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Effect of a community-based multicomponent intervention on cervical cancer behavior among women – A randomized controlled trial

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Abstract:

BACKGROUND: Cervical cancer is the leading cause of death worldwide, especially in developing countries. More than one-fifth of newly diagnosed cervical cancer cases are occurring in India. Cervical cancer is a highly preventable and curable cancer compared with other types of cancer, if detected at an early stage. The present study has been carried out to assess whether a community-based, multicomponent, nurse-led intervention program improves cervical cancer screening behavior of women.

MATERIALS AND METHODS: An experimental randomized controlled trial was carried out by recruiting 419 women in the age group of 30–60 years (246 in the experimental group and 173 in the control group) residing in a selected rural community (selected tribal settlements) of Idukki district of Kerala, India, using multistage cluster sampling. The intervention comprising small group education followed by reinforcement session, telephonic reminders, navigation and guidance for Pap smear, and follow-up visit by the investigator was administered to the experimental group, and the control group did not receive any intervention. Knowledge, attitude, and screening behavior of women related to prevention of cervical cancer were assessed before and twice after the intervention.

RESULTS: The experimental and control groups were homogenous in all baseline sociodemographic variables. The community-based intervention program was effective in improving knowledge (P<0.001), attitude (P<0.001), and screening behavior (P<0.001) of women regarding the prevention of cervical cancer. A significant moderate positive correlation was found between knowledge and screening behavior (r = 0.408). Significant association was found between knowledge, attitude, and practice regarding prevention of cervical cancer with education, age at the time of marriage, and number of pregnancies.

CONCLUSION: The community-based, multicomponent, nurse-led intervention program was effective in improving cervical cancer screening behavior among women. Repeated motivation and reinforcement are needed to bring behavioral change and to increase uptake of screening services among rural women.

Keywords:

Attitude, cancer screening, cervical cancer, intervention, knowledge, rural, women

Introduction

Cervical cancer is the second most common cancer among women worldwide. The International Agency for Research on Cancer (IARC) highlights that priority should be given to breast and cervical cancer prevention among women internationally. Almost 266,000 deaths are occurring worldwide every year due to this preventable disease. Cervical cancer is a significant health problem for Indian women and is the second largest cause of

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cancer death after breast cancer. More than 80% of the global burden of the disease is occurring in developing and underdeveloped countries, where it is the most common cancer among women. This discrepancy is due to lack of effective control measures in these countries. ^[1,2]

Despite being a preventable cancer, so many deaths are happening because of cervical cancer, especially in the developing countries. Both primary and secondary preventive strategies are highly effective in preventing cervical cancer. Secondary prevention of cervical cancer includes early diagnosis and treatment by using various screening strategies. Screening and early detection are very effective in preventing cervical cancer among women. Early diagnosis and treatment of precancerous lesions are associated with better cure rate and prognosis, whereas failure to detect precancerous lesions increases premature death, morbidity, and mortality associated with the disease. [4]

High-income countries have achieved impressive screening coverage and reduction in cervical cancer incidence and mortality by effectively incorporating Pap smear-based screening services to medical and health services. [5] But low- and middle-income countries do not have adequate manpower, material resources, and strong infrastructure for implementing nationwide screening program. Cervical cancer is one of the most preventable cancers by conducting regular screening programs and engaging in healthy lifestyle practices. A hospital-based pilot study conducted in India among 812 women attending obstetrics and gynecology OPD reported insufficient public health education, sociocultural customs and beliefs, lack of patient-friendly screening services, and personal factors like economic issues and lack of support from husbands and family as the major factors increasing nonattendance in screening services. The study also revealed that there were no dynamic awareness programs against cervical cancer like the efficient campaigns conducted against human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS), malaria, and tuberculosis. [6] It is important to develop culturally sensitive interventions to motivate women to participate in cervical cancer screening and to reduce cervical cancerrelated health disparities. [7] These sociocultural barriers can be dealt with by planning and implementing screening programs effectively.

On the whole, the most important tool to fight against cervical cancer is prevention. Without proper awareness and access to screening services, women from poor communities usually seek care only in the advanced stage of the disease and during this stage, cure is not possible. Vallikad reported that cervical cancer burden is higher among women from low socioeconomic status and rural women in India. [8] Lack of awareness

and inaccessibility to adequate screening services are reported as the main reason for the huge burden of the disease among rural Indian women. [9] Many studies have reported that women's knowledge about cervical cancer is very low in spite of its high prevalence. [10,11] Insufficient knowledge and awareness regarding cervical cancer can become a barrier to cervical cancer screening. [12] Moreover, a systematic review carried out to identify challenges to health promotion and education strategies to prevent cervical cancer in India highlighted the role of public health authorities to initiate appropriate actions to educate and motivate general population toward cervical cancer prevention and to improve cervical cancer screening facilities. [13] So, the present study was undertaken to assess the effect of a community-based intervention program in improving cervical cancer screening behavior among women.

Materials and Methods

Study design and sampling technique

An experimental randomized controlled trial (pretest-posttest longitudinal design) was carried out in six tribal settlements of a selected rural community of Idukki district of Kerala, India, from June 1, 2015 to December 31, 2016. Sample size for the final study was estimated based on the findings of the pilot study by power analysis at 80% of statistical power and Type I error (alpha) of 0.05. Minimum sample size estimated in each group was 171. Adult women in the age group of 30–60 years of age, who could understand Malayalam and were willing to participate in the study were selected as subjects. Those who were chronically ill or bedridden and had already been diagnosed with cervical cancer were excluded from the study.

Four hundred and thirty women who met the study inclusion and exclusion criteria were recruited from six tribal settlements of selected rural community of Idukki district, Kerala, using multistage cluster sampling. From Idukki district of Kerala, one block panchayat was selected through purposive sampling. From the selected block panchayat, one panchayat was selected randomly. Six tribal settlements from the available 22 tribal settlements in the selected panchayat were selected randomly. These six selected tribal settlements were randomly allocated to the experimental and control groups (three in experimental group and three in control group). All the women who met the inclusion and exclusion criteria from the selected tribal settlements were allocated to the experimental and control groups. From three tribal settlements, 251 subjects and from the other three tribal settlements, 179 subjects were allotted to the experimental and control groups, respectively. Schematic representation of the selection of sample and setting is given in Figure 1.

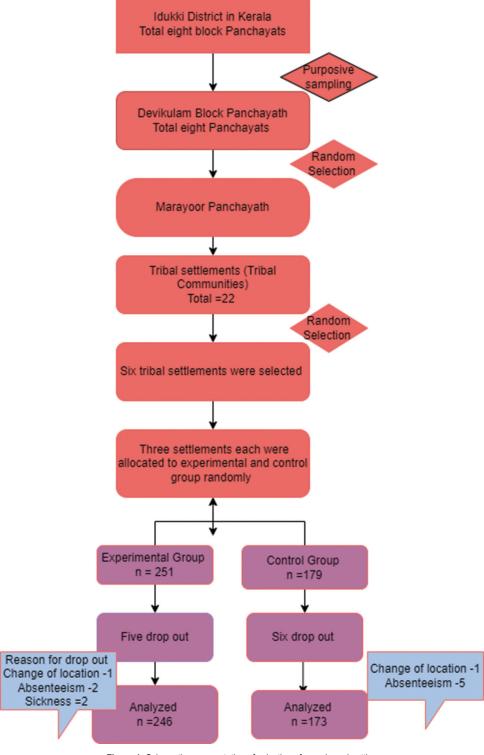


Figure 1: Schematic representation of selection of sample and setting

Data collection tools and techniques

Data was collected using a self-reported questionnaire to assess the sociodemographic data, knowledge, and screening behavior of women, and a 5-point Likert scale was used to assess the attitude of women on prevention of cervical cancer, which was prepared by

researcher based on the objectives of the study and an extensive review of literature. Appropriate validity and reliability were established before data collection. Content validity was obtained from a panel of experts, and content validity index was calculated and found to be appropriate. Cronbach's alpha was calculated for all

data collection tools to establish internal consistency. Cronbach's alpha values for the questionnaire to assess knowledge (α = 0.92) and screening behavior (α = 0.96) and for the Likert scale to assess the attitude (α = 0.89) of women on prevention of cervical cancer were found to be appropriate.

Intervention

An intervention program regarding prevention of cervical cancer was developed based on literature review, expert guidance, and set objectives. The current community-based multicomponent intervention program utilized all the approaches recommended by the World Health Organization (WHO) for health promotion intervention, namely, issue based, population based, and setting based. Community-based intervention program included a 2-h small group (one group comprising 30-40 women) teaching session on cervical cancer and preventive strategies, which was followed by reinforcement sessions of 30 min duration at the first and third month. Reinforcement session was administered to participants in the experimental group in small group session (one group comprising 30–40 women). Other components of intervention included telephonic reminders about screening, navigation and guidance for Pap smear screening, follow-up visit by the investigator once after the first follow-up, and arrangement of screening camp in the nearby area to improve the screening rates. After the baseline assessment and the first training session, every month, a screening camp was arranged in the nearby health center and monthly telephonic reminders were sent to the study subjects till the fifth month. Subjects of the experimental group received intervention and the control group did not receive any intervention. Post-interventional assessment was done at 1 and 6 months after the baseline assessment by the researcher by contacting the subjects. The total data collection period was 6 months.

Data analysis

Collected data was analyzed using Statistical Package for the Social Sciences (SPSS) version 21, and significance was set at 0.05 level. Data analysis was done based on the normality of data, and appropriate descriptive and inferential statistics was used. Various sociodemographic variables were presented in frequency and percentage, and for checking the homogeneity of the group for baseline characteristics, Chi-square test was used. Comparison of mean knowledge, attitude, and practice score between experimental and control groups was done by using independent *t*-test (unpaired *t*-test).

Ethical considerations

Ethical clearance for conducting the study was obtained from the Institutional Ethics Committee (3716010 dated 10/17/2013). Permission for conducting the study was taken from concerned state and district authorities. Written informed consent was taken from

each subject prior to data collection. A written informed consent was taken from each participant prior to data collection. Participation in the study was voluntary, and confidentiality of the collected information was maintained. Moreover, same intervention was given to the control group after the completion of the study as a part of research ethics.

Results

The experimental and control groups were homogenous with regard to all baseline demographic and clinical characteristics. Tables 1 and 2 give description of subjects in the experimental and control groups, according to various sociodemographic variables.

During pretest, 4.1% and 4.6% of subjects in the experimental and control groups, respectively, had undergone Pap smear screening. While considering the first posttest percentage of subjects who had undergone Pap smear screening, it had increased to 16.7% in the experimental group and no difference was found in the

Table 1: Frequency and percentage distribution of subjects in experimental and control groups according to age, age at the time marriage and pregnancy, and number of pregnancies (*N*=419)

Variable	Experimental (n=246)	Control (n=173)	P
Age in years			
30-40	135 (54.9%)	104 (60.1%)	0.461 ^{ns}
40-50	72 (29.3%)	48 (27.7%)	
50-60	39 (15.9%)	21 (12.1%)	
Age at the time			
of marriage			
≤15	43 (17.5%)	26 (15%)	0.336 ^{ns}
16-20	152 (61.8%)	120 (69.4%)	
21-25	35 (14.2%)	21 (12.1%)	
26 and above	16 (6.5%)	6 (3.5%)	
Age at the time of first pregnancy			
Nulliparous	10 (4.1%)	2 (1.2%)	0.114 ^{ns}
13-17	56 (22.8%)	32 (18.5%)	
18-21	121 (49.2%)	105 (60.7%)	
22-25	37 (15%)	23 (13.3%)	
26 and above	22 (8.9%)	11 (6.4%)	
Number of pregnancies			
Nil	10 (4.1%)	2 (1.2%)	0.06 ^{ns}
1-2	116 (47.1%)	72 (41.6%)	
3-4	89 (36.2%)	64 (37%)	
5 and above	31 (12.6%)	35 (20.2%)	
Number of children			
No children	13 (5.3%)	4 (2.3%)	0.346 ^{ns}
1-2	141 (57.3%)	94 (54.3%)	
3-4	77 (31.3%)	62 (35.8%)	
5 and above	15 (6.1%)	13 (7.5%)	

Chi-square test: nsnot significant

Table 2: Frequency and percentage distribution of subjects in experimental and control groups according to the type of family, religion., family income, education, occupation, age at menarche, and age at menopause (*N*=419)

Variable	Experimental (n=246)	Control (<i>n</i> =173)	P
Type of family			
Nuclear	178 (72.4%)	134 (77.5%)	0.239 ^{ns}
Joint	68 (27.6%)	39 (22.5%)	
Religion			
Christian	30 (12.2%)	17 (9.8%)	0.449^{ns}
Hindu	216 (87.8%)	156 (90.2%)	
Family income per month (in Indian rupees)			
1865-5546	122 (49.6)	85 (49.1)	0.136 ^{ns}
5547-9248	84 (34.2)	59 (34.1)	
9249-13,873	37 (15.0)	27 (15.6)	
13,874-18,497	3 (1.2)	2 (1.2)	
Educational status			
No formal education	55 (22.4%)	35 (20.2%)	0.224 ^{ns}
Primary or upper primary	110 (44.7%)	69 (39.9%)	
High school or higher secondary	74 (30.1%)	67 (38.7%)	
Undergraduate degree and above	7 (2.8%)	2 (1.2%)	
Occupation			
Housewife	106 (43.1%)	80 (46.2%)	0.918 ^{ns}
Own business	16 (6.5%)	12 (6.9%)	
Private job	17 (6.9%)	4 (2.3%)	
Government job	3 (1.2%)	4 (2.3%)	
Others (laborer)	104 (42.3%)	73 (42.2%)	
Age at menarche			
11-12	103 (41.9%)	81 (46.8%)	0.484 ^{ns}
13-14	127 (51.6%)	79 (45.7%)	
15-16	16 (6.5%)	13 (7.5%)	
Age at menopause			
Below 45 years	21 (35.0)	12 (40.0)	0.569 ^{ns}
Above 45 years	39 (65.0)	18 (60.0)	

Chi-square test: nsnot significant

control group. However, during the second posttest at 6 months, most of the subjects in the experimental group (71.5%) had undergone Pap smear screening. Significant difference was found between mean knowledge, attitude, and screening behavior score of experimental and control groups at the first posttest at the first month and the second posttest at the sixth month. Therefore, community-based intervention program was effective in improving cervical cancer screening behavior of women. Table 3 gives a pretest and posttest comparison of mean knowledge, attitude, and screening behavior score of the experimental and control groups.

Repeated measures analysis of variance (ANOVA) was used for within-group comparison of knowledge, attitude, and practice scores of experimental and control groups, and post hoc analysis was done for

Table 3: Comparison of mean knowledge, attitude, and screening behavior scores of experimental and control groups during pretest, first posttest, and second posttest (*N*=419)

Period	group (n=246)	Control group (<i>n</i> =173)	t	P
	Mean±SD	Mean±SD		
Knowledge				
Pretest	6.260±2.735	6.711±2.322	1.766	0.078^{ns}
Posttest 1	12.102±2.017	8.231±2.920	16.049	0.000***
Posttest 2	13.927±1.857	7.156±2.438	32.245	0.000***
Attitude				
Pretest	53.171±9.445	54.098±8.232	0.961	0.337^{ns}
Posttest 1	73.533±8.736	59.451±9.997	-15.298	0.000***
Posttest 2	74.797±8.734	53.426±8.995	-24.522	0.000***
Screening behavior				
Pretest	5.138±1.273	4.896±1.466	-1.800	0.07^{ns}
Posttest 1	6.951±1.299	5.080±1.594	13.200	0.000***
Posttest 2	9.678±1.131	4.838±1.341	39.190	0.000***

Independent t-test: ***significant at 0.001 level; nsnot significant

pairwise comparison if repeated measures ANOVA was significant.

Significant difference was found between pretest, first posttest, and second posttest knowledge scores of the experimental group (F value = 1.8143, P < 0.001) and control group (F value = 93.539, P < 0.001). In pairwise comparison using post hoc analysis, significant improvement was seen between the mean knowledge scores of the experimental group during pretest and first posttest (mean difference = -5.841, P < 0.001), pretest and second posttest (mean difference = -7.667, P < 0.001), and first posttest and second posttest (mean difference = -1.825, P < 0.001). But in the control group, significant difference was found between the mean knowledge scores only during pretest and first posttest (mean difference = -1.520, P < 0.001). However, no improvement was seen between the knowledge scores of the control group between first posttest and second posttest and also between pretest and second posttest.

Significant difference was found between mean pretest, first posttest, and second posttest attitude scores of the experimental group (F value = 1.04603, P < 0.001) and control group (F value = 159.306, P < 0.001). During post hoc analysis of the experimental group, significant improvement was seen between mean pretest and first posttest attitude scores (mean difference = -20.362, P < 0.001), mean pretest and second posttest scores (mean difference = -21.626, P < 0.001), and first posttest and second posttest scores (mean difference = -1.264, P < 0.001). But in the control group, significant improvement was seen between mean the attitude scores during pretest and first posttest (mean difference = -5.353,

P < 0.001) only. Second posttest attitude score was significantly lower than the pretest score (mean difference = 0.671, P < 0.001) and the first posttest score (mean difference = 6.023, P < 0.001).

Significant difference was found between the mean practice scores of the experimental group (F value = 1053.474, P < 0.001) and the control group (F = 1.008, P < 0.001) during pretest, first posttest, and second posttest. In pairwise comparison using post hoc analysis in the experimental group, significant improvement was seen between mean the pretest practice score and the first posttest score (mean difference = -1.83, P < 0.001), the mean pretest score and the second posttest practice score (mean difference = -4.541, P < 0.001) and the first and second posttest scores, which was significant (mean difference = -2.728, P < 0.001). However, in the control group, significant improvement was seen only in the mean practice scores during pretest and first posttest (mean difference = -0.185, P < 0.001). No significant improvement was seen between the pretest and second posttest practice scores (mean difference = 0.058, P = 0.431). Mean practice score during the second posttest was lesser than that of first posttest, which was significant (mean difference = 0.243, P < 0.001). So, progressive increase in knowledge, attitude, and practice scores of the experimental group from pretest to first posttest and second posttest indicates the effect of intervention in improving knowledge, attitude, and practice of women on cervical cancer prevention.

Study findings revealed a significant moderate positive correlation between knowledge and practice (r = 0.408). However, only significant weak positive correlation was found between attitude and practice (r = 0.192) and also between attitude and knowledge (r = 0.282). Table 4 explains the correlation between knowledge, attitude, and practice regarding the prevention of cervical cancer. In the current study, significant association was found between knowledge, attitude, and practice on the prevention of cervical cancer and age at the time of marriage, age at the time of pregnancy, parity, time duration after marriage, education, and income. Higher age at the time of marriage and pregnancy and higher number of parity were associated with good knowledge, attitude, and screening behavior. Educated women were found to have higher level of knowledge,

Table 4: Correlation between knowledge, attitude, and practice of women regarding prevention of cervical cancer (*N*=419)

Calicel (N=413)		
Variable	r	P
Knowledge and attitude	0.282	0.000***
Knowledge and practice	0.408	0.000***
Attitude and practice	0.192	0.000***

Pearson's correlation coefficient: ***significant at 0.001 level

attitude, and screening behavior toward prevention of cervical cancer.

Discussion

The present study conducted among rural women residing in selected tribal settlements of Idukki district of Kerala, India, revealed that the intervention program significantly improved women's knowledge, changed their attitude, and motivated them to adopt good lifestyle practices, and also improved the screening behavior of women. In the present study, significant difference was found between the mean knowledge score of the experimental group and control group after the intervention program (P < 0.001). Mean knowledge score of the experimental group improved from 6.260 during pretest to 12.102 during the first posttest and 13.926 during the second posttest, which was statistically significant (P < 0.001). Consistent findings were reported in the studies conducted by Mary et al., [14] Pirzadeh et al., [15] and Shojaeizadeh et al. [16] According to Perkins et al., community-based intervention program improved cervical cancer awareness among women.^[17] Significant improvement was also reported in the mean attitude scores of the experimental group compared to the control group (P < 0.001), which was supported by Shojaeizadeh et al.[16]

The present study also revealed a considerable increase in cervical cancer screening behavior of the intervention group, which was also supported by other studies. The mean practice score of the experimental group increased from 5.14 to 6.95 and 9.68 during the first posttest at 1 month and second posttest at 6 months (P < 0.001). The study conducted by Pirzadeh et al.[15] and Shojaeizadeh et al.[16] found that intervention based on health belief model was effective in improving cervical cancer screening behavior among women. Perkins et al. demonstrated the effect of inexpensive community-based intervention using radio broadcast and lecture in improving cervical cancer screening behavior in developing countries.^[17] Daryani et al.[18] and Parsa et al.[19] found education and group counseling based on health belief model as an effective strategy to improve cervical cancer screening behavior of women. The study carried out in Iran found significant effect of health belief model-based education through telegram instant messaging in improving Pap smear screening rate. [20] Additionally, group training based on health belief model was effective in changing the belief of Iranian women about cervical cancer screening. [21] On the other hand, a study conducted by Tabeshian et al.[22] used KAP (Knowledge, Attitude and Practice) design to improve the health behaviors of teachers in Isfahan county to do Pap test revealed contradictory findings and reported no significant differences in the participants'

behaviors before and after the intervention. Another study to examine the effect of educational intervention using the health belief model also revealed no significant difference in terms of history of performing the Pap smear test (P = 0.414).^[23]

A cluster randomized controlled trial done by Abdulla *et al.*^[24] based on transtheoretical approach found that call–recall program consisting of invitation and reminder for Pap smear screening as an effective measure in improving pap smear screening rate among women. Lay health advisor (LHA) intervention based on transtheoretical approach targeted to Ohio Appalachian women revealed improved screening rates.^[25] A parallel three-arm, randomized controlled trial conducted by Thompson *et al.*^[26] revealed high-intensity education combined with home visits among women compared to low-intensity intervention by sending video to women on cervical cancer screening as an effective measure in improving Pap smear screening.

A significant association was found between knowledge, attitude, and practice regarding cervical cancer and education. This was in line with the findings of the studies conducted in India. Consistent findings were reported by Bansal et al.[11] and Singh et al.[27] Better education and occupation were found to have significant impact on the awareness of cervical cancer screening in a study conducted in Puducherry, India. [28] On the other hand, contrast findings were found in a descriptive cross-sectional study conducted in a rural community of Kerala.^[29] Increased level of knowledge about cervical cancer prevention and screening among educated women may indicate that women with better education have better communication skills and the ability to absorb information. Women who are employed or students have a greater opportunity for social interaction, hence they get to know more about the disease.

As reported in many studies, significant association was found between knowledge, attitude, and practice regarding cervical cancer and income. Higher level of knowledge, attitude, and practice regarding cervical cancer prevention among women with higher income was supported by a cross-sectional study conducted by Singh *et al*. in a tertiary care hospital of New Delhi. [27] Similarly, significant association between knowledge, attitude, and practice of women and parity was also supported by studies conducted in India. Higher number of pregnancies was associated with less compliance with cervical cancer screening behavior in a study conducted in Maharashtra, India. [30] Another study conducted in rural South India revealed that multiparous women had higher compliance with cervical cancer screening.^[31]

A significant positive correlation was found between knowledge and practice regarding the prevention of cervical cancer. Consistent findings of the association between low level of awareness and non-utilization of cervical cancer screening program have been reported in a study conducted in a rural community of Tamil Nadu, India. ^[28] A significant association was also evident between knowledge of screening for cervical cancer and Pap test and screening behavior in a survey conducted in a rural area of Kerala, India. ^[29] The study carried out by Roy and Tricia in Kolkata also found higher level of preventive practices regarding cervical cancer screening among women having good awareness on screening services. ^[32]

Limitations of the Study

Although the present study revealed significant effect of community-based interventions with multiple components including health education, follow-up visit, and telephonic reminders to improve cervical cancer screening behavior among women, self-report bias could not be excluded from the study as assessment of all variables in the study was based on self-report measures. The researchers could not control mass media and familial influence also. The study reveals the need for prescribing behavioral change interventions in a simple and culturally appropriate way to have positive impact, and future research should focus on strategies to sustain long-term behavior change. Community health nurses and health workers must anticipate the needs of women and should engage in health promotion activities, including health surveys and awareness programs on prevention of cervical cancer, at the community level using various communication strategies. This emphasizes the importance of developing need-based health education, barrier-specific counseling, and community-based interventions targeting eligible women in developing countries like India to improve cervical cancer screening behavior among women. Mobile health camps and outreach clinics should be opened in remote and rural areas to make cervical cancer screening available, affordable, and accessible in those areas. Government should play its part by increasing health-care budgets and giving priority to cervical cancer prevention by establishing a national-level awareness campaign, spreading screening services all over the country using cheap screening procedures that have been found to have good sensitivity and specificity. The study sheds light on the need and accountability of health-care professionals to develop a body of knowledge on various cost-effective interventions aimed at the population level in different settings and to test their effectiveness in improving cervical cancer screening behavior among women.

Conclusion

The present study used a combination of interventions like health education, follow-up visit, and telephonic reminders with navigation and guidance for Pap smear screening to improve cervical cancer screening behavior of the community. The current study revealed a multicomponent intervention strategy with repeated reinforcement and follow-up as an effective measure to improve cervical cancer screening behavior among rural women. The study highlights the importance of implementing health promotion interventions with well-organized cervical cancer screening program including health education component in a simple and culturally sensitive way, and repeated reinforcement and motivation with the involvement of local bodies and health workers in developing countries through primary health centers to make cervical screening accessible and affordable to rural women and to improve their screening behavior. Awareness campaigns regarding Pap smear test are needed to improve knowledge, which in turn helps to change the belief system of women and motivate them to receive Pap smear test, and it is important in reducing cervical cancer mortality and future cervical cancer burden in developing countries like India.

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Ethical approval and consent to participate

Ethical Clearance for conducting the study was taken from the institutional ethics committee of Thrissur Medical College, Kerala, India, and written informed consent was taken from the participants prior to data collection.

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Conflicts of interest

There are no conflicts of interest.

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