RESEARCH ARTICLE

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The Impact of Nurse-Led Intervention on Breast Cancer Screening and Early Detection in China: Randomized Control Trial

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Abstract

Objective: To evaluate whether nurse-led intervention with the assistance of community health workers (CHWs) increases breast cancer awareness and uptake of breast cancer screening among Chinese women. **Background:** Breast cancer is the leading cause of cancer death among women, with breast cancer incidences being on the rise in China. Early detection through cancer screening and awareness of cancer prevention is imperative. **Methods:** The study recruited women from 16 communities (n=2050) who met the inclusion criteria and randomly assigned them to the intervention group (n=1,143) and control group (n=907). A Komen breast health toolkit was utilized for educational purposes, and the modified Chinese Mammogram Screening Beliefs Questionnaire was employed to assess knowledge and awareness regarding breast cancer and screening practice. **Results:** Results showed that implementing nurse-led CHW involved educational interventions for breast cancer improves breast cancer screening behavior (t=545, 761, $p < .001$) and awareness (4.92±3.59, 8.64±1.90, $p < .001$) in the intervention group when compared to the control group. **Conclusion:** This study provides information for future research and development of an educational intervention for breast cancer screening among Chinese women.

Keywords: Breast cancer- cancer screening- health education- underserved- intervention effects

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Introduction

According to the International Agency for Research on Cancer [IARC], breast cancer is not only the most diagnosed cancer worldwide but also the leading cause of cancer deaths among women [1, 2]. While the incidence in China is relatively lower than those in Western countries [1], the trend of breast cancer incidence and mortality is still climbing drastically, with approximately 187,213 new cases and 47,984 deaths in 2012 to 416,371 new cases and 117,174 deaths in 2020 [3, 4]. Notably, the trend of increased incidence is higher when compared to European countries or the United States (U.S.) [5, 6]. The age distribution also showed a different pattern, whereas the mean age at diagnosis of breast cancer is 49–55 in China, which is younger than that in most Western countries [7, 8]. In contrast, a lower percentage of patients aged 60 and older with breast cancer in China (31.30%) was found compared to the U.S. (56%) [8].

Several evidence-based studies showed that breast cancer screening can improve the early diagnosis rate and reduce the mortality rate [9, 10]. Breast cancer mortality has been continuously declining in the past two decades in the U.S. by implementing population-based cancer screening [11]. The 5-year survival rate for breast cancer drops to 20% when diagnosed in later stages compared with almost 100% in early stages, highlighting the importance of early detection [12]. The World Health Organization's (WHO) Global Breast Cancer Initiative sets the target of increasing the proportion of women diagnosed with stage I and II to at least 60% for sustained breast cancer mortality reductions [13]. Unfortunately, many Chinese women from areas with low socioeconomic status were diagnosed with stage III and stage IV [14]. A recent study revealed that most breast cancers in China were diagnosed when women presented their self-discovered symptoms to healthcare providers instead of through screening, which further delays timely diagnosis and treatment, ultimately hampering long-term survival [15]. Furthermore, following the breast cancer diagnosis, patients experienced mental distress, anxiety,

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and depression, which can negatively affect treatment adherence, social functioning, and overall quality of life [16, 17]. Based on a systematic review, the results showed positive mental health effects of screening along with the potential for increasing positive patient behaviors for patients without known risk factors [18].

Participation in breast cancer screening is less than optimal in low- and middle-income countries [19]. As a new round of medical reform in 2009, the Chinese government introduced breast cancer screening efforts as part of Two-Cancer (breast and cervical cancer) Screening Program among rural women and the Cancer Screening Program in urban regions. Nevertheless, these initiatives were accessible only to a small number of women, leaving a substantial number of women in China who still did not have access to breast cancer screening [20]. Lack of nationwide population-based breast cancer screening programs can lead to a lower screening rate among Chinese women [21]. While the benefits of breast cancer screening have been promoted by the Chinese Center for Disease Control and Prevention (CDC), Chinese women have low awareness of breast cancer screening [22-24]. A population-based cohort study that consisted of 63,219 Chinese female participants revealed a breast cancer awareness rate of 10.2%, with even lower rates among never-screened and inadequately screened women [25]. The study also showed factors associated with low awareness were low income and education level, those who have agricultural occupations, smokers, and lack of professional recommendations.

China's breast cancer screening guideline includes that breast cancer screening should start at 45 years for women at average risk but at 40 years for women at high risk [26]. Previous studies have shown that trained healthcare professionals can improve early breast cancer diagnosis by increasing breast cancer awareness and practice for patients and healthcare professionals [27-29]. Implementing interventions using community health workers to deliver cancer-related information and screening to community members has shown effectiveness for the hard-to-reach population or individuals who live in rural areas [30, 31]. Nevertheless, no studies in China have utilized community health workers (CHWs) to implement breast cancer health screening interventions and explore the long-term effects of these interventions [32-34]. There is a critical need to develop and implement effective interventions to improve breast cancer screening rates in this country.

The study utilizes the tenets of the Health Belief Model (HBM) to analyze the impact of nurse-led educational intervention. The study intervention applies an educational model that considers major HBM factors in improving breast cancer knowledge, guidelines, and overall screening practices among Chinese women in mainland China. Applying the HBM constructs, the intervention focused on participants' health beliefs regarding the threat of breast cancer (perceived susceptibility of developing breast cancer, perceived severity of breast cancer diagnosis, and perceived impact on quality of life). Building on these, the intervention sought to increase awareness on the perceived benefits of screening practices, early diagnosis, and improved health outcomes while also reducing perceived screening barriers. Ultimately the intervention aims to strengthen women's self-efficacy for acting towards breast cancer screening.

This study examined how community-level nurses-led intervention with CHWs influenced Chinese women's knowledge about breast cancer and cancer screening uptake. Intervention strategies were designed to improve breast cancer knowledge, breast cancer screening awareness, and screening behaviors among Chinese women. The study extends the existing literature by establishing an evidence base for the efficacy of a nurse-led breast cancer screening intervention.

Materials and Methods

Study design and setting

The study was designed as a two-arm randomized trial with pretest (baseline) and post-test during follow-ups to determine the effects of nurse-led educational intervention with CHW on breast cancer screening behavior and breast cancer awareness. This study was conducted in Sichuan province, a developed and industrialized region of western China and from Aug. 2020-May. 2022. The study protocol was reviewed and approved by the Eastern Michigan University Institutional Review Board of the first author, registered under UHSRC-FY18-19-64.

Participants

The study recruited participants from 16 different communities in several cities and districts of the Sichuan Province, China. The inclusion criteria were set as follows: 1. Women aged 40-69 years, 2. Reside in Sichuan Province for ≥ 1 year, 3. Have no history of breast cancer. The exclusion criteria were set as follows: 1. Professionals working in the breast cancer medical services field, and 2. Individuals who have already participated in an established standardized breast cancer screening program. Participants who met the inclusion criteria and completed the baseline assessment with demographic information were randomly assigned using employing a computer program containing a random number generator and assigned participants to the intervention or control group. The intervention group received a nurse-led education with assistance of CHWs while the control group received heart health information. We followed the Consolidated Standards of Reporting Trials (CONSORT 2010); flow diagram of enrollment, allocation, intervention, and follow-up is shown in Figure 1.

Study Intervention

The nurse-led multicomponent intervention was designed and implemented by researchers and nurses in collaboration with community-level partners. The community involvement was achieved through two primary means. First, involving CHWs who were trained volunteers at the Street-alley-office (Jie-Dao-Ban) or known as community unit office; their roles included advising the project team on participant recruitment, intervention materials, and procedures for data collection. Their input assisted the study team in tailoring the study

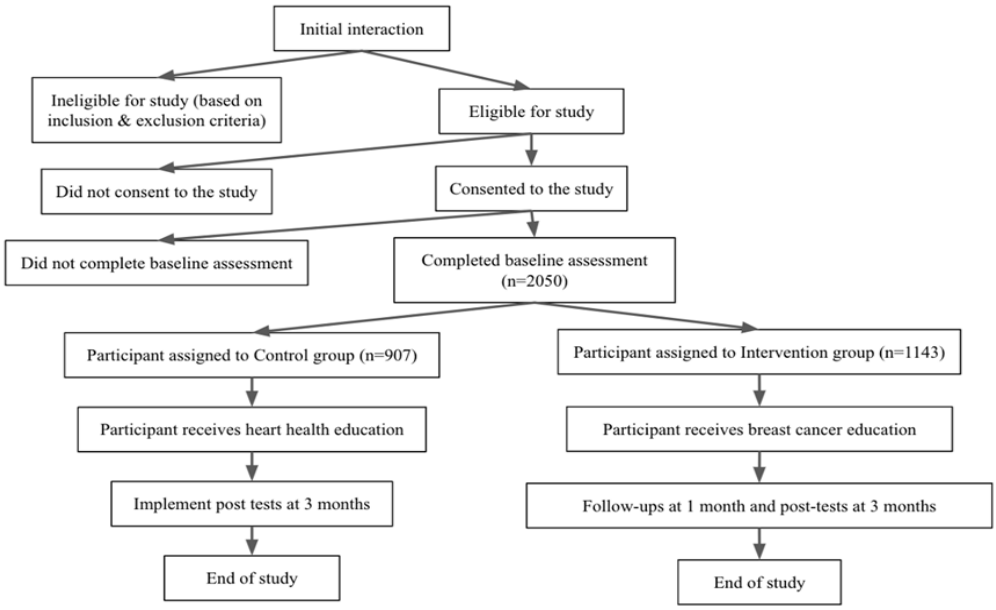

Figure 1. The Flow Chart of the Research

intervention to the needs and interests of each site and assisting with planning and promoting intervention activities. The study team met with CHWs on a monthly or bi-monthly basis to assess study site needs, plan program events, and provide feedback regarding participants' feedback with study intervention. This process fostered a sense of program "ownership" and provided skills and educational materials for stakeholders for sustaining the program beyond the period of external funding.

Breast health education was adapted from the Komen educational toolkit and consisted of content regarding risk factors for breast cancer, breast cancer screening options and associated benefits, breast self-awareness messages, and healthy lifestyle recommendations for reducing breast cancer risks [35]. Nurses and CHWs utilized materials from the toolkit that included recorded videos, brochures, and PowerPoint presentation slides to conduct breast health education for participants in the intervention group.

Study Measurement

The measurement tools employed in this study was the validated Chinese Mammogram Screening Beliefs Questionnaire (CMSBQ) [36]. The modified CMSBQ comprised demographic information, health history/ family history of breast cancer and other diseases, screening behaviors, knowledge and awareness about breast cancer, and screening methods questions. For primary outcome indicators (screening), it was measured by screening modalities, 1) clinical breast examination (CBE), 2) ultrasound, or 3) mammography. Secondary outcome indicator was the composite score of breast health knowledge, including risk factors (six items, scoring range 0-6), symptoms (5 items, scoring range 0-5), and screening guidelines (one item, scoring range 0-1); total score ranges from 0-12; the higher the score, the greater the breast cancer knowledge is.

Ethical Considerations

Ethical approval was obtained from the Eastern Michigan University Institutional Review Board of the first author. The study team staff explained the aim and scope of the current research to each patient. Study participants were also informed that their participation was voluntary, and they had the right to withdraw from the study whenever they wanted to without any harm. Anonymity and confidentiality were maintained. Informed consent was obtained from the patients who agreed to participate, and participants were informed that results will be presented in an aggregate format.

Study Procedure and Data Collection

The participant list with individuals who met eligibility was generated and the study team used a computer program containing a random number generator to randomly assign the participants to either of these groups. Upon the enrollment was completed, participants in both groups completed the study instrument and informed consent in paper format at the first encounter. Post-test data were collected virtually for participants' convenience through a telephone call or an app, WeChat, commonly used in China.

The study intervention was delivered by trained nurses at different sites, including community/general hospitals, clinical, and/or community centers. Trained nurses engaged with the participants and conducted breast cancer risk assessment, reviewed the results of the assessment with the participants, and provided them with education and the appropriate breast cancer screening referrals. The one-on-one intervention was done using educational materials developed by the study team. The intervention group was followed up for 1 month to evaluate and reinforce their knowledge on breast cancer and screening guidelines. At 3-months, post-tests were performed to collect data on screening behavior and screening results.

Participants in the control group were educated with

health-promoting content using the Chinese Guideline on Healthy Lifestyle to Prevent Cardiometabolic Diseases, which included weight management, a healthy diet, exercise methods, and the importance of monitoring blood pressure and glucose as well as other physiological indicators [37]. The control group also was followed up at 3 months from the baseline education for breast cancer awareness and screening behaviors using the same study measures as the intervention group.

Statistical Analysis

The research was performed using SPSS 26.0 software. Data were expressed as percentages, and the X2 represents the distribution of two groups. In the Mean ± SD normal distribution, the t-test was used in independent groups to compare knowledge and awareness. Screening rate = The number of people who had received at least one breast examination, breast ultrasound, or mammogram/number of participants × 100%. Differences were considered statistically significant at $p < 0.05$.

Results

Participant Demographics at Baseline

A total of 2,050 study participants were included, 1,143 in the intervention group and 907 in the control group, with an age range of 40 to 69 (52.41 ± 7.15) years, 78.7% were from rural areas, 91.5% were married women, 69.5% had junior high school education or less, 84.5% had a mid-month household income less than 10,000 yuan (US $1,427), 65.4% had health insurance, 11.2% had insurance covering insurance to cover the cost of breast cancer screening, and 42.1% reported having regular medical checkups (Table 1).

Breast Screening Behavior Practices and Screening Awareness

At the baseline, there was no statistically significant difference in screening behaviors (except mammography) and screening awareness between the intervention group and the control group ($p = 0.748$, $p = 0.898$). There was an increase in clinical breast exams (CBE) and ultrasound in the intervention group from baseline to post-intervention (CBE: 716/1143, 62.6% post-test, 367/1143, 32.1% baseline; Ultrasound: 552/1143, 48.3% post-test, 465/1143, 40.6%). On the contrary, both CBE and ultrasound decreased from baseline to post-tests for participants in the control group. The finding was statistically significant when compared with the control group ($p < 0.001$), see Table 2.1.

At baseline, total Breast Cancer Screening Practices didn't significantly differ between the intervention and control groups. After the intervention, there were statistical differences ($p < .001$) in total screening practices between the intervention and control groups. Compared to the control group, the intervention group showed significant improvement in breast cancer screening practices over time after controlling demographics, age, marital status, birthplace, income, and education (Table 2.2; Figure 2).

There was no difference in baseline between two groups for breast cancer knowledge. During post-intervention, there were statistical differences ($p < .001$) in breast cancer knowledge, particularly in all three areas: risk factors knowledge, symptoms knowledge, and screening guidelines knowledge. Compared to the control group, the intervention group showed significant changes in breast cancer knowledge in all three areas over time (Table 3). After adjusting for Age, Birthplace, Marriage, Income, and Education, the intervention group shows significant improvements compared to the control group (Figure 2.1; Figure 2.2; Figure 2.3).

Discussion

As the Coronavirus pandemic raged in 2020, the number of people getting screened for cancer globally dropped dramatically due to various reasons, facility closures, staffing shortage, patients being afraid to go into hospitals/clinical settings, etc. Professional and healthcare groups formed collaborative efforts to close

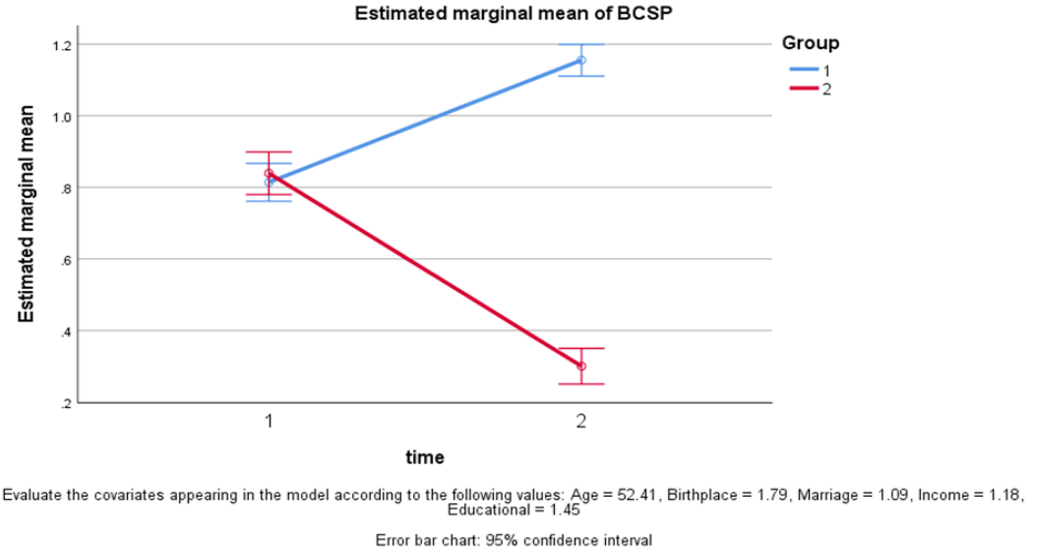

Figure 2. Breast Cancer Screening Practice: Intervention vs. Control Group Over Time

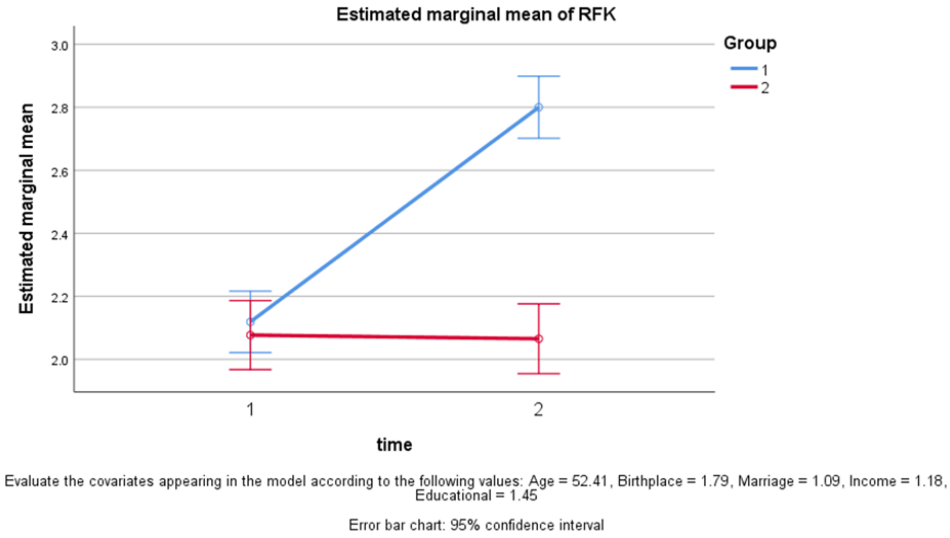

Figure 2.1. Breast Cancer Risk Factor Knowledge: Intervention vs. Control Group Over Time

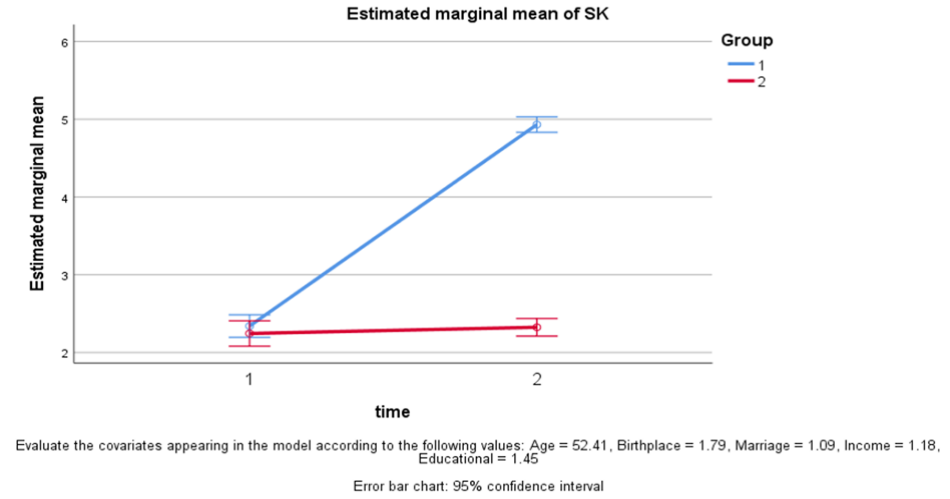

Figure 2.2. Breast Cancer Symptoms Knowledge: Intervention vs. Control Group Over Time

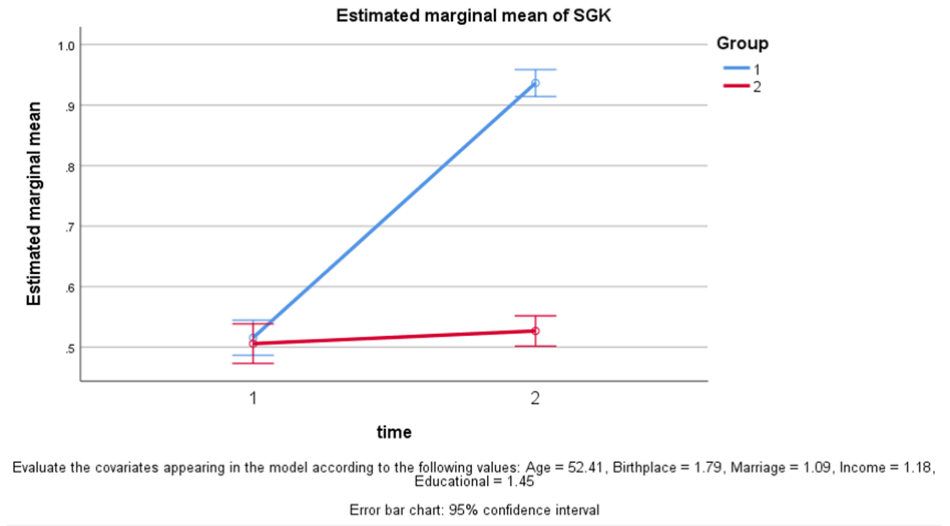

Figure 2.3 Breast Cancer Screening Guideline Knowledge: Intervention vs. Control Group Over Time

Table 1. Demographic Characteristics of the Study Population

Features	Total (n=2050)		Intervention group (n=1143)		Control group (n=907)		χ2	p
	n	%	n	%	n	%		
Age								
40-49	790	38.5	377	33	413	45.5	46.02	< 0.001
50-59	944	46	547	47.9	397	43.8		
60-69	316	14.4	219	19.1	97	10.7		
Birthplace							20.15	< 0.001
Urban	437	21.3	285	24.9	152	16.8		
Rural	1613	78.7	858	75.1	755	83.2		
Marriage							4	0.045
Married	1875	91.5	1058	92.6	817	90.1		
Other	175	8.5	85	7.4	90	9.9		
Education							4.8	0.091
Middle school and below	1425	69.5	809	70.8	616	67.9		
High school	321	15.7	182	15.9	139	15.3		
College/bachelor and above	304	14.8	152	13.3	152	16.8		
Total monthly household income							13.49	0.001
<10,000	1732	84.5	988	86.4	744	82		
10-30,000	263	12.8	120	10.5	143	15.8		
≥30,000	55	2.7	35	3.1	20	2.2		
Insurance covers screening							0.659	0.417
Yes	230	11.2	134	11.7	96	10.6		
No	1820	88.8	1009	88.3	811	89.4		
Breast cancer in first-degree relatives							0.15	0.704
Yes	25	1.2	13	1.1	12	1.3		
No	2025	98.8	1130	98.9	895	98.7		
Breast biopsy or surgery							0.23	0.63
Yes	57	2.8	30	2.6	27	3		
No	1993	97.2	1113	97.4	880	97		
Breast cancer screening done							0.1	0.748
Yes	971	47.4	545	47.7	426	47		
No	1079	52.6	598	52.3	481	53		

Abbreviation: χ2, Chi-square test

the COVID-induced screening gap. The current study documented a community-based nurse-led educational intervention with CHWs for improving breast cancer awareness and breast cancer screening in China.

While health education and screening for cancer prevention and increasing awareness of breast cancer are recommended to have breast cancer screening from the age of 40 [38, 39], the status of breast cancer screening

Table 2.1. Breast Cancer Screening Practices before and after the Intervention in Study Groups

Time	Group	n	Clinical breast examn (%)	Ultrasoundn (%)	Mammographyn (%)	Received at least one screening n (%)
Pre-intervention	Intervention	1143	367 (32.1)	465 (40.7)	76 (6.6)	545 (47.7)
	Control	907	324 (35.7)	343 (37.8)	117 (12.9)	426 (47.0)
	χ^2 Value		2.955	1.739	23.167	0.103
	p		0.086	0.187	< .001	0.748
Post-intervention	Intervention	1143	716 (62.6)	552 (48.3)	13 (1.1)	761 (66.6)
	Control	907	138 (15.2)	163 (18.0)	12 (1.3)	212 (23.4)
	χ^2 Value		468.029	204.717	0.145	378.578
	p		< 0.001	< 0.001	0.704	<0.001

Frequency (%) χ2, Chi-square test

Table 2.2. Breast Cancer Screening Scores before vs. after Intervention in Study Groups

Time	Breast Cancer Screening Practices			
	Intervention	Control	F	p
Pre-intervention	0.79± 0.94	0.86± 1.05	0.38	0.54
Post-intervention	1.12 ± 0.89	0.35 ± 0.68	619.74	< 0.001
F	99.92	197.17		
p	< 0.001	< 0.001		
Overall test				
Between-group (F, p)	227.38, <0.001			
time (F, p)	31.25, <0.001			
Interaction (F, p)	288.76, <0.001			

Note: Screening scores were based on women's uptake of clinical breast exam, ultrasound and/or mammogram.

Table 3. Breast Cancer Knowledge before and after the Intervention in Study Groups

Time	Risk Factors Knowledge				Symptoms Knowledge				Screening Guidelines Knowledge			
	Intervention	Control	F	p	Intervention	Control	F	p	Intervention	Control	F	p
Pre-I	2.10 ± 1.58	2.10 ± 1.78	0.31	0.58	2.31 ± 2.49	2.28 ± 2.49	0.73	0.39	0.51 ± 0.50	0.51 ± 0.50	0.19	0.66
Post-I	2.78 ± 1.63	2.09± 1.77	92.86	<0.001	4.93 ± 0.569	2.32± 2.50	1137.81	<.001	0.93 ± 0.251	0.53 ± 0.499	565.43	<0.001
F	450.95	0.102			1338.22	1.01			1405.03	2.75		
p	<0.001	0.749			< 0.001	0.316			< 0.001	0.098		
OT												
BG (F, p)	29.26, <.001				286.12, <0.001				133.78, <.001			
Time (F, p)	11.20, 0.001				2.49, 0.115				2.93, 0.087			
Interaction (F, p)	202.44, <.001				545.63, <0.001				550.75, <.001			

Pre-I, Pre-Intervention; Post-I, Post Intervention; OT, Overall Test; BG, Between Group.

and awareness in China is less than optimal [40, 41]. Early detection remains as the cornerstone of breast cancer control [42]. Implementing community-level interventions that include trained CHWs to deliver information to community members was shown to engage the hard-to-reach population [31, 31] and increase breast cancer awareness and knowledge as well as screening rates within the target population [43, 44]. Nonetheless, public health in China is currently focused more on chronic diseases such as cardiovascular diseases and diabetes mellitus and lacks concerted efforts in the community, health systems, and the public to promote cancer screening and prevention [45]. Given the potential benefits of such community-based interventions and the success seen elsewhere [42], there is an opportunity to incorporate breast cancer screening and prevention programs utilizing CHWs in community settings in China. Particularly, utilizing CHWs' connections with marginalized and underserved populations has the potential to reach many Chinese women with limited resources and healthcare providers.

Our nurse-led educational intervention with CHWs collaborated with community unit offices for recruitment and achieved a positive effect. The study intervention successfully improved breast cancer screening behaviors, overall knowledge about symptoms, and awareness regarding risk factors of breast cancer. Healthcare providers such as nurses can benefit from CHWs' connections that bridge health programs with local communities and increase the efficiency of the intervention. In addition, implementing the CHW model produced improvements in more than 16 communities of Sichuan Province, China, highlighting the community-led initiative can improve breast cancer screening with limited funding mechanisms and healthcare providers. The model strengthened the community and clinical linkage for follow-up and referrals [46] and provided important insights for replicating future CHW-based breast cancer screening programs.

Like Jiang et al. and Wang et al.'s study, the current study showed increased breast cancer knowledge and awareness with the nurse-led intervention in improving breast cancer screening behaviors which in turn, can lead to early detection and improving treatment outcomes [33, 47, 48]. Specifically in the current study, CBEs rose significantly from 32.1% to 62.6% after the intervention, and nearly 50% of the participants underwent ultrasound

examinations. Nevertheless, the current study did not show an increased mammography uptake, in part due to China's guidelines using CBE and ultrasound as screening modalities [39]. The incidence and mortality rate of breast cancer in China are 36.1 per 100,000 and 8.8 per 100,000, respectively, which is lower than other Western countries [49]. Nevertheless, the overall awareness of breast cancer and screening guidelines is inadequate due to patient awareness, economic, and environmental influences [50, 23]. The demographics of study participants were with low income (84.5%), low awareness and health literacy (69.5%), and born in rural areas (78.7%), which were considered as vulnerable populations that could further benefit from breast cancer screening. The statistics showed Chinese women in age the 40-49 group has the highest breast cancer screening rate with a prevalence of 36% [51] and control group has slightly more participants (45%) vs. intervention group (35%) in this age group. Previous studies showed women residing in urban areas are more likely to undergo screening compared to rural women (24.5% and 20.6%, respectively) [51, 52]. Both intervention and control groups consisted of majority of participants born in rural areas improved screening practices. After adjusting income, education level and birthplace, study results still showed the nurse-led intervention with CHWs improved breast cancer screening behaviors and awareness in vulnerable communities. With low literacy and financial constraints, the China CDC initiated breast cancer screening for rural women in 2009 and later in 2022 [53], the National Health Commission expanded the screening program to include both women residing in rural areas and those with low-income [41]. Despite the implementation of these two programs, China still lacks a population-based screening model and has not implemented systematic strategies to reach marginalized populations. Built upon lessons learned from current study, a similar community-based intervention whereas healthcare professionals (nurses, doctors, etc.) collaborate with CHWs can potentially reach more vulnerable communities in China. To our knowledge, this is the first study that deploys nurses in community settings as educators and CHWs to address the issue of care accessibility within China, providing insights about how healthcare providers work with vulnerable communities in cancer control. Recognizing the vital role that nurses can play in increasing cancer awareness and screening behaviors, the study findings have implications for researchers and policymakers in developing health policies and community-level screening programs to improve breast cancer outcomes through increasing breast cancer screening and early detection in China.

Limitations

This study has the following limitations: Due to the nature of the cross-sectional study and study participants represented from Sichuan province, generalizations cannot be made to women in other regions of China. Due to the limitations of the COVID-19 pandemic, we were not able to use a randomized sample; instead, we selected sites that agreed to participate in the study. Future studies are warranted to use more rigorous randomized trials to conduct implementation research. Furthermore, the nature of self-report of the outcome variable has potential bias to influence study results.

In conclusion, breast cancer incidence has been rising in the last two decades in China and remains the leading cause of cancer death in women. Early detection through cancer screening and awareness of cancer prevention is imperative. This paper reported the first comprehensive nurse-led intervention with the CHW model that improved women's knowledge and screening practices related to breast cancer in China. Future studies to replicate nurse-led interventions in other geographic regions and low-resource settings among marginalized communities are warranted to mitigate the burden of breast cancer among Chinese women.

Author Contribution Statement

Tsu-Yin Wu: Conceptualization, Methodology, Supervision, Writing-Original draft, Funding acquisition; Guorong Wang: Data curation, Project Administration, Supervision; Shou-Li Chen: Data Curation, Formal analysis; Tian Zhang: Data Curation, Reviewing and Editing; Hui Chen: Software Visualization Writing-Reviewing and Editing; Sania Srivastava: Data curation, Writing- Reviewing and Editing; Szu-Hsien Chen: Data curation, Writing- Reviewing and Editing.

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Ethical Consideration

Ethical approval was obtained from the Institutional Review Board at Eastern Michigan University (UHSRC-FY18-19-64). The research team staff explained the purpose and scope of the study to each participant. Participants were also informed that their involvement was voluntary and that they had the right to withdraw from the study at any time without any consequences. Anonymity and confidentiality were upheld. Informed consent was obtained from all participants.

Availability of Data

The data supporting the findings of this study are available upon request from the corresponding author, TW. The data are not publicly available due to protection of privacy and confidentiality of research participants.

Declaration of Competing Interest

All authors declare that they have no conflicts of interest in this paper.

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