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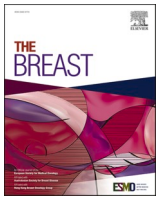

# Raising awareness of alcohol as a modifiable risk factor for breast cancer: A randomized controlled trial comparing the efficacy of accessing an interactive website with a non-interactive website

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ABSTRACT

*Background:* Alcohol consumption is a potentially modifiable risk factor for breast cancer (BC). Reducing alcohol consumption within the daily amount at low-risk for alcohol-related consequences (daily alcohol threshold) may contribute to preventing BC new cases. However, most women are unaware of risk factors for BC, the daily alcohol threshold, and how to measure alcohol use. We aimed at investigating the efficacy of accessing an interactive website in increasing the knowledge that alcohol is a BC risk factor.

*Methods:* We conducted a randomized controlled trial among women waiting for mammography. Women completed a questionnaire to investigate their knowledge before and after accessing an interactive (intervention group) and non-interactive (control group) website.

*Results:* We recruited 671 women, randomized 329 (49.0 %) and 342 (51.0 %) to the intervention and control groups, respectively. At baseline, most women were not aware of most modifiable BC risk factors. Accessing either website significantly increased the percentage of women who acquired the knowledge on BC risk factors, with the interactive website achieving better results: 82 % and 69 % of women acquired the knowledge that alcohol is a risk factor for BC in the intervention and control groups, respectively ($p < 0.001$). Among women with lower levels of education, the probability of acquiring this knowledge was higher in the intervention group than control group.

*Conclusion:* Our results show that accessing an interactive website may increase the percentage of women who acquire the knowledge that alcohol is a BC risk factor especially among women of lower levels of education.

## 1. Introduction

Breast cancer (BC) is the most prevalent cancer worldwide with approximately 7.8 million women, estimated at the end of 2020, diagnosed in the previous 5 years [1]. Despite effectiveness of treatments for BC improving, mortality rates remain high [1,2].

Alcohol use, physical inactivity, being overweight or obese, and hormone replacement therapy (HRT) are potentially modifiable BC risk factors, responsible for approximately 30 % of new BC cases [1,3,4]. The relationship between alcohol consumption and the risk of developing BC is dose-dependent [5], with an increased risk of approximately 10 % for each additional daily standard unit of alcohol (AU). This corresponds to approximately one glass of wine, a can of beer, or a small glass of spirits [1,6].

In Europe, almost 11,000 new cases of BC per year are related to light to moderate drinking levels (less than 2 AU per day [7]), with no alcohol

*Abbreviations:* AU, standard unit of alcohol; BC, breast cancer; HRT, hormone replacement therapy; RCT, randomized controlled trial.

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consumption as the lowest risk [8]. However, as most of the general population consume alcohol, many countries have produced 'lower risk' thresholds at which alcohol-related consequences are minimized to help people adopt healthier behaviors [6,9]. In general, healthy, non-pregnant, and non-breast-feeding women should avoid alcohol consumption higher than one AU per day, and women at higher risk of BC due to other factors, such as family history of BC or obesity, should completely avoid alcohol or consume alcohol only occasionally [10]. In France, it has been estimated that perfect adherence to daily thresholds between 2015 and 2050 would prevent more than 61,000 new BC cases [11]. Similar data have been estimated by other studies conducted in Australia [12], Canada [13], as well as worldwide [14].

To adhere to these recommendations, women should be aware of modifiable BC risk factors, how to quantify alcohol consumption into AU, and the daily alcohol threshold. In fact, most women are neither aware of modifiable risk factors for BC nor how to quantify alcohol consumption into AU [15]. Recently, asking a sample of women to list BC risk factors, we found that less than 20 % mentioned obesity, alcohol use, lifestyle, and use of exogenous hormones and most ignored how to measure alcohol consumption into AU [16].

These data advocate the urgency to develop evidence-based educational programs to increase the knowledge of BC risk factors [1]. Digital tools have shown promising results in reducing at-risk drinking [17] as well as improved health processes [18]. On the other hand, two recent reviews concluded that further studies are needed to clarify the effectiveness of interactive digital tools to help pregnant women [19] and adolescents [20] to manage weight gain. Promising results were achieved by studies investigating the effectiveness of interactive digital tools in improving psychological well-being, and/or quality of life of BC patients [21–23]. Accordingly, a growing number of studies are starting to evaluate the effectiveness of these tools in increasing the knowledge of BC risk factors among healthy young women [24,25]. These latter studies are mainly focused on healthy diet and physical activity [24–26].

Our study was aimed at evaluating the efficacy of an interactive website compared to a validated noninteractive website in increasing the knowledge of alcohol as a BC risk factor. We hypothesized that this interactive tool may be more effective in increasing women's awareness than a similar but non-interactive digital tool.

## 2. Methods and material

### 2.1. Study design

We conducted a randomized controlled trial (RCT) in agreement with the Declaration of Helsinki and Good Clinical Practice guidelines. The study was approved by the Ethic Committee of the University Hospital of Cagliari, Italy.

### 2.2. Procedures

Participants were adult women (age >18 years), able to speak the Italian language, understand and give informed consent. Women were recruited at two Hospitals in Cagliari, Italy (the University Hospital and the Civil Hospital) among outpatients waiting to undergo mammography for organized BC screening or other reasons like personal initiative, symptoms, family history of BC, and/or previous BC diagnosis. Based on the results of our previous study [16], we planned to recruit a sample of approximately 600 women and divide them randomly using a computer-generated list, into two arms, the intervention and control groups, in which women accessed an interactive and a non-interactive website, respectively.

Before accessing the websites (Fig. 1), participants were submitted a questionnaire investigating their baseline knowledge of BC risk factors, the alcohol content of common alcoholic beverages expressed in the number of AU, and the daily recommended threshold to avoid high alcohol-related risks (see Appendix A, Supplementary Box 1, Questionnaire). Information on age, civil status, employment, education, reason for medical assessment, family history of BC, was also collected.

Then, each participant received a tablet already linked to the homepages of the interactive and non-interactive websites, for the intervention and control groups, respectively. For the intervention group, we used a modified draft of the "Abreast of health", created by the University of Southampton, UK (freely available at the link https://abreastofhealth.github.io/) to increase women's knowledge on BC risk factors in a simple and interactive way. Information is provided as minimal text and several figures. Briefly, it contains the questionnaire AUDIT-C [27,28] and other questions on smoking, height, and weight. The image provided with AUDIT-C questions describes the content in AU

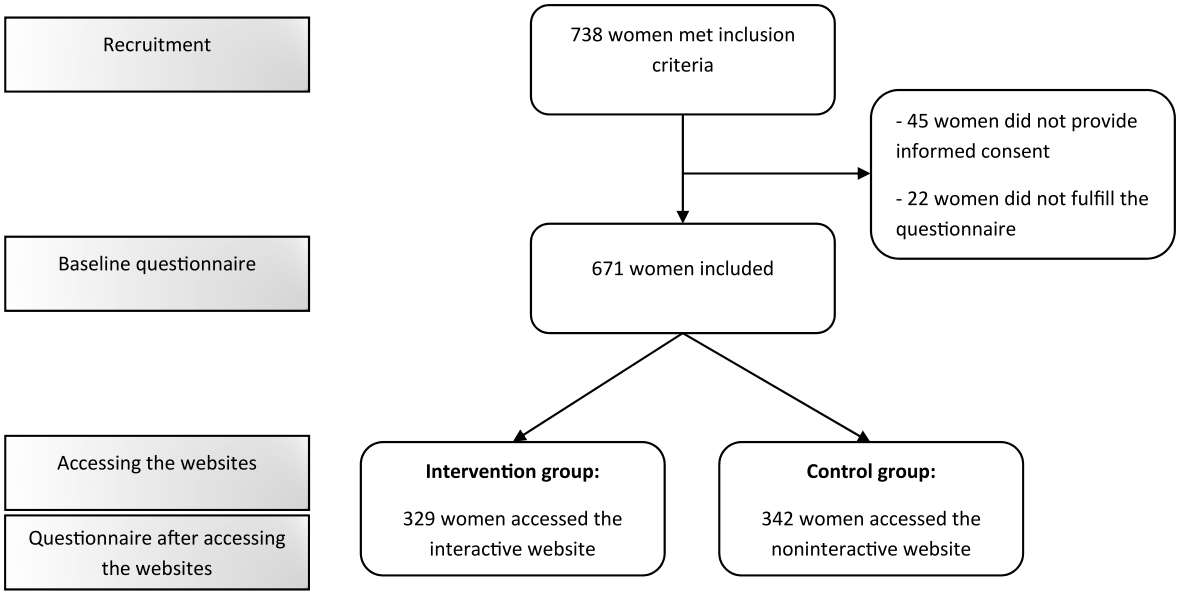


**Fig. 1.** Flow-chart diagram of the study.
The graph shows the recruitment of the sample of women while waiting to undergo mammography, the administration of the questionnaire at baseline, the division of the sample of participants into two groups who accessed the interactive and the not-interactive website, and the administration of the questionnaire after accessing the websites.

of the most common beverages to help women to quantify their alcohol use. After that, the website provides tailored feedback. In agreement with the lead author of the UK team (JS), we adapted the text for use in Italy. Furthermore, as the content of alcohol in a 'standard drink' varies between the UK (8 g) and Italy (12 g) [6], we also adapted the images of the alcoholic beverages corresponding to an AU in Italy. For instance, we substituted the image of the half pint with a can of beer. The Italian version was re-translated into English and the new English version was submitted to the authors of the original version to ensure consistency between the two English versions The Italian version is freely available at the link "https://allasalute.github.io". Replies given by participants to the questions of the interactive website were not registered.

For the control group, we used the website devoted to BC created by the Italian Ministry of Health, freely available at Il tumore della mammella (salute.gov.it), containing certified information on BC but without interaction or figures.

Participants of both groups accessed the websites for as long as they wished, then they returned the tablets back to the researcher, and were re-submitted the same questionnaire administered at baseline (Fig. 1; Appendix A, Supplementary Box 1). We also measured the time spent accessing the websites.

### 2.3. Outcomes

The primary outcome was the increase in the knowledge of alcohol as a BC risk factor evaluated as the rate of women who mentioned alcohol as a BC risk factor in section 3 of the questionnaire. Secondary outcomes were the increase in the knowledge of the other modifiable BC risk factors, the alcohol content of common alcoholic beverages expressed in the number of AU, and the daily recommended threshold to avoid high alcohol-related risks.

### 2.4. Statistical analysis

Student *t*-test was carried out to assess differences in age between groups; Mann Whitney test was carried out to assess differences in time spent browsing the assigned website. Chi-squared tests were carried out to verify that the baseline knowledge of control and intervention groups did not differ. McNemar's tests for paired data were used to assess the efficacy of both websites comparing baseline to post-intervention knowledge. Chi-squared tests were also carried out to assess differences in the efficacy between the two websites. Multivariable logistic regression analysis was performed to explore socio-demographic factors affecting the probability of acquiring knowledge of alcohol as a BC risk factor. Detailed statistical procedures are reported in Appendix A, Supplementary data.

## 3. Results

### 3.1. Sample description

Recruitment occurred between January to June 2023. Overall, 738 women met our inclusion criteria and were invited to participate (Fig. 1): 67 (9 %) refused or did not complete the final questionnaire because they were called for mammography, and 671 (91 %) were included in the study. Participants were randomly allocated to 329 (49.0 %) in the intervention and 342 (51.0 %) in the control group. Women did not differ in sociodemographic characteristics between the two groups (Table 1).

### 3.2. Baseline knowledge

Baseline knowledge of BC risk factors, alcohol content in AU of alcoholic beverages, and the daily alcohol threshold did not differ between the intervention and control groups (Table 2). In detail, only 20 % of women of both the groups mentioned alcohol as a BC risk factor.

**Table 1**
Demographics of survey participants divided into intervention group and control group.

| | | Intervention group (n = 329) | Control group (n = 342) | Chi square p value |
|---|---|---|---|---|
| Age | Years (mean value, SD) | 56.6 (8.9) | 56.7 (9.3) | 0.826 |
| Reasons for the mammography | Spontaneous BC screening | 109 (33 %) | 116 (34 %) | 0.829 |
| | Organized BC screening | 220 (70 %) | 226 (66 %) | |
| Studying or working in healthcare | Yes | 30 (9 %) | 32 (9 %) | 0.915 |
| | No | 299 (91 %) | 310 (91 %) | |
| Civil status | Single or unmarried | 57 (17 %) | 76 (22 %) | 0.112 |
| | Other | 272 (83 %) | 266 (78 %) | |
| Education level | Middle school | 132 (40 %) | 135 (40 %) | 0.580 |
| | High school | 125 (38 %) | 121 (35 %) | |
| | Degree | 72 (22 %) | 86 (25 %) | |

Abbreviation: SD: standard deviation.

**Table 2**
Baseline knowledge expressed as % of women who rightly mentioned BC risk factors, reported the right number of AU, and identified the daily alcohol level at low-risk for alcohol-related consequences.

| | | Intervention group (n = 329) | Control group (n = 342) | Chi square p value |
|---|---|---|---|---|
| BC risk factors | Alcohol | 65 (20 %) | 68 (20 %) | 0.967 |
| | Diet | 166 (50 %) | 182 (53 %) | 0.474 |
| | Physical inactivity | 61 (19 %) | 57 (17 %) | 0.524 |
| | Cigarette smoke | 135 (41 %) | 143 (42 %) | 0.838 |
| | Contraceptive pill | 30 (9 %) | 34 (10 %) | 0.717 |
| | Age | 4 (1 %) | 5 (1 %) | 1.000 |
| | Being female | 1 (0 %) | 6 (2 %) | 0.124 |
| | Family history of BC | 166 (50 %) | 161 (47 %) | 0.381 |
| | Overweight/ obesity | 36 (11 %) | 28 (8 %) | 0.225 |
| | HRT | 29 (9 %) | 39 (11 %) | 0.267 |
| Content of alcohol of the most common alcoholic beverages | Half a glass of wine (0.06 l) | 133 (40 %) | 129 (38 %) | 0.473 |
| | A glass of wine (0.125 l) | 215 (65 %) | 234 (68 %) | 0.913 |
| | A can of beer (0.33 l) | 166 (50 %) | 174 (51 %) | 0.939 |
| | A mug of beer (0.5 l) | 39 (12 %) | 48 (14 %) | 0.400 |
| | A glass of aperitif (0.08 l) | 226 (69 %) | 226 (66 %) | 0.471 |
| | Two glasses of aperitif (0.08 l) | 31 (9 %) | 30 (9 %) | 0.769 |
| Daily threshold | ≤1 unit of alcohol | 284 (86 %) | 305 (89 %) | 0.258 |

Abbreviations: AU: alcohol unit; BC: breast cancer; HRT: hormone replacement therapy. Unit of alcohol: a beverage containing approximately 12 g of alcohol, corresponding to approximately one glass of wine, a can of beer, or a small glass of spirits.

Women in the intervention group spent a longer time accessing the interactive website than non-interactive one (median value in minutes: 2.35 vs 1.98; $p < 0.001$).

### 3.3. Efficacy of accessing the websites in increasing the knowledge of BC risk factors

According to McNemar's tests' results, accessing both websites significantly increased the percentages of women acquiring knowledge of most BC risk factors examined (Table 3; Fig. 2). Specifically, compared to their baseline values (20 % in both groups), the percentages of women who mentioned alcohol as a BC risk factor were 85 % ($p < 0.001$; Table 3) and 75 % ($p < 0.001$; Table 3) in intervention and control groups, respectively. Regarding the content in AU of commonly consumed beverages, accessing both the websites significantly, although weakly, increased the percentages of women who reported the right content except for "a mug of beer" in the control group (Table 3). Regarding the daily alcohol threshold, at baseline most women were already aware of this value (Table 2). Accessing both the websites significantly but slightly increased this knowledge (both groups, $p < 0.001$; Table 3).

### 3.4. Comparing the efficacy of accessing the interactive website to accessing the not interactive website

Analyzing only those women who were not aware of risk factors at baseline, Table 4 shows that accessing the interactive website resulted in higher percentages of women acquiring knowledge on most BC risk factors than the non-interactive site, although the control group were more likely to acquire the knowledge on age as a risk factor. Specifically, among women who were not aware at baseline, those who acquired this information were 82 % and 69 % of the intervention and control groups, respectively ($p < 0.001$; Table 4). Finally, we found no differences between the two groups in acquiring knowledge on diet, contraceptive pills, being female, and family history of BC. Regarding the content in AU of commonly consumed beverages (can of beer, mug of beer and two shot glasses), Table 4 shows that the intervention group achieved better results compared to the control group in half of the beverages investigated with no differences in the other beverages.

Regarding the daily alcohol threshold, Table 4 shows that accessing the interactive website induced better results than the non-interactive website.

### 3.5. Factors associated with the acquisition of knowledge that alcohol is a BC risk factor

Table 5 shows factors significantly associated with the probability of acquiring knowledge that alcohol is a BC risk factor. In detail, the level of education interacts with the specifically accessed website, while civil status and reasons for mammography influence this probability independent by of other factors:

- women with middle-school level education are more likely to gain increased knowledge when included in the interventional rather than the control group (OR 2.64; $p = 0.01$)
- women with high school education are more likely to increase their knowledge when included in the interventional group compared to the control group (OR 2.56; $p = 0.01$)

**Table 3**
Baseline *vs* post accessing websites in each group: Knowledge expressed as % of women who rightly mentioned BC risk factors, reported the right number of AU, and identified the daily alcohol level at low-risk for alcohol-related consequences.

| | INTERVENTION GROUP (n = 329) | | | CONTROL GROUP (n = 342) | | |
|---|---|---|---|---|---|---|
| | Baseline knowledge | Post accessing websites knowledge | Mc Nemar's p value | Baseline knowledge | Post accessing websites knowledge | Mc Nemar's p value |
| Alcohol | 65 (20 %) | 280 (85 %) | **<0.001** | 68 (20 %) | 256 (75 %) | **<0.001** |
| Diet | 166 (50 %) | 208 (63 %) | **<0.001** | 182 (53 %) | 239 (70 %) | **<0.001** |
| Physical inactivity | 61 (19 %) | 147 (45 %) | **<0.001** | 57 (17 %) | 123 (36 %) | **<0.001** |
| Cigarette smoking | 135 (41 %) | 262 (80 %) | **<0.001** | 143 (42 %) | 238 (70 %) | **<0.001** |
| Contraceptive pill | 30 (9 %) | 35 (11 %) | 0.359 | 34 (10 %) | 40 (12 %) | 0.286 |
| Age | 4 (1 %) | 4 (1 %) | 1.000 | 5 (1 %) | 19 (6 %) | **<0.001** |
| Being female | 1 (0 %) | 1 (0 %) | 1.000 | 6 (2 %) | 8 (2 %) | 0.727 |
| Family history of BC | 166 (50 %) | 190 (58 %) | **0.005** | 161 (47 %) | 200 (58 %) | **<0.001** |
| Overweight/obesity | 36 (11 %) | 130 (40 %) | **<0.001** | 28 (8 %) | 76 (22 %) | **<0.001** |
| HRT | 29 (9 %) | 58 (18 %) | **<0.001** | 39 (11 %) | 46 (13 %) | 0.230 |
| Half a glass of wine (0.06 l) | 133 (40 %) | 169 (51 %) | **<0.001** | 129 (38 %) | 170 (50 %) | **<0.001** |
| A glass of wine (0.125 l) | 215 (65 %) | 269 (82 %) | **<0.001** | 234 (68 %) | 270 (79 %) | **<0.001** |
| A can of beer (0.33 l) | 166 (50 %) | 229 (70 %) | **<0.001** | 174 (51 %) | 207 (61 %) | **<0.001** |
| A mug of beer (0.5 l) | 39 (12 %) | 70 (21 %) | **<0.001** | 48 (14 %) | 40 (12 %) | 0.115 |
| A glass of aperitif (0.08 l) | 226 (69 %) | 276 (84 %) | **<0.001** | 226 (66 %) | 252 (74 %) | **<0.001** |
| Two glasses of aperitif (0.08 l) | 31 (9 %) | 59 (18 %) | **<0.001** | 30 (9 %) | 35 (10 %) | **<0.001** |
| Daily threshold | 284 (86 %) | 313 (95 %) | **<0.001** | 305 (89 %) | 322 (94 %) | **<0.001** |

Abbreviations: AU: alcohol unit; BC: breast cancer; HRT: hormone replacement therapy. Unit of alcohol: a beverage containing approximately 12 g of alcohol, corresponding to approximately one glass of wine, a can of beer, or a small glass of spirits. Bold font indicates statistical significance.

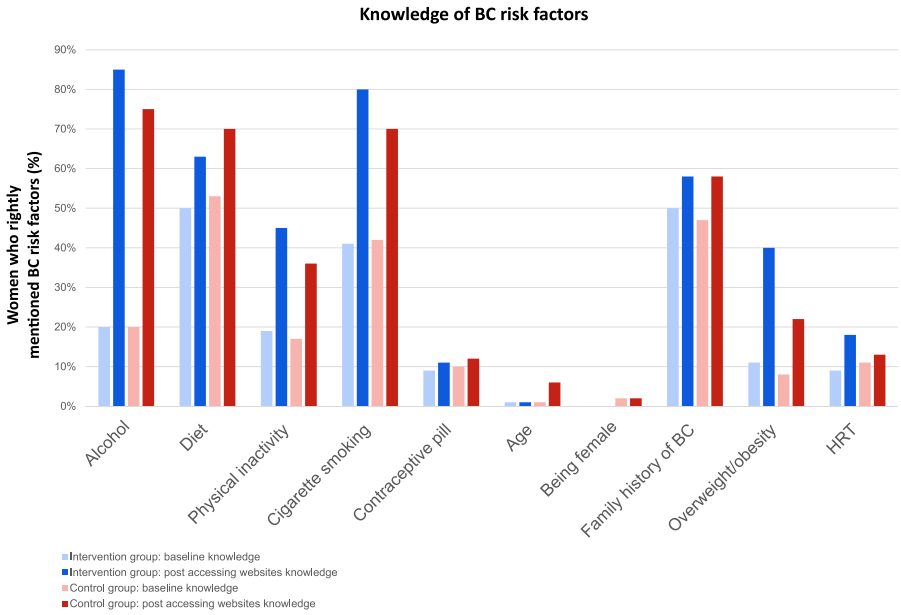


**Fig. 2.** Knowledge of BC risk factors.
The graph shows the knowledge of BC risk factors expressed as % of women who rightly mentioned each BC risk factor at baseline and after accessing the interactive and not-interactive website. Abbreviation: BC: breast cancer.

**Table 4**
Women who acquired the right knowledge among women with incorrect answers at baseline: Comparison between the interactive website (intervention group) vs noninteractive website (control group).

| | INTERVENTION GROUP | | CONTROL GROUP | | Chi square p value |
|---|---|---|---|---|---|
| | Women who were not aware at baseline n | Acquired knowledge only after accessing website n (%) | Women who were not aware at baseline n | Acquired knowledge only after accessing website n (%) | |
| Alcohol | 264 | 216 (82 %) | 274 | 188 (69 %) | **<0.001** |
| Diet | 163 | 57 (35 %) | 160 | 70 (44 %) | 0.106 |
| Physical inactivity | 268 | 94 (35 %) | 285 | 68 (24 %) | **0.004** |
| Cigarette smoking | 194 | 139 (72 %) | 199 | 105 (53 %) | **<0.001** |
| Contraceptive pill | 299 | 12 (4 %) | 308 | 14 (5 %) | 0.746 |
| Age | 325 | 3 (1 %) | 337 | 15 (4 %) | **0.005** |
| Being female | 328 | 1 (0 %) | 336 | 5 (1 %) | 0.107 |
| Family history of BC | 163 | 46 (28 %) | 181 | 56 (31 %) | 0.581 |
| Overweight/obesity | 293 | 100 (34 %) | 314 | 52 (17 %) | **<0.001** |
| HRT | 300 | 33 (11 %) | 303 | 16 (5 %) | **0.01** |
| Half a glass of wine (0.06 l) | 196 | 51 (26 %) | 213 | 56 (26 %) | 0.95 |
| A glass of wine (0.125 l) | 114 | 62 (54 %) | 108 | 46 (43 %) | 0.079 |
| A can of beer (0.33 l) | 163 | 72 (44 %) | 168 | 47 (28 %) | **0.002** |
| A mug of beer (0.5 l) | 290 | 36 (12 %) | 294 | 6 (2 %) | **<0.001** |
| A glass of aperitif (0.08 l) | 63 | 30 (48 %) | 70 | 26 (37 %) | 0.222 |
| Two glasses of aperitif (0.08 l) | 298 | 29 (10 %) | 312 | 9 (3 %) | **<0.001** |
| Daily recommended threshold | 45 | 31 (69 %) | 37 | 17 (46 %) | **0.036** |

Abbreviations: AU: alcohol unit; BC: breast cancer; HRT: hormone replacement therapy. Unit of alcohol: a beverage containing approximately 12 g of alcohol, corresponding to approximately one glass of wine, a can of beer, or a small glass of spirits. Bold font indicates statistical significance. For each item, only women who did not have the knowledge at baseline were included in the analysis.

- women with a university degree do not differ in their probability of increasing knowledge when included in either interventional or control groups (OR 0.75; p = 0.55)
- for the entire sample, single or unmarried status was negatively associated with the probability of increasing their knowledge compared to those with any other civil status (OR 0.56; p = 0.03)
- for the entire sample, participating in spontaneous BC screening was positively associated with the probability of increasing their knowledge compared to participating in organized screening programs (OR 1.61; p = 0.04).

## 4. Discussion

The results of the present study support the use of digital tools to improve the knowledge of alcohol as a modifiable risk factor for BC, the daily alcohol threshold, and how to measure alcohol consumption. In addition, our results suggest that accessing interactive websites is more

**Table 5**
Factors significantly associated with the probability of acquiring knowledge of alcohol as a BC risk factor after accessing the randomized websites: results of the logistic regression.

| | Odds ratio | 95 % Confidence interval | p value |
|---|---|---|---|
| University degree | | | |
| Interactive website *vs* non-interactive website | 0.75 | 0.29–1.93 | 0.55 |
| High school education | | | |
| Interactive website *vs* non-interactive website | 2.56 | 1.27–5.18 | **0.01** |
| Middle school education | | | |
| Interactive website vs non-interactive website | 2.64 | 1.45–4.81 | **0.02** |
| Single or unmarried women *vs* other civil status | 0.56 | 0.33–0.95 | **0.03** |
| Women participating in BC spontaneous screening *vs* organized one | 1.61 | 1.03–2.53 | **0.04** |

Abbreviations: BC: breast cancer. Bold font indicates statistical significance.

effective than accessing non-interactive websites, especially among people with lower levels of education.

Educational programs aiming at increasing the knowledge of modifiable BC risk factors, including alcohol use, should consider alcohol health literacy [29,30]. Health literacy defined as "the motivation, knowledge, and competencies to access, understand, appraise and apply health information to make judgments and take decisions in everyday life" [31] is a key field of activity in health promotion. Accordingly, educational programs aiming at increasing the knowledge of BC risk factors should consider the degree to which people may process and understand information on alcohol use, alcohol-related consequences, contents of alcoholic beverages expressed in AU, and the daily alcohol threshold. From an empowerment perspective, increasing women's alcohol literacy is needed to guarantee their right to make informed choices on alcohol consumption. Women need to understand and learn the impact of alcohol on their health and how to measure alcohol consumption into AU to be able to adhere to alcohol recommendations [29,30].

It is noteworthy that accessing the interactive website obtained better results than the non-interactive website among participants with lower education levels. Education level is a proxy indicator of socioeconomic status and, in general, the lower the education level, the lower the level of health literacy [29–31]. Our interactive website was co-created to be a "literacy friendly" tool, with women presenting for breast screening [32], also suitable for people with low levels of education, with poor reading skills, for whom the acquisition of knowledge by written texts, as in the case of the non-interactive website of the control group, could be more difficult. The free availability of this digital tool could also have important implications in terms of equity of access to simple yet scientifically correct information to make informed choices, contributing to reducing BC burden.

Although it appears there has been a sustained reduction in alcohol consumption in Italy [33], the incidence of new cases of BC has been increased over the same time period [34]. However, the observed reduction does not include unrecorded alcohol consumption (e.g., home-produced alcoholic beverages). Furthermore, in Italy as well as in other Western countries, alcohol consumption has increased in women in recent years instead of reducing [35–37]. Accordingly, among female population, breast malignant tumors' incidence increased between 2008 and 2016 in all age groups [34]. However, this increased incidence could be at least in part due to the introduction of organized screening programmes as well as by the widespread use of opportunistic screening [38,39].

Our study faced the challenges of adapting a tool realized for use in the UK to Italy. The main problem concerned the difference in the contents of alcohol of the AU between Italy and the UK. Although AU represent a useful tool to simplify the evaluation of alcohol consumption, how AUs are defined differs between countries ranging from 8 g in the UK to 19.75 g in Japan [6]. As part of the translation of any questionnaire it needs to ensure good face validity to participants, and so in our study, we modified the images of alcoholic beverages corresponding to the AU to take this difference into account. However, in planning the study, we realized that this problem also concerns some screening tools. As an example, despite the AUDIT being a WHO developed tool, the third question of the AUDIT investigates alcohol consumption equal to or greater than six AU on a single occasion in both the Italian and English versions despite such consumption corresponds to different amounts of alcohol in Italy (72 g) and the UK (48 g). Difficulties due to these differences deserve to be addressed by further studies.

Some limitations of this study should be acknowledged. The lack of a control group without any information would have allowed an appreciation of the efficacy of accessing both the websites in increasing the knowledge of our sample of women. However, engaging women in research in this area and then leaving them with incorrect knowledge about BC risk factors would have been unethical.

Our digital platform also has some limitations. For instance, both accessing the interactive and non-interactive websites only slightly increased knowledge about alcohol contents in AU of the most common alcoholic beverages. For some beverages, we found no differences between the two groups. This negative result may be due, at least in part, to the ambiguity of the images showing the content in AU. Both the image of a wine drink and aperitif may be subject to interpretation and may have confused the 'visual memory' of our participants who visited the interactive website [40]. In the light of these results, we intend to adapt these images during our next iteration of the platform to make them clearer.

Finally, our results show that most women were already aware of the daily alcohol threshold at baseline. This finding appears to differ from the results observed in a younger population [41]. This may be due in part to the different ages of the populations. However, it may also be due to the response option "1 AU" representing both the right reply and the lowest threshold. Accordingly, women can have chosen it from a "precautionary principle" perspective.

Our study did not evaluate the persistence of the acquired knowledge in the middle and long-term. The results demonstrate the efficacy of our interactive website in transferring comprehensible information to a sample of women, including low education participants. Future studies will be conducted to evaluate the persistence of this acquired knowledge, and its impact on behaviour.

Finally, accessing the interactive website did not increase the knowledge of certain BC risk factors (i.e., contraceptive pill, age, being female) and did not differ in the efficacy compared to control group in others (i.e., diet, contraceptive pill, being female, family history of BC). This is because the website was developed to examine the change in knowledge in alcohol within the context of understanding risk factors for BC. As a research tool this in part mitigates that information on risk factors was given to both groups. The design of the website enables similar testing of the other risk factors (e.g., weight and diet) in a similar fashion. This is a strength of the method that it takes as modular approach. In future studies, other modules of our interactive website devoted to other modifiable BC risk factors like contraceptive pills and diets will be developed and tested.

## 5. Conclusions

Digital tools are promising instruments to increase people's awareness of healthy behaviors; however, their efficacy needs to be evidence-based and verified [1]. To the best of our knowledge, our study is the first RCT conducted to specifically evaluate the efficacy of an interactive website specifically designed to increase the knowledge of alcohol as a BC risk factor. Our results show evidence of the effectiveness of accessing this tool in increasing women's awareness and that the

interactive website is being more effective compared to the non-interactive one, especially among women with lower education levels.

## CRediT authorship contribution statement

**Claudia Sardu:** Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Fabrizio Angius:** Writing – review & editing, Formal analysis, Data curation. **Paolo Contu:** Writing – review & editing, Formal analysis, Data curation. **Sofia Cosentino:** Writing – review & editing, Formal analysis, Data curation. **Monica Deiana:** Writing – review & editing, Formal analysis, Data curation. **Matteo Fraschini:** Writing – review & editing, Validation, Supervision, Software, Methodology, Formal analysis, Data curation. **Clelia Madeddu:** Writing – review & editing, Visualization, Investigation, Data curation. **Elena Massa:** Writing – review & editing, Visualization, Investigation, Data curation. **Alessandra Mereu:** Writing – review & editing, Formal analysis, Data curation. **Luigi Minerba:** Writing – review & editing, Formal analysis, Data curation. **Carola Politi:** Writing – review & editing, Visualization, Investigation, Data curation. **Silvia Puxeddu:** Writing – review & editing, Formal analysis, Data curation. **Francesco Salis:** Writing – review & editing, Formal analysis, Data curation. **Julia M.A. Sinclair:** Writing – review & editing, Validation, Supervision, Software, Methodology, Conceptualization. **Roberta Agabio:** Writing – review & editing, Writing – original draft, Supervision, Software, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

## Data sharing statement

Data are available from the authors upon reasonable request.

## Ethical approval and consent to participate

The study was approved by the Ethic Committee of the University Hospital of Cagliari, Italy (Prot. 2022/33; December 14, 2022; see Appendix A, Supplementary data). The study was conducted in full accordance with the guidelines for randomized clinical trials and ethical principles of the Declaration of Helsinki and Good Clinical Practice, including rules concerning the protection of personal data. All participants provided written informed consent.

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## Declaration of competing interest

The authors declare no conflicts of interest.

## Appendix B. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.breast.2024.103868.

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