SAFE: Een eHealth interventie voor vrouwen die slachtoffer zijn van partnergeweld

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21754

Source
NTR

Brief title
SAFE

Health condition

Intimate Partner Violence; Domestic Violence, Domestic Abuse; Wife Battering, Violence Against Women; partnergeweld, huiselijk geweld, geweld tegen vrouwen; eHealth; online hulp; self-support

Sponsors and support

Primary sponsor: Radboudumc, Primary and Community Care, Gender&Women's Health
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

1. 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 (á0.78-0.94) [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

2nd outcomes

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. E-health 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 (á 0.88) [106, 107]. The MOS-SS5 will take about 5 minutes to complete.

4. Actions & Activities, measuring what activities or services the participant has used over the past six months. The first part of this questionnaire is adapted from the WEAVE service use & activities questionnaire to the Dutch situation [108]. If the participant answers ‘yes’ to

any items, a second question drops down asking whether it was helpful (yes/no). The second part consist of a modified list of self-care activities derived from the Diamond study on depression [109]. Women are asked if they have started doing, or increased the frequency, of any of the listed self-care activities. If she answers ‘yes’ to any items, a second question drops down asking whether it was helpful (yes/no). We hypothesize that participants in the intervention group show a higher mean number of actions for safety and wellbeing that are helpful than the comparison group, at 6 months post-baseline. The Actions & Activities Questionnaire takes about 5 minutes to complete.

5. 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.

6. 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.

2.4.3 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 behavioral norms typically ascribed to men and women in society. Therefore we will also collect data on self-identified gender and gender-related variables. These variabeles 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) [110-112]. 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 (á 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 [113] 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

Intimate Partner Violence (IPV) is defined as any physical, sexual, psychological, or economic violence that occurs between former or current spouses or partners. It is a common social problem worldwide, and one that is distinctly gendered. The prevalence of IPV is particularly alarming in light of its association with a range of negative health outcomes for women and children. Research consistently shows that abused women are at increased risk of depression, anxiety, posttraumatic stress disorder, and suicide [8], as well as physical problems. About one out of three women have experienced either physical and/or intimate partner violence or non-partner sexual violence in their lifetime. 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. 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. One in three will become a perpetrator or victim themselves in their future partner relationships: the intergenerational transmission of violence.

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. Many women feel uncomfortable revealing their experience with IPV, even if the issue is raised in a sensitive manner by the health professional. 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. 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.

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. 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. Social support, furthermore, has proven to be effective in adults exposed to violence and is associated with good mental and physical health outcomes. 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. Overall, evidence suggests that eHealth cognitive therapy interventions for depression and anxiety are effective, especially if healthcare providers are involved. Lintvedt et al. (2013) point out that an internet-based intervention is constantly available and accessible from any location. 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. 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.

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 blinded 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 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.

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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?

This registration concerns the RCT, answering the following questions:

1. “Is SAFE an effective intervention to increase awareness, self-efficacy and perceived support?”

2. “Is SAFE an effective intervention to lower (mental) health symptoms in women exposed to IPV?”

Study design

Data will be collected at baseline (T0), after completion of every of the four modules (T1), and six months after completion of all modules (T2). All data will be self-reported online. Automated reminders will be prompted after 1 week and after 2 weeks.

Intervention

SAFE, a selfsupport eHealth intervention for women exposed to intimate partner violence, which has yet to be developed

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Eligibility criteria

Inclusion criteria

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. 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. Once the trial is completed, the website will be available to women of all ages.

Exclusion criteria

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

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	198
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-08-2017
Application type:	First submission

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
NTR-new	NL7108
NTR-old	NTR7313
Other	SAFE : 849200002

Study results