SAFE: a self-support eHealth intervention to support women exposed to intimate partner violence.

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Victims of IPV, living in an unsafe and unhealthy situation, are faced with a broad range of physical and emotional symptoms. Standard and easy-accessible care to facilitate change into a safer situation is lacking. The project aims to launch an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46401

Source
ToetsingOnline

Brief title
SAFE

Condition

- Other condition
- Anxiety disorders and symptoms
- Family issues

Synonym
Intimate partner violence

Health condition

depressieve stemmingsstoornissen en -afwijkingen

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: eHealth, family violence, intimate partner violence, self-support

Outcome measures

Primary outcome

We chose Self-efficacy, measured by The General Self-Efficacy Scale (GSE) as primary outcome measure. This scale assesses a general sense of perceived self-efficacy, aiming to predict coping ability and adaptation to stressful life events. The Scale has 10 questions with response choices on a 4-point scale: Not at all true/Hardly true/ Moderately true /Exactly true. The GSE has been validated in both the Dutch and international community (a0.78-0.94) [94-96]. We hypothesize that the intervention group scores a higher mean self-efficacy score than the comparison group, immediately after intervention completion and at 6 months post-baseline. The GSE will take about 5 minutes to complete.

Secondary outcome

1. Anxiety and Depression, measured by the Hospital Anxiety and Depression Scale (HADS). Existing mental health research supports the mediating effects of self-efficacy on mental health, specifically depression. EHealth has been shown effective to reduce depressive symptoms [53, 97-101]. The HADS is commonly used to determine the levels of anxiety and depression that a patient is

experiencing. The HADS is a fourteen item scale that generates ordinal data. Seven of the items relate to anxiety (HADS-A) and seven relate to depression (HADS-D). Cronbach's alpha for HADS-A varied from.68 to.93 (mean.83) and for HADS-D from.67 to.90 (mean.82) [102-104]. We hypothesize that participants in the intervention group show a lower mean depression score than the comparison group, as measured by the HADS at 6 months post-baseline. The HADS takes about 5 minutes to complete.

2. Awareness, measured by a modified version of the Contemplation Ladder, as used in the I-decide study [87]. Women will indicate their position on a modified version of the Contemplation Ladder [105], a tool originally developed to measure readiness to cease smoking. The ladder is designed to measure awareness of abuse from 0*10 based on how ready the woman is to make positive changes to her situation. The Contemplation Ladder, modified version will take about 5 minutes to complete.

3. Perceived support (social), measured by the Medical Outcomes Survey - Social Support, 5-item version (MOS-SS5). This is a 5-item version of the MOS social support survey. The questions ask the woman how often she has access to support from someone in her life, with response options on a 5-point Likert scale (a 0.88) [106, 107]. The MOS-SS5 will take about 5 minutes to complete.

4. Fear of Partner, measured by a visual analogue scale (VAS) (0-100). The participant will be asked to rate their current level of fear of their partner

or ex-partner, on a sliding scale from 0 (not at all afraid) to 10 (very afraid). We hypothesize that participants in the intervention group show a lower mean fearfulness score than the comparison group, as measured on a visual analogue scale of current level of fear of partner (0*100), at 6 months post-baseline. The Fear of Partner VAS takes about 2 minutes to complete.

5. Perceived support (website), measured by a Visual Analogue Scale (VAS). The participant will be asked after completing every module to rate how supported they feel by the website on a sliding scale from 0 (completely unsupported) to 10 (completely supported). The VAS takes about 2 minutes to complete.

Other Outcomes

1. General characteristics questionnaire. A general questionnaire will assess general participant characteristics at baseline, containing questions on sex, ethnicity, education, household income, living situation, marital status, children, and use of alcohol/tobacco/drugs. Gender-roles are the behavioural norms typically ascribed to men and women in society. Therefore we will also collect data on self-identified gender and gender-related variables. These variables are: information on being the primary earner in the household, personal income, responsibility for housework, level of stress at home, and the measures of masculinity and femininity from the Bem Sex Role Inventory (BSRI) [108-110]. The BSRI is a measure of masculinity-femininity and gender roles. It assesses how people identify themselves psychologically. The test is formatted with 60 different personality traits which participants rate themselves based

on a 7-point Likert scale. Traits are evenly dispersed, 20 masculine, 20 feminine, and 20 filler traits thought to be gender neutral. All traits in the BSRI are positively valued personality aspects (a 0.78 for femininity scales and 0.87 for the masculinity scale). As social differences and roles could influence health outcomes, we will use these data to look for a gender story in the data. The general questionnaire takes about 5 minutes to complete at baseline, and about 10 minutes to complete after completion of the modules and follow-up, as we will add an open question on their experience with SAFE and their current living situation.

2. The Web Evaluation Questionnaire (WEQ) as used above in the development of SAFE will be modified for the RCT. The WEQ asks the participants questions on relevance, language, lay-out, understandability, completeness, structure, findability and ease of use [111] and takes about 10 minutes to complete. The WEQ is only completed once, after completing all four modules of SAFE and only for the participants of the Intervention arm.

Study description

Background summary

Background
Intimate Partner Violence (IPV) is defined as any physical, sexual, psychological, or economic violence that occurs between former or current spouses or partners [5]. It is a common social problem worldwide, and one that is distinctly gendered [5-7]. The prevalence of IPV is particularly alarming in light of its association with a range of negative health outcomes for women and

children [5]. Research consistently shows that abused women are at increased risk of depression, anxiety, posttraumatic stress disorder, and suicide [8], as well as physical problems [6]. About one out of three women have experienced either physical and/or intimate partner violence or non-partner sexual violence in their lifetime [9-12]. In the Netherlands at least 20% of women have been ever physically abused by a former or current partner, 11% is victim of sexual violence by a former or current partner and one out of eight of all Dutch women have been raped ever during their lifetime [12-19]. Children growing up in a violent home are more often direct victims of child abuse and are exposed to violence acts as well. Being a witness of intimate partner violence has similar consequences as to being a direct victim of child abuse [20-24]. One in three will become a perpetrator or victim themselves in their future partner relationships: the intergenerational transmission of violence [25]. Despite the negative outcomes of being a victim of IPV, there is limited evidence of effectiveness for interventions in health care settings, with inconclusive results in terms of the effects on women*s physical and psychosocial well-being [26-30]. Many women feel uncomfortable revealing their experience with IPV, even if the issue is raised in a sensitive manner by the health professional [31]. They may feel that the abuse is not serious enough to mention or worry about disclosure if their abusive partner sees the same health care professional [32]. The pathway to disclosure can be long and challenging for women, and by the time the health professional becomes aware of the abuse, if at all, they may have missed a valuable opportunity to intervene earlier and more effectively [33].

EHealth is a rapidly developing and upcoming mode of therapy. Although eHealth is still in its infancy, more attention has been paid to the theory and different categories of eHealth interventions in recent years. In a recent systematic review of online health interventions, Webb, Joseph, Yardley, and Michie (2010) examined the role of theoretical background, behaviour change techniques, and mode of delivery on the intervention*s effectiveness [34]. They found that increased use of theory to inform the intervention led to a greater effect size. In terms of behaviour change techniques, the most valuable were found to be information provision, self-monitoring, and problem solving, with action planning and the provision of feedback also having significant positive effects. Interventions that provided an *enriched information environment* and offered automated tailored feedback were found to have significant effects on behaviour change. From the literature, we know that peer and social support are effective methods to change behaviour, both offline and online [35-41]. Social support, furthermore, has proven to be effective in adults exposed to violence and is associated with good mental and physical health outcomes [42, 43]. Offering an IPV intervention in an online format may assist in overcoming some of the barriers encountered in health care settings. Online interventions are being increasingly used as a way of self-managing health conditions, with promising results [44-51]. Overall, evidence suggests that eHealth cognitive therapy interventions for depression and anxiety are effective, especially if healthcare providers are involved [52]. Lintvedt et al. (2013) point out that an internet-based intervention is constantly available and accessible from any

location [53]. This flexibility allows women to access the intervention at unexpected times when an abusive partner is not present, as opposed to the health care setting where they must schedule an appointment. Delivering an intervention online also allows women to self-identify and self-manage without disclosure to a third party. This may be particularly beneficial for women who are unable to disclose the abuse to a health care professional and are not ready to attend a specialized support service [54]. The internet provides an anonymous environment where women can safely search for information and explore possibilities for help. Women who do not have safe Internet access at home often have access in other locations such as family or friends* homes, public libraries, or community agencies or access the Internet wirelessly using a Smartphone [55-57].

Relevance

Intimate Partner Violence (IPV) has been defined within the ZONmw program Gender and Health (4b) as one of the gender based themes that are threatening the (mental) health of women showing knowledge gaps on insights into the healthcare needs of victims. In the Netherlands 200.000 women yearly are victim of IPV and one in three women have encountered partner violence at some time in their lives. Abused women are at risk of psychiatric conditions as well as medical unexplained physical symptoms [6]. IPV is therefore strongly interconnected with two other themes defined within the ZONmw program Gender and Health as important: Unexplained physical symptoms (4e) and Psychological and psychiatric conditions (4f). As violence against women has several health consequences, studies have shown that the burden of diseases related to intimate partner violence is high. Victims are more likely to consult their GP, have more chronic complaints and use more painkillers and antidepressants [58,59].

It is estimated that the costs of healthcare for the physical and psychological treatment of female victims of violence against women (visits to health care, pharmaceuticals, emergency room, hospital stay, mental healthcare) are 1200-3200 euro per victim per year, which does not include absence in work or social life [3, 4]. The total costs estimated of IPV are ¤280 million annually for official services (police, emergency, shelters) and ¤74-129 million yearly for employers due to absence of work [2]. IPV has thus a major impact on society with a tremendous loss of wellbeing and health and increasing costs. The limited evidence of effectiveness of interventions to diminish violence and negative consequences in a population that is difficult to reach, asks for easy accessible low-costs interventions [26, 27, 30]. Within usual health care settings many victims worry about privacy and safety [32] and find provided care not attune to personal needs. Without any doubt also an important barrier for victims to disclose is not being ready to accept help [60]. The relevance of an eHealth intervention certainly is that an eHealth intervention might improve the awareness and readiness of victims to disclose their violent experiences, as a first step without any health care contact to get ready to change and to increase the willingness to tailored treatment. Disclosure by victims of IPV makes it also possible to deal with violence in an early stage.

By offering an internet-based intervention online we might overcome the earlier mentioned barriers, which will lead to an increased awareness of being in an unhealthy situation with possibilities to change and to decrease (mental) health symptoms. Internet has the advantages of a constant availability and easy accessibility. The added value of an internet based intervention lies in facilitating equity of access for most victims as they are afraid of losing safety and privacy, being blamed as victim, especially for the women who might otherwise be disadvantaged such as women in remote locations, ethnic minorities, or women closely monitored by an abusive partner. Above all it guarantees anonymity and safety, which is highly important for minority groups in our society [61]. Besides, we chose women only as our target group, as involvement of male participants
could be a threat for female victims of IPV, and should ask a very different design of the internet intervention.
Our project will strive to include adult persons with a variety on socio-economic status, ethnicity and sexual orientation, in all ages except children and adolescents as these youngsters need special legal prerequisites. The strategy followed in Feel the ViBe for dissemination online resulted in a diverse group of participants [1]. Patient participation is organized by the patient representatives in our project group. They will construct a patient advisory board consisting of 8 victims with a diverse background and who will be involved in all phases of this project, from start to implementation.
This innovative project combines the experiences of multiple experts from different fields (victims, primary care, medical psychology, gender medicine, gender based violence and eHealth interventions), which will support the development of a valuable internet-based intervention named SAFE. As women compared to men are more vulnerable and susceptible to suffer from violence an intervention focussing on female victims will greatly diminish the gender gap in health. The unique approach of qualitative and quantitative methods including a RCT is also considered to be a very successful basis to ameliorate health inequalities.

Study objective

Victims of IPV, living in an unsafe and unhealthy situation, are faced with a broad range of physical and emotional symptoms. Standard and easy-accessible care to facilitate change into a safer situation is lacking. The project aims to launch an internet-based self-support intervention to enhance awareness and decision making, for women exposed to IPV named SAFE. As low threshold access is important, we aim to make SAFE freely available and as accessible as possible for functionally illiterates, migrants and other non-native Dutch-speaking participants (by collaboration with the national institute Pharos). Our hypotheses is that using SAFE will lead in victims to an increased awareness of being in an unhealthy situation with possibilities to change, an increase of self-efficacy and perceived support, a decrease of (mental) health symptoms such as
depression and anxiety and lastly to person-tailored changes in their violent

living situation.

The project consists of several parts:
1. The development of SAFE, based on victim*s experiences, expert opinions, comparable eHealth interventions and literature.
2. A randomized controlled parallel-group trial to evaluate the effectiveness and efficacy of the SAFE intervention (RCT),
3. A process evaluation of SAFE to gain insight into meaningful usage parameters to evaluate the use of a fully automatic web-based intervention, including feasibility measures, and using mixed-methods.

The Research Questions following are:
1. What are key elements of SAFE, an eHealth intervention for women exposed to IPV, according to victims and experts?
2. Is SAFE an effective intervention to increase awareness, self-efficacy and perceived support?
3. Is SAFE an effective intervention to lower (mental) health symptoms in women exposed to IPV?
4. Does SAFE lead to change concerning their violent living situation?
5. Is SAFE a feasible tool to deliver care to women exposed to IPV?

Study design

Interview study: To start the development of SAFE we will perform semi-structured interviews with female victims of IPV to identify wishes and needs for eHealth, as well as key elements for SAFE. Additionally we will address safety as an important factor and ask them to
their needs concerning their safety when participating in SAFE. Finally we will ask female victims of IPV how disseminate the existence of SAFE. The interview study will have a qualitative design using semi-structured face-to-face interviews. This method allows one to gather rich data about a difficult subject in a vulnerable group. The participants engage in semi-structured interviews, using an interview guide that will be based on literature and expert opinions. Interviews are audio taped with the interviewees* consent. Interviews will last 45-60 minutes. The recorded interviews will be transcribed verbatim and emailed to the participants (when they allow) for member check.

RCT: A randomized controlled parallel-group trial (SAFE vs. Minimal Intervention).
For the development of SAFE we will address female victims of IPV with help of an organisation that supports female victims of IPV and ask these women to engage in a series of two meetings. In the first meeting we will present the pilot version of SAFE and ask for feed-back on facilitating and hindering factors for participation in SAFE. Additionally, we will provide them with a login and ask them to evaluate the intervention with help of a structured list. This structured list will consist of 1) a Web Evaluation Questionnaire and 2) the *checklist toegankelijke informatie* from Pharos. The web evaluation

questionnaire (WEQ) will contain questions about content, layout, the perceived effectiveness and usefulness of the website, as well as the question to give the website a motivated overall score from 0 to 10, based on their experiences and taking into account their own wishes and needs. A final question is a so-called free text field, to catch suggestions and new ideas. The WEQ will be derived from an earlier version used for Feel the ViBe [84] and has as goal to identify issues for further improvement, to collect possible facilitators and barriers for using, and to evaluate if the website will meet the expectations of the target group. We will ask all women if they prefer to complete the structured list on their own or with help, and if they need a device to access SAFE. All women who completed the structured list will be asked to join a second meeting. In the second meeting we will
discuss their findings and possible changes to the intervention based upon these findings until we reach consensus on the final content of SAFE. To be able to perform an RCT (see hereunder; Q2), we will consequently lock the intervention for further changes for the duration of the RCT. Women who took part in the development are free to use their login during the RCT, but will be excluded from any analysis.

RCT: Women will be recruited by either entering the public website of SAFE, which they found on Google or trough related pages; or directed by healthcare professionals or posters and flyers in waiting rooms. The public website of SAFE will contain a specific research page on which women can find information on the research. Women can choose to participate by entering SAFE trough a large button, after which they enter the registration process. Participants that are registered and have given consent will answer the baseline questionnaire (T0). After completion participants will be randomly allocated by computer by a statistician who is blinded to the baseline data (with an allocation ratio of 1:1) to either SAFE or a minimal intervention providing only general background information on IPV and e-mail support In Case of Emergency (ICE). Data will be collected at baseline (T0), at 3 months (T1), at 6 months (T2) and at 12 months (T3). Furthermore, participants are asked to complete 2 short questionnaires after completing a module (VAS). All data will be self-reported online.

Process evaluation: Participants in the RCT study who completed all follow-up questionnaires are asked to participate in semi-structured interviews. The audio of the interviews will be recorded and transcribed verbatim.

Intervention

At this stage we expect SAFE to be a pure self-support intervention without therapist contact, consisting of four modules: 1. providing information about IPV thereby raising awareness; 2. identifying the social environment thereby increasing support; 3. increasing self-efficacy by learning problem solving techniques; and 4. providing information on professional help. Within the modules we will possibly use psycho-education, assignments, assessments and

life stories of fellow sufferers in Video or Diaries. The use of a general forum, chat, online library and an e-mail support line could support the four modules. At this stage, SAFE could be designed as a website or as an application. While both have advantages, we expect a website optimized for mobile devices to fit the target group the best, as applications are, in nature, installed on a device, which could lead to dangerous situations when the perpetrator of the violence would control these devices. Besides, websites are available from all
devices, while apps are not. An escape-button, deleting search history and instructions on how to use private web navigation will be included.
The participants complete questionnaires at four moments: at registration (T0), at 3 months (T1), at 6 months (T2) and at 12 months (T3). Furthermore, participants are asked to complete 2 short questionnaires after completing a module (VAS).
The control group receives a minimal intervention consisting of general background information on intimate partner violence and e-mail support in case of emergency.

Study burden and risks

We will ask the Committee on Research Involving Human Subjects of the Radboudumc (Dutch initials: CMO) to assess this study. We expect no negative effects of participation in SAFE and therefore we think that this study does not fall within the remit of the Medical Research Involving Human Subjects Act (WMO).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Interview study: Participants will be selected by an organisation that supports female victims of IPV and will also be identified by posting messages on several websites. Participants are female victims of IPV.;RCT: Women, aged 18 years and older, self-identifying themselves as being a victim of IPV through a series of questions and consequently registering online for SAFE. Additionally, eligible women need to have access to a safe computer and/or mobile phone and Internet connection.

Exclusion criteria

Interview study: We will exclude participants who are in acute need of care; not speaking the Dutch
language; or unable to participate in a face-to-face interview.;RCT: The upper age limit has been set at 50 for the trial because women of childbearing age bear the greatest health burden associated with DV, and are the most likely to be in relationships where IPV is present.
Women are excluded if in a follow up contact they identify that they have not been in an unhealthy or abusive relationship or experienced fear of partner in the past 6 months. Participants not reading the Dutch language are excluded in the RCT, because content of the website (at start) and all outcome measures are in Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2018
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	04-06-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	27748
CCMO	NL64508.091.18