

A promoting early presentation intervention sustains increased breast cancer awareness in older women for three years: a randomised controlled trial

Short title

Promoting Early Presentation of Breast Cancer

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Abstract

The Promoting Early Presentation intervention (PEP) increased older women's breast cancer awareness after 2 years in a randomised controlled trial. We measured whether this increase was sustained at 3 years and the effect on breast screening self-referral. We randomly allocated 867 women attending their final invited breast screening appointment to the PEP Intervention or usual care. We examined breast cancer awareness after 3 years and breast screening self-referrals after 4 years. Women in the PEP intervention arm had higher breast cancer awareness at 3 years than the usual care arm (odds ratio 10.4, 95% confidence interval 3.1 to 34.8). There were no difference in proportions self-referring for breast screening between arms, but statistical power was limited. The PEP Intervention has a sustained effect on breast cancer awareness in older women. The effect on self-referral for breast screening is unclear.

Keywords

- Cancer Early Diagnosis
- Cancer Screening
- Breast cancer awareness
- Health Knowledge, Attitudes, Practice

Introduction

Women who delay presentation of breast cancer symptoms have poorer outcomes and evidence suggests this is because they present with more advanced disease^{1,2}. This is a particular problem in older women, who are more likely to have poor breast cancer awareness, to delay presentation with breast cancer symptoms, and have worse survival from the disease^{3,4}.

In the UK, women are invited for breast screening every three years from the age of 50 to 70 with some women being invited from 47 to 73 as part of a trial⁵. Following women's final invited appointment for breast screening, women may contact the screening service every three years to request further screening. This is known as self-referral, however, the proportion of women aged 70 and over who self-referring for breast screening is relatively low at about 20%⁶. This report summarises further results of the randomised controlled trial: the effect of the PEP Intervention on breast cancer awareness after three years, and self-referral for breast screening in the four years after randomisation.

Methods

We developed the Promoting Early Presentation (PEP) Intervention to provide older women with the knowledge, motivation, confidence and skills to present promptly with breast cancer symptoms^{7,8}. Delivered by a health professional in a few minutes, it is supported by a booklet.

The PEP Intervention was delivered women attending their final invited breast screening appointment. The intervention was a scripted ten-minute one-to-one interaction which was supported by a booklet. The details of the trial's methods have already been published; in brief, eight hundred and sixty seven women aged 67-70 attending their final routine

appointment for breast screening in the NHS Breast Screening Programme were randomly allocated to receive the PEP Intervention or usual care⁹.

The main outcome was breast cancer awareness, a validated composite score encompassing knowledge of breast cancer symptoms, age-related risk of breast cancer and frequency of breast checking¹⁰. Participants were considered breast cancer aware if they recognised 5 or more non-lump symptoms, identified a 70 year old as most at risk of developing breast cancer (compared with a 30 year old, a 50 year old or a woman of any age) and reported checking their breasts at least once a month. These items were combined to form an ordinal composite score of breast awareness. Each component was given equal weighting and contributed one point to the total score ranging from 0 to 3 with a score of 3 being breast cancer aware.

The PEP Intervention increased breast cancer awareness compared to usual care at two years follow up (Forbes 2012). This report focuses on reporting the re-assessment of breast cancer awareness at three years follow-up and the rates of self-referral for breast screening after four years.

Breast cancer awareness was assessed by postal questionnaire 3 years after receiving the intervention. Four years after every participant had attended their final routine breast screening appointment we asked NHS Breast Screening Services to tell us which women in the trial had self-referred for further breast screening.

Analysis

We used generalized estimating equations to analyse the change in proportion that was breast cancer aware from baseline to three years, comparing PEP Intervention versus usual care arm. The analyses were carried out by intention-to-treat. In subsequent analyses, we

adjusted the estimates controlling for health professional, centre, and demographic characteristics at baseline.

We examined whether, four years after recruitment, there were differences in the proportions that had self-referred for breast screening between the PEP intervention and usual care using logistic regression.

All analyses were performed using Stata version 11.2 (College Station, TX).

Results

The data, and consort diagram for this trial have been shown in a previous report ¹¹. At three years, 457/565 (81%) of randomised women completed the breast cancer awareness questionnaire: 222/279 (78%) in the PEP Intervention arm and 235/286 (82%) in the usual care arm. Women who completed the questionnaire at three years were more likely to be of White ethnic group and to live in less socioeconomically deprived areas than those who did not, but there were no differences in educational status or baseline breast cancer awareness. Non-response by these characteristics was very similar in both arms.

Breast cancer awareness

Women in the PEP Intervention arm were more likely to be breast cancer aware compared with the usual care arm at three years (17% versus 4%, odds ratio (OR): 10.4, 95% confidence interval (CI) 3.1 to 34.8; $p < 0.001$) (Table 1). The most striking effect of the PEP Intervention was on knowledge of the age at which women were most at risk of breast cancer. In the PEP Intervention, the proportion who knew that a 70 year old was at higher risk than a younger woman or a woman of any age was about 22%, compared with 8% in the

usual care arm (OR: 3.7; CI: 1.9-7.4; $p < 0.001$). Including centre, health professional, and baseline demographics in the model made very little difference to the results.

In the usual care arm 64.9% identified 5-9 non-lump symptoms compared to 73.2% in PEP intervention group (OR: 1.2; CI: 0.8-1.8; $p = 0.3$) and 66.2% in usual care who check breasts at least once month to 78.2% in PEP intervention group (OR: 1.7; CI: 1.1-2.5; $p < 0.01$).

Self-referral for breast cancer screening

Three-hundred and forty-one women were included in the analysis of breast screening attendance. We excluded 232 women from this analysis because they had died or withdrawn consent ($n = 33$), they were known to be taking part in other studies of breast screening or promoting early presentation of breast cancer ($n = 157$), or they were invited for an additional round of screening by the breast screening service ($n = 42$).

There were no significant differences in the proportions who had self-referred for breast screening between PEP Intervention and usual care arms (35/168 versus 31/173; 21% versus 18%; OR 0.8; CI 0.5 to 1.4).

Table 1. Breast cancer Awareness at baseline and three years post-randomisation

| | Baseline | | Three years | |
|--|-------------------|-------------------|-------------------|-------------------------------|
| | Usual care | PEP Intervention | Usual care | PEP Intervention |
| Breast cancer awareness | | | | |
| Number (%) breast cancer aware* | 9/267 (3.4) | 5/272 (1.8) | 9/225 (4.0) | 36/210 (17.1) |
| Odds ratio [†] (95% CI), p value (versus usual care) | | | 1.0 | 10.4 (3.1 to 34.8) p<0.001 |
| Knowledge of breast cancer symptoms | | | | |
| Identified five or more non-lump symptoms | 111/284 (39.1) | 122/280 (43.6) | 148/228 (64.9) | 158/216 (73.2) |
| Odds ratio [†] (95% CI), p value (versus usual care) | | | 1.0 | 1.2 (0.8 to 1.8) p=0.3 |
| Knowledge that risk increases with age | | | | |
| Identified a 70 year old as at highest risk of breast cancer | 30/269 (11.2) | 28/276 (10.1) | 18/233 (7.7) | 47/215 (21.9) |
| Odds ratio [†] (95% CI), p value (versus usual care) | | | 1.0 | 3.7 (1.9 to 7.4) p<0.001 |
| Breast checking | | | | |
| Reported breast checking at least once a month | 152/285 (53.3) | 154/284 (54.2) | 155/234 (66.2) | 172/220 (78.2) |
| Odds ratio [†] (95% CI), p value (versus usual care) | | | 1.0 | 1.7 (1.1 to 2.5) p<0.01 |

* A woman was considered breast cancer aware if she: identified at least five non-lump symptoms AND identified that a 70 year old woman is most at risk of breast cancer (rather than a 30 year old, a 50 year old or a woman of any age) AND reported checking her breasts at least once a month.

[†] Crude odds ratios – not adjusted for baseline characteristics

Conclusion

The PEP Intervention increased breast cancer awareness in older women and the effect was sustained at three years but diminished over the three years. The effect was most striking for knowledge that the risk of breast cancer increases with age. We found no effect of the PEP intervention on self-referral for breast screening.

A strength of the analysis of breast cancer awareness is the very high response rate.

Moreover, we found no evidence that response bias i.e. differences in pattern of response by arm - could explain the results.

In both arms, knowledge that the risk of breast cancer increases with age was low compared to knowledge of breast cancer symptoms and frequency of breast checking, limiting the overall proportion of participants being able to achieve a score of 3 for breast cancer awareness. Future work should investigate why knowledge that risk of breast cancer increases with age is difficult for participants to retain and to develop better methods of communicating this message.

The analysis of self-referrals was limited by low numbers: we would have needed a sample of about 7000 women to find the observed difference in proportions self-referring between PEP intervention and usual care arms statistically significant, with 80% power and significance level of 5%. It is also possible that we collected data too soon after randomisation (four years) and that some women may have self-referred for breast screening later.

The PEP intervention has recently been tested in routine clinical practice and has been found to be effective at increasing breast cancer awareness with sustained effects at one year (Lindsay Forbes/Rachael Dodd, personal communication)¹². In 2013, the All Party

Parliamentary Group on Breast Cancer (2013) recommended that the PEP Intervention should be rolled out in more breast screening services, in order to evaluate the effect on stage at diagnosis and survival, and be tested in a variety of community-based health care settings¹³. If the PEP Intervention is implemented across the whole NHS Breast Screening Programme, it has potential to prevent avoidable deaths from breast cancer, resulting from delayed presentation of cancer symptoms in older women.

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