the treatment, and fine-tune study procedures. No RCT has previously assessed an e-health intervention in IPV among pregnant women in comparison with a control group with a delay intervention. In this pilot trial, we chose to perform a pilot RCT with a modified Zelen's design rather than a pilot RCT for several reasons. Participants who take part in standard RCTs will make a judgment of their preferred treatment and often expect to be allocated to the treatment group[12]. If this does not occur, it can be followed by dissatisfaction and distrust in those who approached them to take part[13]. Consequently, randomisation to a control group may lead to dropout after allocation. The original Zelen design involved randomisation before consent, with consent only required from those allocated to the intervention, whereas the control group receive their usual care[3]. Baseline outcomes are collected from medical records (with ethical approval). However, it is not possible to interact with the control group during follow-up, as they are not informed of their presence in a study. Taking all of this into consideration, we have hypothesised that women would accept the intervention when they perceived it as a need for support, but it was also expected that if they perceive it like

this, they may not want to be randomised into control group. To overcome this expected drop-out in the control group, we followed the input of IPV survivors in a focus group, the opinion of the participant representative and a systematic review that concluded that a delay intervention could be an effective way of minimising dropout[14].

3.2.2 Support from the Patient and Public Involvement perspective in health and social care research

Following the Patient and Public Involvement perspective in health and social care research, we consulted IPV survivors and professionals working with IPV victims about the possibility of having a control/standard care group. We also consulted this with pregnant women exposed to IPV participating in the STOP cohort study. These agents support the need to provide an intervention to IPV positive women assigned to the control group - at least a delayed intervention. All assured that they would prefer to be offered a delayed intervention than standard care or any other control intervention (such as a referral card with resources, website with IPV information, etc.). In the following lines we have included some of the thoughts of the IPV survivors from the focus group discussion where their notions related to having a control group without intervention or just standard care were recorded:

Woman 3*:*

> [...] If you have to admit that you are in that situation [ed. of IPV], and you take the risk of participating in the study that could be dangerous for you, and then you are allocated in a control group and they tell you: "*Now you are not going to receive the treatment*" and you say: "*Why am I going to get into this?*"

In addition, two women previously exposed to IPV (one Spanish and one Danish) helped us to develop a more pregnant women-centred information sheet in line with the well-known need to involve citizens in science[15]. They were concerned about the possibility of putting a woman in risk of danger by assigning her to the control group. To eliminate any potential danger to the women, the health providers checked the items of the ISA related to physical IPV and the psychological IPV items measuring fear of the partner to determine if the women invited to the pilot are at extreme level of IPV risk. Among those women who responded positive to the above items, the providers have evaluated the level of danger with the Severe Intimate Partner Violence Risk Prediction Scale-Revised (EPV-R, $\alpha = .72$)[35] before randomisation. If the level of danger was confirmed to be high, women were not included in the control group, and they were routinely treated and supported according to the standard protocol in each country.

3.3. Main Limitations of the pilot RCT found during implementation.

The analyses of the pilot showed that we have at least two main obstacles to get the pilot sample for each group and to implement the eHealth intervention. The first general obstacle has been the high drop out. Reviewing the flowchart (Annex Figure 1) complete information was only obtained in seven out of 17 included women revealing a drop-out percentage above 50%. The situation is even worse in the control group where only two out of seven women who accepted the allocation, completed the post-intervention measures.

The second major obstacle was the control group itself. Although offering a delayed intervention seemed to be the optimal solution for not leaving positive IPV pregnant women without an intervention, we observed that this was not always the case. Some women interviewed in the cohort in Spain answered that they would reject to be part of the control group because of the delay:

Woman 6*:*

> I think I would reject to participate. I wouldn't participate. Well... If you offer me this help and I need it in that moment and I feel very very bad... If you say the word "delay", it's not a good approach.

Woman 3:

> If it's not immediate, I don't know what I would have said. I don't know... Well, I think I would have accepted because I really needed to talk with someone... I think I would accept, but other people, I don't know... [...] I wouldn't make them (women) wait.

However, all the women who accepted to be part of the control group were Spanish. The fact of those Spanish women who accepted to be part of the control group did not complete the baseline measurement (n=4) or dropped out when the time of video counselling was planned to start, may be related with the time of pregnancy itself. In other words, it is possible that these women wanted to participate when they were invited, but after the delay being almost more than five months pregnant or even closer to the delivery could make them think that it was not a good time for starting an intervention.

In the Danish context, all the women offered to be part of the control group rejected due to the delay. Hence, the Danish women were ready and motivated to start the counselling sessions after disclosing their IPV exposure and found the sooner they could initiate the counselling the better. Below a few quotations illustrating the women's notions:

Woman 1:

> It makes no sense to wait

Woman 2:

> I think the sooner you start, the sooner the women can be helped. If you wait 8 weeks, then we are almost at the end of the pregnancy. And I think that would be a shame.

Woman 3:

> In reality, all that needs to be done is to prevent any form of violence against women. And that is not possible. But the sooner you start the better.

Woman 4:

> In my eyes, I just think that you get too little out of the offer. In reality, something like this should start already after the first doctor's visit, I think (ed. in gestational week 6-8)

It is relevant to have in mind is that, although both countries had the intention to start the screening no later than gestational week 12, the administrative workflow of the questionnaire in Denmark did not allow this. Hence, the Danish women started the intervention around week 20 of pregnancy and therefore had more difficulties in coping with the delay of the intervention in comparison with the Spanish women who started earlier.

4. LITERATURE REVIEW

A systematic literature review and meta-analysis published in 2020 by members of the STOP project group examined the evidence of the effect of digital health interventions targeted women exposed to IPV on reduction of IPV, PTSD and depression. Randomised controlled trials were included in the review, and a systematic search was conducted on five scientific databases (Embase, Medline, Cochrane Central Register of Controlled Trials, PsycInfo, Scopus, Global Health Library) and two trial registries (ClinicalTrials.gov and International Clinical Trials Registry Platform)[16].

A total of 14 trials were included in the review (8 published, 3 unpublished and 3 ongoing trials). Overall, the content of the digital interventions, recruitment strategies and primary outcome measures varied (table 2). Only two trials involved pregnant women exposed to IPV (one finished published trial and one ongoing trial). The finished trial targeted American pregnant women who were seeking mental health care (Zlotnick et al, 2019) whilst the ongoing trial concerned culturally diverse Norwegian women attending antenatal clinics who screened positive for IPV.

Table 2. Overview of finished, published trials with digital interventions

Author, year	Country	Trial size	Recruitment	Intervention	Comparator
Hegarty et al, 2019	Australia	422	Online advertisement; compensation for time up to Aus $150 (US $110)	Online safety decision aid	Control website
Koziol-McLain et al, 2018	New Zealand	412	TV advertisements and flyers at health clinics	Online safety decision aid	Control website
Zlotnick et al, 2019	United States	53	Pregnant women seeking mental health care who screened positive for IPV	Online education on IPV	Online popular TV shows
Glass et al, 2017	United States	721	Online advertisement, flyers at health clinics and public toilets	Online safety decision aid	Control website
Constantino et al, 2015	United States	32	Family court waiting areas, legal services, women's shelters	Email modules with IPV support (arm 1)/face-to-face modules with IPV support (arm 2)	Standard care
Stevens et al, 2015	United States	253	Women at paediatric emergency departments who screened positive for IPV	Telephone support	Standard care
Braithwaite et al, 2014	United States	104	Online, posters, and newspaper advertisements	Emails, modules with relationship communication skills, and problem-solving training	Placebo emails; modules with information about depression, anxiety, and healthy relationships
McFarlane et al, 2002	United States	150	Family violence unit	Telephone support	Standard care

Seven out of eight published trials were included in the meta-analysis, which showed that there was no evidence for a beneficial effect of digital interventions on (1) overall IPV [SMD −0.01; 95% CI −0.11 to 0.08; I^2=0%; 5 trials, 1668 women]; (2) physical IPV [SMD 0.01; 95% CI −0.22 to 0.24; I^2=58%; 4 trials, 1128 women], (3) sexual IPV [SMD 0.07; 95% CI −0.12 to 0.25; I^2=40%; 4 trials, 1129 women], or (4) psychological violence [SMD 0.36; 95% CI −0.18 to 0.91; I^2=0%; 2 trials, 1029 women]; or (5) depression [SMD −0.13; 95% CI −0.37 to 0.11; I^2=78%; 5 trials, 1600 women] and (6) PTSD [MD −0.11; 95% CI −1.04 to 0.82; I^2=0%; 5 trials, 1267 women]. However, the types of outcomes and how they were measured were very heterogenous across trials, which limited the possibility of pooling results and identifying patterns across studies. It was recommended that core outcome sets were established to harmonise outcome reporting with the field of IPV[16].

5. OTHERS STUDY DESIGN OPTIONS FOR FUTURE RESEARCH

The revision of the literature could help us to highlight how other research groups are approaching the difficulties of conducting a RCT with pregnant women exposed to IPV. The above literature review highlighted that there are actually not many trials that include pregnant women who participate in standard screening as part of antenatal care, hence, they may not have faced the same difficulties as we did. In addition, it is important to underline that of those studies included in the review[16], only two of them were developed in the European Union. In this sense, the generalisability to the European context is uncertain[17–23].

In another recent RCT[24] conducted with pregnant women and mothers of children under 5 exposed to IPV, the control group almost received the same program as the intervention group without an added interpersonal psychotherapy component. This may have increased the willingness to accept and participate for those assigned to the control group. A fullscale RCT was conducted in Norway[25] to promote a safe pregnancy intervention for IPV among culturally diverse pregnant women. While the intervention group watched a video that presented information about IPV and safety behaviours, the controls watched a video promoting healthy pregnancy in general. Further, in a RCT conducted in Iran[26], which focused on the level of self-esteem and IPV against pregnant women, they offered a counselling of 2-45 minutes gestalt-based sessions while the control group only attended prenatal care visits and after the post-test evaluation and received an educational pamphlet. Another RCT also developed in Iran in 2021 with the aim to improve the violence rate and quality of life of pregnant women at risk of domestic violence provided no intervention to the control group while the intervention group received a counselling based on the solution focused approach[27]. Finally, Rastegar et al.[28] aimed to investigate the impact of preventive interventions on IPV among pregnant women through a RCT study in Iran. The intervention group received a group-counselling (based on the PEN-3 model) while the control group only received standard care.

However, from an ethical point of view, we deem it difficult to use these types of control groups in a Danish and Spanish context. If pregnant women screened positive in IPV, we would find it unethical to just provide them the standard care or an unrelated control comparator, which was also the opinion of our patient representative, professionals and even other IPV survivors which stressed that we had to offer the intervention to the women in the control group, at least a delayed intervention. Perhaps the control group could comprise of women who receive face to face counselling or a group who receive a series of videos which inform the women about IPV and possible preventive actions.

6. CONCLUSION

We conclude that any future large scale randomised trial with the design that we used is at high risk of failure. This is because of the difficulties observed in convincing ethics committees to approve

randomisation, encouraging people to consent to receive control, persuading participants to comply, and failing to complete follow up for outcome data. Whether such risks are worthwhile in awarding a future research grant is a matter for funders who would have to balance the importance of the topic versus the high probability of failure inherent in the research to be undertaken. The STOP pilot study confirms that without an extremely large investment of effort, recruitment, retention, and completion of follow up is unlikely. For any prudent funder and researcher, there will be the need to build in a strong mitigation plan in the research proposed from the outset including an internal pilot phase with clear stop-go rules set a priori for oversight by an independent data monitoring committee who should advise the independent steering committee. Alternate approaches to randomisation are strongly advised. These include observational comparisons, that typically suffer selection bias. Such studies would have to be planned with close attention to confounder data collection and analysis to generate valid findings.

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Pilot RCT. OCT 2021 to JULY 2022

Screening and Enrollment

Approached women (n= 5557)

Excluded (n= 590)
- Decline to participate (n= 46)
- Incomplete (n=6)
- Underage (n= 6)
- Excluded for not having partner (n= 5)
- Other reasons (n = 527) DK

Completed screening (n= 4967)

Excluded (n= 4656)
- Screen negative (n= 4656)

Women screen positive (n= 311)

Excluded (n= 169)
- Decline to continue participation (to receive VC) (n= 169)
- Other reasons (n = 0)

Women contacted by the counsellor (n= 220)

Excluded (n=19)
- Declined to take part in the randomisation of the trial (n = 19) (DK)

Women consent to take part in Video Counselling (VC) (n=51) COHORT STUDY

Post-randomisation exclusion (n=3)
- Exclusion criteria: Pregnant women with suspicious of extreme severity of IPV (n=3)

Randomization (n=32)

Allocation

Excluded (n = 3)
- Drop out. Do not complete the baseline questionnaires

Woman allocated in Intervention Group (n=17)

Women invited to take part in pilot control group **(n=12)**

Excluded (n = 9)
- Declined to take part in control group (n = 5)
- Drop out (n = 4)

Do not complete the baseline questionnaires

Assessment

Intervention Group (n=14)
(e-health package after screening, as cohort)

Control group (n=3)
Delayed intervention (e-health package 8 weeks later)

Baseline measurement (n=14)

Baseline questionnaires (n= 3)

Intervention

Allocated to intervention (n= 14)
- Received allocated intervention (n= 7)
- Did not receive allocated intervention (because they did not attend first session) (n= 7)
- Other reasons (n = 0)

Allocated to control (n=3)
- Baseline measurement right before intervention (n = 2)
- Received allocated intervention eight weeks later (n= 2)
- Did not receive allocated intervention (because she did not attend first session when the intervention started) (n= 1)

Follow-up and Assessments

Post-intervention measurement (n= 7)

Post-intervention measurement (n= 2)

Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (give reasons) (n= 0)

Lost to follow-up (give reasons) (n=)
Discontinued control (give reasons) (n=)