Breast Project 4.7. Effectiveness of an educational intervention for the prevention of breast cancer by modifying risk behaviors through the use of a Web-App.

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1. INTRODUCTION

Breast cancer (BC) is the most frequently diagnosed malignant tumor in women regardless of the country's level of development. In 2018, at a European level it accounted for approximately 28% of the total cancers diagnosed in this sex[1] and, specifically in Spain, the estimated incidence that same year was 101/100,000 women[1].

The scientific advances that have occurred in recent years have improved its prognosis. Screening or early detection strategies have notably contributed to this evolution for some age groups and the elderly. Knowledge of risk factors by the population[2,3].

However, it is necessary to take into account that some screening methods have side effects and that they can act to the detriment of detection early[4,5]. On the other hand, there is abundant literature that reveals the relationship of various biological, behavioral and environmental factors in the development of CM[6-66]. Specifically, in the case of behaviors, making women aware of their influence makes it possible for them to establish preventive measures[67,68].

Additionally, it is worth noting the individualized estimates of the risk of develop CM[69]. According to Shiek et al.[70] these can contribute to less testing, a lower number of false positives, and fewer treatments. At present, there are algorithms that have been designed to estimate the probability of developing BC. Its use makes it possible to determine which risk reduction options are most effective in preventing its development[68,71]. One of the first and most popular is the one developed by Gail et al.[72]. Subsequently, validations were carried out to adjust the risk to specific conditions[73]. Although its validity has been demonstrated for estimations population, it seems to be limited for individualized estimates[74]. The parameters that it includes in its current version are the age of the woman (from 35 years), age of the first period, age of the woman in which her first child was born (in the case of having them), number of relatives of first degree cancer, number of previous biopsies, and race. Despite its effectiveness, some authors point out the need to continue with research that allows the development of more specific tools[75].

On the other hand, the use of technology is becoming a common channel of communication, from a care perspective, between the population and healthcare personnel. There are even terms to refer to it specifically. For example, eHealth or the use of information and communication technology in the field of health and, more specifically, mHealth as the use of mobile devices in the field of health [76,77].

The Internet is a great source of information used by between 30 and 50% of patients to seek information about their illness[78]. The fact that patients are well informed and understand the process of their disease contributes to improving their relationship with healthcare personnel and who adopt a more active role in their health [78,79]. Although these means make it possible for patients to have accessible information quickly and permanently, it must not be forgotten that the absence of quality criteria in some sources available online can work against it and this justifies the need to help patients to discriminate what information is correct, truthful and appropriate to the characteristics of each one.

In this sense, it should be noted that there is beginning to be evidence that includes the benefits and ways of using web-apps as means to get people to modify risky behaviors and/or acquire healthy behaviors to prevent pathologies such as overweight, diabetes and the cancer [80,81].

2. JUSTIFICATION

The use of digital media, such as a web-app, to publicize MC risk factors makes it possible to specifically establish measures aimed at reducing its prevalence, which in turn will contribute to reducing the number of cases of CM.

On the other hand, making women aware of their BC risk factors, as well as quantifying the risk of developing the tumor, is useful for them to be aware of the magnitude of the problem and take steps to minimize your risk.

Since there is no digital strategy in Asturias that informs and reduces the risk of developing breast cancer, through the modification of the main risk factors, in young women, the present study has been proposed with the objectives indicated below. continuation.

3. HYPOTHESIS AND OBJECTIVES

Based on the reviewed bibliography, it can be affirmed that establishing measures that contribute to improving knowledge related to the prevention of a health problem and help to perceive the risk of developing said problem, contribute to increasing the development of preventive behaviors.

3.1. Hypothesis

The hypothesis that this study will try to demonstrate is that an educational intervention, based on the use of a web-app, will be effective in improving knowledge and risk behaviors for breast cancer in women between the ages of 25 and 45, residents in health area 7 of the Principality of Asturias.

3.2. Objetives

3.2.1. Main Objetive

To evaluate the effectiveness of an educational intervention for the prevention of breast cancer risk through the use of a Web-App in women residing in health area VII of the Principality of Asturias.

3.2.2. Specific Objetive

- Evaluate adherence to behavioral recommendations before and after after the educational intervention for each group separately.
- To compare adherence to behavioral recommendations after the intervention between the intervention and control groups.
- Evaluate, in each group separately, the knowledge in relation to the risk factors and symptoms of breast cancer before and after the intervention.
- To compare the level of knowledge in relation to the risk factors and symptoms of breast cancer between the intervention and control groups before and after the intervention.
- Estimate the risk and self-perception of developing breast cancer before and after the intervention for each of the groups.
- To compare the risk and self-perception of developing breast cancer between the intervention and control groups after the educational intervention.

4. METHODOLOGY

4.1. Design

Experimental, randomized, with a control group without intervention.

4.2. Study population

It will be made up of women belonging to the VII health area of the Principality of Asturias, aged between 25 and 45 years, without a previous diagnosis of BC.

All women who give written consent to participate in the study will be included. Those who: (i) do not have adequate physical or psychological characteristics to participate in the study will be excluded; (ii) do not have the means to regularly access the web-app that will be used to carry out the educational intervention; (iii) your contact by email is not possible.

The recruitment of women will be carried out, between the months of January and February 2022, by sending a letter of invitation to participate from the health area. A random sample of 361 women will be sufficient to estimate, with 95% confidence and an accuracy of +/- 5 percentage units, a population percentage that is expected to be approximately 75%. The percentage of necessary replacements has been predicted to be 20%.

The health area VII technician and member of the research team (María Dolores Martín) will draw up a list of all the women likely to be included in the study. The members of the research team prepare a letter for each of the women and they will be sent from the management of Sanitary Area VII to the women by postal mail.

The letter contains a contact email to which they will write if they are interested in participating. The women will be answered as the emails are received and when we have obtained the necessary sample, the project will be explained in detail with an information sheet that they may have at their disposal and they will be given their consent informed, which they will sign by selecting the box "I wish to participate voluntarily" that will appear at the end of the consent. Finally, they will be asked for a username and password to access the web-app. In other words, the user or pseudonym to access the web-app will be selected by the woman herself.

The selected women will be distributed, in March 2022, between the intervention (IG) and control (CG) groups using the simple randomization method and with a 1:1 ratio.

4.3. Data collection: tools and procedure

The data collection will take place during the months of March (pre-test) and June 2022 (post-test). At both times it will be done virtually, using a digital form. Participants will access this form through the project's web-app. The pre-test collection will be carried out after signing the consent and the post-test, after the educational intervention, that is, at 12 weeks.

At both moments, information will be collected related to personal, anthropometric, and behavioral variables (diet and physical activity), self-examination, knowledge related to risk factors and symptoms of breast cancer, perception of risk of developing breast cancer, and barriers to carry out. take actions to prevent it.

Additionally, after the educational intervention, satisfaction with the use of the web-app will be evaluated.

The information on the behavioral variables will be recorded using the Motiva.Diaf questionnaire. It includes 12 items that measure adherence to and motivation to carry out recommendations related to nutrition (questions 1 to 7) and physical activity (questions 8 to 12). Each item presents a Likert-type response format with a range from 0 (lack of motivation to make the recommendation) to 5 (intrinsic motivation). In addition, each separate recommendation can be interpreted dichotomously (makes=1 or does not make the recommendation=0). Finally, the synthetic variable adherence to healthy recommendations is elaborated as a result of scoring each item in its dichotomous interpretation (range 0=worst adherence to healthy recommendations to 12=greatest adherence to healthy recommendations).

The self-examination is carried out by means of the question, do you perform the breast self-examination once a month.

The information related to knowledge, risk perception and barriers with the MARA questionnaire. This questionnaire, specifically related to breast cancer, consists of 31 items that measure the following constructs: knowledge related to risk factors (9 items), knowledge related to signs and symptoms (9 items), perception of risk of developing breast cancer breast (6 items) and perceived barriers to carry out prevention strategies (7 items). Items related to knowledge have a score of 0 (error) and 1 (correct), therefore the range of scores, both for risk factors and for signs and symptoms, is between 0 and 9. The score of the other two scales is represented on a Likert-type scale ranging from 1

(totally disagree) to 5 (totally agree), the total perception score being between 6 and 30 points (the lower the score, the lower the perception of risk and the barriers between 7 and 35 points (the lower the score, the fewer perceived barriers).

4.4. Educational intervention

The IG women will receive an intervention based on the use of a web-app with a duration of 12 weeks, which will be complementary to the preventive activities carried out in the health area. The CG participants will not have access to the web-app during the 12 weeks that the intervention lasts and will only receive the usual health care.

The design and evaluation of the intervention is based on the Behavior Change Wheel (BCW)82 model and the web-app will be used as the central axis of the same.

The web-app will consist of 6 sections: information related to BC risk factors; self-exploration; feeding; physical activity; news and community the risk factors section will be merely informative. It will collect information in relation to the modifiable and non-modifiable factors that increase the risk of developing this tumor.

The self-examination section will include information related to the signs compatible with the CM and an explanatory video on how to perform the examination of your breasts. This information will enable women to identify the symptoms and signs that are consistent with the onset of cancer.

The food will be subdivided into 3 sections: nutritionist; recipes; tips. A nutrition expert will provide information in the form of videos about the characteristics of a healthy diet. In the recipes section, information related to healthy recipes will be provided. Finally, the advice section will be included where information obtained from secondary sources will be provided.

The physical activity section will also be subdivided into 3 sections: your 30 minutes; routes; options in your environment. First, information will be provided about the importance of doing 30 minutes of physical activity a day, indicating "walking" as an essential activity. In addition, 4 videos will be included with routines that women can perform at home. The routes section will include links to the pages of the municipalities belonging to the VII health area where the routes that can be taken in the area appear. The last section will include the health assets that women can find in the basic health

area (parks, sports spaces, walks...) with basic information about the type of activity that can be carried out in each of them.

Links to resources related to any aspect that may be of interest to the participants will be uploaded in the news section.

Finally, the community section will have a blog structure through which participants will be encouraged to make contributions (routes, recipes, information...) that may be of interest to the rest of the participants. This information will not be public until it is validated by the members of the research team.

5. STATISTICAL ANALYSIS

Initially, the normality of the distribution of the variables will be verified, the Kolmogorov-Smirnov test will be used. A description of the variables will be made using percentages, means (standard deviation) or median (interquatile range) depending on their nature and distribution.

To determine the association between variables, the chi-square test, McNemar for qualitative variables, will be used. For qualitative variables, they will be determined based on the distribution of variables.

Linear regression analyzes will be carried out to determine which variables best predict the score after the intervention in terms of knowledge about risk factors, signs-symptoms of early detection of breast cancer, knowledge and adherence to healthy behaviors.

The analyzes will be carried out using the IBM SPSS version 24.0®, considering that the results were statistically significant when the value of p is ≤ 0.05.

6. ETHICAL CONSIDERATIONS

In general, the precepts of the Declaration of Helsinki will be respected. This defines the principles that must be scrupulously respected by all the people involved in the present investigation. Specifically, informed consent will be requested, the free will to abandon the research will be respected without this causing any harm to the person, and the confidentiality of the data of the subjects participating in the study will be respected. The treatment, communication and transfer of personal data of all participants will comply with the provisions of Organic Law 3/2018, of December 5. The project has been

reviewed and authorized by the Research Ethics Committee of the Principality of Asturias and prior to its start it will be registered in ClinicalTrials.gov.

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INFORMED CONSENT

I, Mrs..... ...., with ID no.....I have been informed of the objectives of the “Breast4-7” research project and I have had the opportunity to make questions about him, for which I have obtained sufficient clarifying information.

I know that the "Breast4-7" project is an investigation that will evaluate the effectiveness of an educational intervention, through the use of a web-app, to reduce the risk factors of breast cancer in women of the health area VII of the Principality of Asturias.

I know that the project is developed by the Precam research team of the University of Oviedo/ISPA, and that the VII health area collaborates, and that I can contact them at any time via email precam@uniovi.es.

I understand that the information obtained may not be used to modify in any way my relationship with the Principality of Asturias Health Service, and the data provided will only be used for the purpose of the investigation.

I know that the data I provide to the research team of the “Breast4-7” project is completely confidential and anonymous. In no way will personal data be disclosed. The protection of the information you provide will be governed by the provisions of Organic Law 3/2018, of December 5, on Data Protection.

I am aware that if I decide to withdraw from the study and revoke my consent, I may do so without giving any reason. In this case, my relationship with the health professionals will not be altered, nor will there be any harm in my clinical monitoring or treatment.

I freely and voluntarily give my consent to participate in the "Breast4-7" project, to consult my medical record to complete the information necessary to achieve the objectives of the project and to be contacted by email at the following address.... ....

SIGNATURE DATE

Revocation of participation:

Me, Mrs..... with DNI..... I am requesting my withdrawal from the Breast47 Project. I request that I no longer be contacted and that my data be removed from your database.