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[Intervention Review]

Regular self-examination or clinical examination for early detection of breast cancer

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ABSTRACT

Background

Breast self-examination and clinical breast examination have been promoted for many years as general screening methods to diagnose breast cancer at an early stage in order to decrease morbidity and mortality. The possible benefits and harms remain unclear.

Objectives

To determine whether screening for breast cancer by regular self-examination or clinical breast examination reduces breast cancer mortality and morbidity.

Search methods

For this update, the Cochrane Breast Cancer Group Specialised Register, *The Cochrane Library* and PubMed were searched (October 2007).

Selection criteria

Randomised clinical trials, including cluster randomised trials.

Data collection and analysis

Decisions on which trials to include were taken independently by the authors based on the methods of a trial. Disagreements were resolved by discussion. Intention-to-treat analyses were conducted using a fixed-effect model with 95% confidence intervals.

Main results

Two large population-based studies (388,535 women) from Russia and Shanghai that compared breast self-examination with no intervention were included. There was no statistically significant difference in breast cancer mortality between the groups (relative risk 1.05, 95% confidence interval (CI) 0.90 to 1.24; 587 deaths in total). In Russia, more cancers were found in the breast self-examination group than in the control group (relative risk 1.24, 95% CI 1.09 to 1.41) while this was not the case in Shanghai (relative risk 0.97, 95% CI 0.88 to 1.06). Almost twice as many biopsies (3406) with benign results were performed in the screening groups compared to the control groups (1856) (relative risk 1.88, 95% CI 1.77 to 1.99). One large population-based trial of clinical breast examination combined with breast self-examination was also included. The intervention was discontinued because of poor compliance with follow up and no conclusions could be drawn.

Authors' conclusions

Data from two large trials do not suggest a beneficial effect of screening by breast self-examination but do suggest increased harm in terms of increased numbers of benign lesions identified and an increased number of biopsies performed. At present, screening by breast self-examination or physical examination cannot be recommended.

PLAIN LANGUAGE SUMMARY

Regular self-examination or clinical examination for early detection of breast cancer.

Breast cancer is a common cause of cancer morbidity and mortality in women. Breast self-examination (examination of the breasts by the individual) or clinical breast examination (examination of the breasts by a doctor or a nurse) have been promoted for many years as screening methods to diagnose breast cancer at an early stage, in order to decrease the risk of dying from breast cancer. This review searched for well-designed trials that assessed these methods and found two large population-based studies involving 388,535 women who compared breast self-examination with no intervention. The review of data from these trials did not find a beneficial effect of screening in terms of improvement in breast cancer mortality. The trials showed that women who were randomised to breast self-examination were almost twice as likely to undergo a biopsy of the breast, with 3406 biopsies performed in the screening group compared to 1856 biopsies in the control group. The only large population-based trial of clinical breast examination combined with breast self-examination that was identified was discontinued. This was because of poor compliance with follow up and no conclusions can be drawn from the study.

Some women will continue with breast self-examination or will wish to be taught the technique. We suggest that the lack of supporting evidence from the two major studies should be discussed with these women to enable them to make an informed decision. Women should, however, be aware of any breast changes. It is possible that increased breast awareness may have contributed to the decrease in mortality from breast cancer that has been noted in some countries. Women should, therefore, be encouraged to seek medical advice if they detect any change in their breasts that may be breast cancer.

BACKGROUND

Breast cancer is a common cause of cancer morbidity and mortality in women. Apart from the highly increased risk of getting breast cancer related to rare mutations, for example BRCA1 and BRCA2 (Hofmann 2000; Yang 1999) few risk factors of major importance have been identified. The risk is increased for female relatives of women with breast cancer (Calle 1993; Magnusson 1998) and it also increases with age.

These risk factors cannot be modified but women at high genetic risk sometimes undergo prophylactic bilateral mastectomy to prevent development of breast cancer. Women might potentially benefit from early detection of breast cancer by screening. Survival of women with cancers detected by screening using mammography is very high, for example 97% in Malmö after 10 years of follow up (Janzon 1991). Even within the same stage of the cancer, survival is higher in screen-detected cancers than in cancers detected clinically (Moody-Ayers 2000). However, screen-detected cancers include some cancers that have a favourable prognosis. They may be slow growing and some of them might not have developed into invasive cancer if left alone without treatment (Feig 2000). Hence, some degree of overdiagnosis and overtreatment is an inevitable consequence of screening (Welch 2004). The intuitively attractive principle of detecting cancers early therefore needs to be tested in systematic reviews of rigorously conducted randomised trials.

A systematic review of screening with mammography showed that for every 2000 women invited for screening throughout 10 years, one will have her life prolonged (Göttsche 2006). In addition, 10 healthy women, who would not have been diagnosed if there had not been screening, will be diagnosed as breast cancer patients and will be treated unnecessarily. It is thus not clear whether screening with mammography does more good than harm.

Screening for breast cancer by regular self-examination of the breasts or regular clinical breast examination carried out by a health professional might be a possible alternative or addition to mammographic screening. Such screening might lead to less harm than mammographic screening since slow-growing tumours and tumours that do not develop into invasive cancer might be detected less often. A further advantage is that these methods do not require any technical equipment and can be performed by the women themselves if properly trained (Baines 1986) or by general practitioners or nurses. Based on an individual assessment of benefits and risks some cancer societies and health authorities recommend regular breast self-examination and regular professional examination, for example the American Cancer Society (www.cancer.org, accessed 16 October 2007), while others do not, for example the Cancer Council Australia (www.cancer.org.au, accessed 16 October 2007). It seems unclear, however, whether such examinations can reduce breast cancer mortality and whether they do more good than harm (Russia 1999; Shanghai 2002).

OBJECTIVES

To determine whether screening for breast cancer by regular self-examination or by regular clinical examination, or both, reduces breast cancer mortality and morbidity.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised clinical trials, including cluster randomised trials.

Types of participants

Women not diagnosed with breast cancer.

Types of interventions

- 1) Regular self-examination versus no regular self-examination.
- 2) Regular clinical breast examination versus no regular clinical breast examination.
- 3) Combination methods versus no regular breast examination.
- 4) Comparison of one method to another.

Trials that compared different methods of self-examination, different methods of clinical breast examination or that did not report clinical outcomes were not included.

Types of outcome measures

Mortality from breast cancer (primary outcome).

Total mortality.

Mortality from any cancer.

Tumours identified (subgrouped into stage, size, carcinoma in situ and invasive cancer, if possible).

Use of surgical interventions (biopsy, tumorectomy and mastectomy).

Use of chemotherapy and radiotherapy, and other adjuvant therapy.

Adverse effects of breast examination, e.g. related to false positive findings.

Search methods for identification of studies

For the first full version of this review, the Cochrane Breast Cancer Group Specialised Register, *The Cochrane Library* and MEDLINE were searched (October 2002). For the present update this search was repeated and the searches in *The Cochrane Library* and MEDLINE (PubMed) were updated (9 October 2007).

Search strategies

1. Cochrane Breast Cancer Group Specialised Register
 Details of search strategies used by the group for the identification of studies and the procedure used to code references are outlined in the group's module (<http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/BREASTCA/frame.html>). Studies with the keyword 'screen' and 'high risk' on the Specialised Register were extracted for consideration.

2. The searches in PubMed and *The Cochrane Library* are described in Appendix 1 and Appendix 2, respectively. The updated searches were slightly modified from the 2002 search (Appendix 3 and Appendix 4).

These searches were extended with author names and more general terms, as appropriate, to catch updates of the trials and secondary publications related to the trials. Reference lists were scanned for additional publications. Letters, abstracts and grey literature were accepted in an attempt to minimise the impact of

publication bias and to retrieve as much relevant information as possible.

Data collection and analysis

1. Study selection

Decisions on which trials to include were taken independently by the authors, based on the methods of the trials.

2. Data extraction Data were extracted independently by the two authors; disagreements were resolved by discussion. In addition to the outcomes listed above, extracted data included number of randomised women, the randomisation and blinding procedures, exclusions after randomisation, age of the women, family history for breast cancer, prior breast abnormalities, examination technique, criteria for training and reinforcement, number of examinations and interval between examinations, compliance rate, contamination caused by examination performed in the control group and co-interventions (in particular mammography).

We also contacted the primary investigators in an effort to obtain as complete and homogeneous information as possible on the trials, particularly related to the randomisation methods, baseline comparability, blinding of outcome assessment and exclusions after randomisation. Breast cancer should preferably be defined as histologically confirmed cancer.

Intention-to-treat analyses were conducted, if possible. The outcomes were weighted by the inverse variance. A fixed-effect model was used and 95% confidence intervals (CI) were presented. In case of heterogeneity ($P < 0.10$), the reasons were explored. We also explored whether the effect was related to the quality of the screening programme (including training, compliance and adequacy of follow up of the study groups) and the methodological quality of the trials (with emphasis on the randomisation process, baseline comparability, exclusions after randomisation, consistency in the reported numbers of randomised women and lack of blinding in outcome assessment).

RESULTS

Description of studies

Our search strategy identified six potentially eligible trials. Three of these trials have been included in the review, one was excluded and two are ongoing.

Two large, population-based randomised trials investigating breast self-examination as a general screening method were included (Russia 1999; Shanghai 2002). Final results of the Shanghai study were published in 2002 and the Russian study in 2003. The Russian Federation/WHO study recruited women in St Petersburg and Moscow. Due to lack of follow up and methodological problems in the Moscow branch of the study we included only data from St Petersburg, which was published in English.

The third included study was a large, population-based trial investigating a combination of screening by clinical examination of the breast combined with instruction in the technique of breast self-examination. This study was conducted in the capital Manila of The Philippines (Philippines 2006). Because of poor compliance with the follow up of screen-positive women the active intervention was discontinued after completion of the first screening round.

The search also retrieved a proposed or ongoing population-based, cluster-randomised study in the Trivandrum district of Kerala, India (India 1998). The study is investigating whether clinical breast examination plus teaching of self-examination and visual inspection of the cervix, done by trained female health workers, will lead to a reduction in mortality. This study proposes to randomise a total of 120,000 women between the ages of 30 and 60 years. Further details, including a proposed study design, appear on the webpage of the International Agency for the Research on Cancer (IARC) at <http://screening.iarc.fr/breastindex.php> (accessed 20 October 2007). The study is still in an early phase and the proposed timelines remain unclear. The IARC Screening Group did not provide any further details when we contacted them using the contact form on the webpage.

We also identified a pilot study being conducted in Cairo, Egypt (Boulos 2005). The objective of this study is to test the feasibility of conducting a randomised trial of clinical breast examination and breast self-examination instruction in a defined geographical area. Because this study investigates the prevalence of breast cancer in Cairo it has not been included.

The sixth trial is a randomised trial of 28,788 women (Turner 1984). In this trial, a considerable number of women (6.8%) were excluded from the intervention group on the basis that they had a previous diagnosis of breast cancer. There were no exclusions from the control group. Furthermore, there were no data on breast cancer mortality or overall mortality but only on detection rates. The follow-up time was short, there were no data on compliance and the intervention consisted only of a booklet about breast self-examination that was sent twice to the intervention group. We therefore excluded this flawed trial.

Risk of bias in included studies

Three studies have been included in this review. Two of these studies assessed regular breast self-examination versus no regular breast self-examination (Russia 1999; Shanghai 2002) and one (Philippines 2006) assessed a combination of clinical breast examination and instruction for breast self-examination versus no regular breast self-examination.

Regular breast self-examination versus no regular breast self-examination

The Russian Federation/World Health Organization Study (Russia 1999)

a) Randomisation method

Women aged 40 to 64 years were invited to participate. In St Petersburg, 18 district polyclinics and 10 large enterprise healthcare services were randomised separately at WHO, Geneva, using a table of random sampling numbers, which ensured that there were 9 polyclinics and 5 enterprises in each group. According to one publication (Semiglazov 1992) a total of 120,310 women were randomised in St Petersburg from 1985 to 1989: 60,221 women to the screening group and 60,089 to the control group. According to a later publication (Semiglazov 1999) the numbers were 122,471 with 57,712 randomised to the screening group and 64,759 to the control group. This discrepancy has not been explained. Polyclinics with 'occupational hazards' and previously conducted breast self-examination education programs were excluded. Screening by breast self-examination had not been promoted in the Russian

Federation before the implementation of the study. Because of the discrepancies in numbers, the outcome of the randomisation process is uncertain.

In Moscow, 237 factories were randomised; factories with known 'occupational hazards' were excluded. The first 99 factories were randomised using the fourth digit of their telephone number as discriminator. By casting lots, 46 factories with odd digits were assigned to the study group and 53 factories with even digits to the control group. The remaining 138 factories were randomised at WHO, using tables of random sampling numbers. It is not clear whether the allocation concealment was adequate in the first phase of the Moscow study. Furthermore, the number of women randomised seems not to have been published and the Moscow branch of the study was not mentioned in the most recent paper published in English ([Semiglazov 1999](#)), which suggests that the Moscow branch of the study might have been abandoned.

Baseline comparability between the study group and the control group was not documented for either substudy.

b) Exclusions after randomisation

Women with previous breast cancer or other malignancies were excluded in both cities, but numbers were not stated. Control group women with a history of breast cancer were not identified initially but were supposed to be identified through the routine follow-up procedures of the study.

Women who migrated were lost from analysis in both cities; no data are given for numbers and their allocation group. The investigators stated that this would not bias the trial but considering the major socioeconomic changes Russia was facing during the trial period this assumption may not be tenable.

c) Quality of the screening programme

Training

In St Petersburg, trained nurses or doctors taught breast self-examination to groups of 5 to 20 women at a time, including demonstration of the technique on one of the women. Women answered a questionnaire about demographic data and risk factors and received a leaflet and a self-examination follow-up calendar. Calendars were renewed and the entries reviewed annually. The calendars were based on the method developed by Gastrin, encouraging the women to perform self-examination once a month. This included inspection in a mirror in a standard position with arms above the head; palpation both in a standing and lying position, systematically covering the entire breast and axilla; and squeezing the nipple to detect discharge.

Furthermore, self-examination was encouraged through broadcast messages in the enterprise polyclinics (there was no information about similar activities in the district polyclinics). Women in the intervention group who attended a routine health check received a clinical breast examination, were instructed in self-examination and given a calendar; they were reinforced annually, when returning as instructed. Women in the control polyclinics attending routine health checks received a clinical breast examination but no self-examination instruction. There were no data available about the number of women attending these routine health checks. More cancers per thousand women were detected within the trial as opposed to the general population in St Petersburg, in both the

intervention and control groups. This was possibly due to the availability of a weekly specialist breast clinic, also for those women in the control group; another explanation would be contamination bias.

In Moscow, the teaching was run by trained project staff at the factories. Groups of 5 to 20 women were instructed on breast cancer problems, the value of self-examination, its positive aspects, reasons for non-acceptance, technique and symptoms of benign lesions and cancer of the breast (with the help of slides, figures, films and a model). The duration of the lecture was 20 to 25 minutes. Twice a year, enrolled women were reinforced to practice self-examination every month. Additional information and visual aids about techniques and symptoms of cancer and pre-tumour lesions of the breast were delivered when deemed necessary. There was an annual exchange of calendars, with calendars and technique almost identical to those developed by Gastrin.

In summary, the content and duration of the training programme seemed adequate, especially considering the enormous work involved in implementing such an ambitious screening programme in practice.

Compliance

The percentage of women performing breast self-examination at least five times a year in St Petersburg declined from 82% one year after the education to 56% after four years. A program to re-educate the women was established, which restored the frequency to 82% at five years but which declined to 76% after eight years ([Semiglazov 1999](#)). The overall number of women these percentages relate to was not stated, however, and since the frequency was self-reported, bias cannot be excluded.

The rate of women performing breast self-examination in St Petersburg was assessed by medical personnel a year after the training. The following percentages of women performed specific tasks correctly: inspection (79%); palpation with three fingers (15%); palpation with four fingers (69%); palpation using finger pads (58%); palpation by a) concentric movements (10%), b) radial movements (63%); breast fully examined (71%); axilla examined (78%) ([Semiglazov 1999](#)). The overall number of women these results relate to was not stated.

To assess compliance in Moscow, 10 factories in the intervention group were chosen at random and a random sample of 40 women from each factory were interviewed. Beginning at year five of the study, re-education was being attempted by repeating the self-examination instruction to relevant groups of women in the intervention group. Assessment of compliance in Moscow was not possible because of lack of data.

Adequacy of follow up

Recruitment in St Petersburg took place from 1985 to 1989. After a one-year feasibility study, the trial was planned to last for 15 years in St Petersburg, starting in January 1985. The exact starting date in Moscow was not mentioned.

Newly diagnosed cases were identified for 10 years in St Petersburg and for 12 years in Moscow. Follow up continued for another five years in St Petersburg and three years in Moscow. The statements made between the publications, about the beginning, duration and follow up of the study population, contained minor inconsistencies. Furthermore, because of the long recruiting time it was not clear if

all women were in the age group 40 to 64 years when they entered the study.

d) Blinding of outcome assessment

Blinding of X-ray assessors, pathologists, surgeons, assessors of cause of death and other care takers were not described and, therefore, probably not done.

The Shanghai study (Shanghai 2002)

a) Randomisation method

This was a cluster randomised trial of 519 factories ranging in size from less than 100 female employees to more than 10,000 female employees. The randomisation method was not described. Women born between 1925 and 1958 (approximately 30 to 66 years of age) were identified from factory records and were eligible for the trial. In total 289,392 women were randomised: 146,437 to the intervention (instruction with reinforcement) and 142,955 to the control, including women who were added during baseline breast self-examination instruction after randomisation (exact number not noted).

Informed consent was obtained from all study participants. The two groups appeared to be well balanced; of the 10 risk factors presented only one showed a marked difference (8.0% versus 11.7% had a previous breast examination in the past year).

b) Exclusions after randomisation

Of those randomised, the following post-randomisation exclusions were made: 1336 women (703 instruction and 633 control) because of prior breast cancer; 4987 women (3656 instruction and 1331 control) because they did not answer a baseline questionnaire; and 17,005 women (9099 instruction and 7906 control) were later deemed not eligible because they had been transferred out of the factories (3349), had moved out of Shanghai (3799), could not be located (8239), had died (1467) or were found ineligible because of their date of birth (97). The numbers of women excluded in both study arms were similar apart from the number of women not completing the baseline questionnaire. More women in the instruction group (3656) than in the control group (1331) did not complete the questionnaire. This was mainly attributed to a single factory where 1177 women refused to answer the questionnaire. This left 266,064 women (132,979 instruction and 133,085 control) for the analyses.

c) Quality of the screening programme

Training

The training program was very thorough and well conducted. Participants were recruited from October 1989 to July 1995 with those recruited through the first year being designated to study group 1 and all others designated to study group 2. This resulted in the groups receiving training at different times.

The intervention comprised the following:

- a baseline breast self-examination instruction class (including individual practice) plus two waves of reinforcement activities (including a review of technique and a video) one and three years later. Overall attendance was 98.5% at baseline, 95.1% at first reinforcement and 83.1% at second reinforcement;

- supervised breast self-examination practice four times during the first year after baseline instruction and every six months thereafter, until July 1995. Attendance rates were more than 90% through 1991 and dropped to 48.7% in 1995 because of changes associated with economic reforms;

- additional reinforcement methods, e.g. individual contacts, reminder posters, workshop rounds, individual letters, factory broadcasts, home visits and reminding women when they came to various meetings.

The following breast self-examination technique was taught: inspection in the mirror and palpation in both standing and lying position with the ipsilateral arm above the head. Instruction emphasised using a circular motion with the pads of the three middle fingers while pressing firmly, systematically covering the entire breast and axilla, and squeezing the nipple to detect discharge. Instruction included detailed information and individual instruction and practice for each woman on both breast models and themselves. Breast self-examination was observed and corrected, if necessary. Women were encouraged to practise breast self-examination once a month.

Women in the control group were asked to attend training sessions for prevention of back pain. The ability of randomly selected women to find various types of lumps in breast models was tested. Women in the instruction group consistently found a higher percentage of the lumps than those in the control group.

Screening in the control group was estimated to be 5% and mainly occurred because women working in factories initially randomised to the intervention group were merged with factories in the control group. Only 2% of the cancers in the control group were identified in women who reported having had training in self-examination. Mammography screening was not available. Clinical breast examination was done in only 8% of the factories, in an equal percentage in the two groups.

Compliance

Measures of compliance were based on observed behaviour during the baseline instruction and two reinforcement sessions, from 1989 through 1994. All three sessions were attended by 79.5% of the women. About 2.7% of women received only one session or none. For the individual practice sessions, which took place from 1989 through the first half of 1995, the attendance rate was 83.2% (more than 90% through 1991 dropping to 48.7% in the first half of 1995 due to changes associated with economic reforms).

Adequacy of follow up

The total trial duration was 10 years, with follow up through December 2000. There was a very close and thorough follow up performed by medical workers; tumour and death registries were used as well. A total of 1760 cases of breast cancer were detected in the study cohort through December 2000, which was the last year for which case-finding efforts had been conducted. According to epidemiological estimations based on the Shanghai Cancer Registry the case-finding system of the study was at least as complete as the Registry itself and few cases or deaths could have been missed.

d) Blinding of outcome assessment

Doctors and nurses treating the cancer patients were blinded but might have been informed by the patients or had general

knowledge of the study. Pathologists and assessors of cause of death were blinded.

Combination methods versus no regular breast examination

One large, population-based trial investigating a combination of screening by clinical examination of the breast combined with instructions in the technique of breast self-examination has been included. This study has been conducted in the capital region of Manila, The Philippines. Because of poor compliance with follow-up of screen-positive women, the active intervention was discontinued after completion of the first screening round.

The Philippines study ([Philippines 2006](#))

a) Randomisation method

This was a cluster randomised trial involving 202 health centres (the unit of randomisation) within 12 central municipalities of Manila. Women aged 35 to 64 years were the target population. In total 404,947 women were randomised: 216,884 to the intervention arm and 188,063 to the control group. The first and only screening round started in 1996. Informed consent was obtained from all study participants. Baseline comparability between the study and control groups has not been described.

b) Exclusions after randomisation

Of 216,884 women randomised to the intervention arm, 151,168 (70%) were interviewed and offered clinical breast examination and instruction in breast self-examination. Of these 12,776 (8%) refused to be examined. The number of women examined was therefore 138,392, which corresponded to 64% of the women randomised to the intervention group. Remarkably, refusers were of higher socioeconomic status than compliers.

c) Quality of the screening programme

Training

Five rounds of screening were planned, at intervals of one to two years. Nurses and midwives were recruited and trained in the technique of clinical breast examination using the MAMMACARE programme. Women were interviewed and clinical breast examination was carried out by the trained examiners. Women were also instructed in the technique of breast self-examination and provided with a leaflet in the local language explaining the purpose and methodology of breast self-examination.

Compliance

Compliance with the single screening round of clinical breast-examination was about 92% of the women being interviewed, or 64% of the women randomised to the intervention group. Compliance with breast self-examination was not recorded.

Adequacy of follow up

A total of 3479 women (3% of 138,392 women examined) in the intervention group were judged to have a lump and were referred to the project clinics. Complete diagnostic follow up was achieved for 1220 women (35% of those positive on screening). A total of 1475 women (42%) actively refused further investigation and 23% were lost to follow up. Because of poor compliance with the follow up of screen-positive women, the active intervention was discontinued after completion of the first screening round in December 1997.

d) Blinding of outcome assessment

Blinding of outcome assessment has not been reported.

Effects of interventions

Two large population-based studies (together involving 388,535 women) from Russia and Shanghai that compared breast self-examination with no intervention were included in the analysis. There was no statistically significant difference between the intervention and control groups for breast cancer mortality (relative risk 1.05, 95% confidence interval (CI) 0.90 to 1.24). A total of 587 breast cancer deaths occurred in the studies, 292 in the breast self-examination group and 295 in the control group.

The data from the Phillipines study were not analysed in detail because of the early termination of the study, the low compliance concerning referral for diagnosis in test-positive women and the lack of long-term follow up.

Total mortality (deaths from all causes among all randomised women) was only reported for the Shanghai trial, with 5349 deaths in the breast self-examination group and 5939 deaths in the control group (relative risk 0.90, 95% CI 0.87 to 0.93). This significant decrease of 10% in total mortality is highly implausible and suggests a baseline imbalance in this study.

There was heterogeneity ($P = 0.002$) for numbers of cancers identified. In Russia, more cancers were found in the breast self-examination group than in the control group (relative risk 1.24, 95% CI 1.09 to 1.41); this was not the case in Shanghai (relative risk 0.97, 95% CI 0.88 to 1.06).

The available tumor-staging data were too different to be compared, apart from numbers of T1-tumors (2 cm or less) and the small numbers of carcinoma in situ. There was a large difference for T1-tumours between the results from Russia and Shanghai ($P = 0.01$ for the test of heterogeneity): the relative risks were 1.57 (95% CI 1.17 to 2.10) for Russia and 1.04 (95% CI 0.90 to 1.20) for Shanghai.

Almost twice as many biopsies (3406) with benign results were performed in the screening group compared to the control group (1856), relative risk 1.88 (95% CI 1.77 to 1.99).

So far, data about treatment for detected cancers have only been published for the Shanghai study. The treatment was very similar in the two groups: 4.4% versus 2.7% underwent breast-conserving surgery and 94.4% versus 95.8% underwent mastectomy.

The data from The Phillipines study (404,947 women) were not analysed in detail because of the early termination of the study, the low compliance concerning referral for diagnosis in test-positive women and the lack of long-term follow up. The follow up for mortality was not completed due to the early termination of the project. According to personal information from the authors of the study, and based on follow up to the year 1999, 211 new cases of breast cancer have been identified in the intervention arm (216,884 women) and 218 new cases in the control arm (188,063 women). Information on stage was missing in 16% of the cases; 36% were localised in the intervention group and 31% in controls. Outcome data on harms (for example number of biopsies) have not been published.

DISCUSSION

We were unable to find any benefit of breast self-examination in this review. The Shanghai study was better designed than the Russian study with the instructions provided for breast self-examination being more extensive and a better compliance rate achieved. It is therefore surprising that the Russian study, but not the Shanghai study, found more cancers in the screened group than in the control group. This paradox can probably be explained by the fact that mammography was not available in Shanghai. A possible increased use of mammography in the screened group in Russia (twice as many benign lesions were found as in the control group) could explain why the number of small cancers identified was also larger in that group than in the control group, since many of those cancers would not be identifiable by palpation of the breasts only.

Our conclusion refers to the final results of the Shanghai study and the results of the St Petersburg arm of the Russian study, both of which assessed breast-self examination as a screening method versus no breast self-examination. As described above, the Russian Federation/WHO-study had limitations that raise uncertainty about its reliability; unfortunately the WHO, that funded the study, could not contribute with further information when we approached them. Also the Shanghai study raises questions because of the large difference in all-cause mortality between the screened group and the control group. Both studies were cluster randomised. We were not able to take this design into account in our analyses and it is uncertain whether the trial authors did either, as there is no description of their statistical methods in any of the papers.

Two meta-analyses of breast self-examination from the Canadian Task Force on Preventive Health Care (Baxter 2001) and Hackshaw et al (Hackshaw 2003) are in accordance with our results. These meta-analyses also conclude that there is good evidence of harm from breast self-examination as a result of increased invasive diagnostic procedures. In the Russia/WHO study, a significantly higher rate of needle and excision biopsies was reported (1138 versus 797 in the control group). In the Shanghai study, almost double as many benign lesions were diagnosed in the study group (2761 versus 1505). A considerably higher number of invasive diagnostic procedures have been reported in the screening group (3627 versus 2398). Other potential harms of screening include emotional distress at least once a month (Brett 1998; MacFarlane 1992), breast deformity and scars after invasive diagnostic procedures and a higher rate of diagnostic mammographies.

The Shanghai study is well designed and it is hard to imagine that future studies of this large size would achieve more impressive attendance and compliance rates.

One large, population-based trial of screening by clinical examination of the breast combined with instruction in the technique of breast self-examination fulfilled the formal criteria of this review and has been included (Philippines 2006). However, due to the early termination of the study, the poor compliance and lack of long-term follow up data the study was terminated early and cannot answer the question whether a combination of screening by clinical examination and breast self-examination reduces breast cancer mortality. The reason for the failure of the study was the unforeseen low compliance of women with abnormalities in pursuing diagnosis and treatment. This study is important to consider, however, for any policy maker planning

to introduce and implement cancer screening programs in the developing world.

We did not include the UK trial of Early Detection of Breast Cancer (UK trial 1999) because it was not randomised. There were probably differences in the socioeconomic status of the compared groups and, in addition, breast self-examination teaching consisted of only a single session; attendance rates were quite low, 31% and 51% respectively.

The Canadian National Breast Screening Study (Miller 2000; Miller 2002) is sometimes included in discussions of breast self-examination and clinical breast examination. However, as this well-conducted study randomised participants to mammography screening or no mammography screening in addition to examinations of the breasts, it was not eligible for our review.

Considering the currently available evidence, promotion of breast self-examination as a single screening method cannot be recommended. This is particularly true because there is good evidence of harm and there are also considerable costs related to general screening (Baxter 2001).

Most cancer groups have revised their recommendations relating to breast self-examination (Baxter 2001). For example, both the US National Cancer Institute (<http://www.cancer.gov/cancertopics/pdq/screening/breast/HealthProfessional>) and the US National Breast Cancer Coalition (<http://www.natlbcc.org/bin/index.asp?strid=496&depid=9&btnid=1>) have concluded that there is currently no scientific evidence from randomised trials that screening by breast self-examination saves lives or enables women to detect breast cancer at earlier stages (both accessed 31 October 2007). The US Preventive Services Task Force (<http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm>) could not determine the balance of benefits and potential harms of breast self-examination. Curiously, and against the evidence, The American Cancer Society (http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_Can_breast_cancer_be_found_early_5.asp?sitearea=) currently considers breast self-examination monthly as an option for women aged 20 and over, based on an individual assessment of benefits and risks (both accessed 31 October 2007).

Some women will continue with breast self-examination or will wish to be taught the technique. We suggest that the lack of supporting evidence from the two major studies should be discussed with these women to enable them to make an informed decision.

It would be wrong, however, to conclude that women need not be aware of any breast changes. It is possible that increased breast awareness may have contributed to the decrease in mortality from breast cancer that has been noted in some countries. Women should, therefore, be encouraged to seek medical advice if they detect any change in their breasts that may be breast cancer.

AUTHORS' CONCLUSIONS

Implications for practice

Data from two large trials do not suggest a beneficial effect of screening by breast self-examination whereas there is evidence for harms. One large trial investigating a combination of screening by clinical examination combined with instructions in the technique of

breast self-examination was discontinued due to poor compliance. At present, screening by breast self-examination or physical examination cannot be recommended.

Implications for research

It is unlikely that additional trials investigating breast self-examination as a single general screening method would be worthwhile.

ACKNOWLEDGEMENTS

We thank the Cochrane Breast Cancer Group for searches in their Specialised Register and for provision of paper copies of trial reports.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Philippines 2006

Methods	Population-based randomised trial investigating a combination of screening by clinical examination of the breast combined with instructions in the technique of breast self-examination. Cluster randomisation.
Participants	Women aged 35-64 years. In total 404,947 women were randomised, 216,884 to the intervention arm and 188,063 to control.
Interventions	Five rounds of screening were planned using clinical examination of the breast combined with instructions in the technique of breast self-examination at intervals of 1-2 years.
Outcomes	The primary endpoint of the study was mortality.
Notes	Because of poor compliance with follow up of screen-positive women, the active intervention was discontinued after completion of the first screening round in December 1997.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Russia 1999

Methods	Population-based randomised trial of breast self-examination. Cluster randomisation.
Participants	122,471 women aged 40-64 years at entry into trial were randomised in St. Petersburg during the years 1985 to 1989, 57,712 women to the screening group and 64,759 to the control group.
Interventions	Breast self-examination teaching was run by trained nurses or doctors. Women were encouraged to perform BSE once a month.
Outcomes	Mortality from breast cancer. Number of cancers. Benign lesions. Number of biopsies.
Notes	Data from the Moscow branch of the study was incomplete and was therefore not analysed in this review. There were conflicting statements in the different papers about the number of women randomised and the number of women analysed in St Petersburg. Final results were expected to be published in 2002/2003.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Shanghai 2002

Methods	Randomised trial of breast self-examination. Cluster randomization. Exact randomisation mechanism is not described. Screened group is asked to give verbal consent.
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Shanghai 2002 *(Continued)*

Total trial duration 10 years.

Participants	Women invited were 31 to 59 years at entry into trial (born from 1925 through 1958). A total of 266,064 women (132,979 instruction group and 133,085 control group) in analyses.
Interventions	3 different kinds of interventions from October 1989 to July 1995: 1) Baseline BSE instruction plus reinforcement sessions approximately 1 and 4 years later. 2) Supervised BSE practice every six months after baseline instruction until July 1995. 3) Additional methods, together nearly 1.3 million sessions, not documented specifically.
Outcomes	Mortality from breast cancer. Total mortality. Number of cancers. Benign lesions. Biopsies. Surgical interventions, chemotherapy and radiotherapy.
Notes	Large difference in total mortality might indicate imbalance at baseline.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

BSE: breast self-examination

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Turner 1984	RCT including 28,788 women. Insufficient follow-up time and unknown effect of the intervention which consisted of a booklet about breast self-examination sent twice to the intervention group. There were no data available about compliance and many women (7%) were excluded in the intervention group causing doubt on baseline comparability, in particular since women with previous breast cancer were only excluded from the study group. Furthermore the paper intended not to report data on breast-cancer mortality or overall mortality but only the effect of the intervention on detection rates.

RCT: randomised clinical trial.

Characteristics of ongoing studies *[ordered by study ID]*
Boulos 2005

Trial name or title	Breast screening in the emerging world: high prevalence of breast cancer in Cairo.
Methods	
Participants	4116 women aged 35-64 years.
Interventions	The objective of this pilot study is to test the feasibility of conducting a randomised trial of clinical breast examination and breast self-examination instruction in a defined geographical area of Cairo.
Outcomes	The prevalence of breast cancer in Cairo.

Boulos 2005 (Continued)

Starting date	Not stated, probably beginning of the 21st century.
Contact information	ab.miller@sympatico.ca (AB Miller)
Notes	Pilot study. The study might proceed to a randomised controlled study.

India 1998

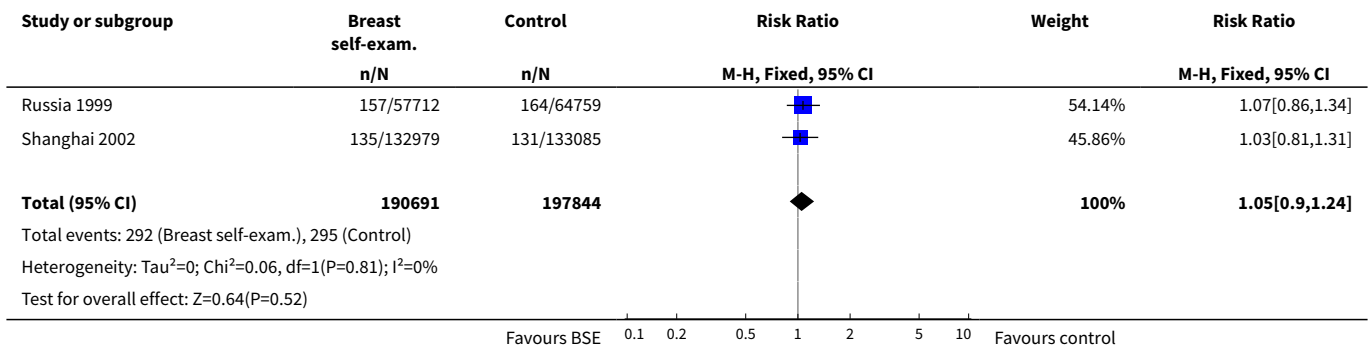
Trial name or title	Early detection of common cancers in women in India.
Methods	
Participants	120,000 socioeconomically disadvantaged women between the ages of 30-60 years are being randomized to 2 arms - one to receive intervention every 18 months for 6 years and the other to act as control.
Interventions	Clinical examination of the breast plus teaching of breast self-examination and visual inspection of the cervix, to be done by trained female health workers.
Outcomes	Mortality due to breast and cervical cancer.
Starting date	Unclear: possibly May 1998.
Contact information	2R01CA74801-05 MITTRA, INDRANEEL. International Agency for the Research on Cancer (IARC): http://screening.iarc.fr/breastindex.php
Notes	A proposed study design can be found on the IARC home page. Further details about the study have not been published and could not be retrieved.

DATA AND ANALYSES
Comparison 1. Breast self-examination versus no breast self-examination

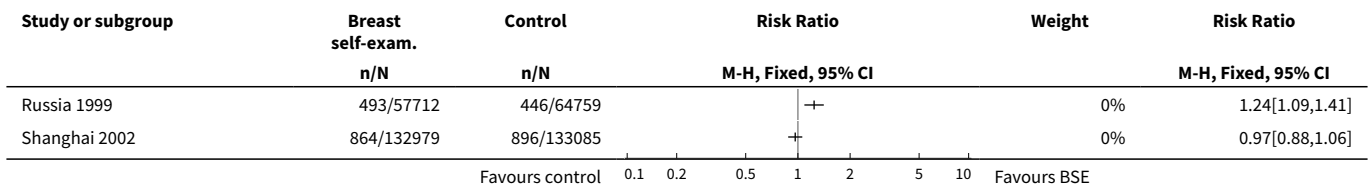
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality from breast cancer	2	388535	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.90, 1.24]
2 Cancers identified	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3 Carcinoma in situ (Tis)	2	388535	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.82, 2.14]
4 T1-tumors (2 cm or less)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Total number of biopsy examinations (both benign and cancer)	2	388535	Risk Ratio (M-H, Fixed, 95% CI)	1.53 [1.47, 1.60]
6 Total number of breast biopsies with benign histology	2	388535	Risk Ratio (M-H, Fixed, 95% CI)	1.88 [1.77, 1.99]

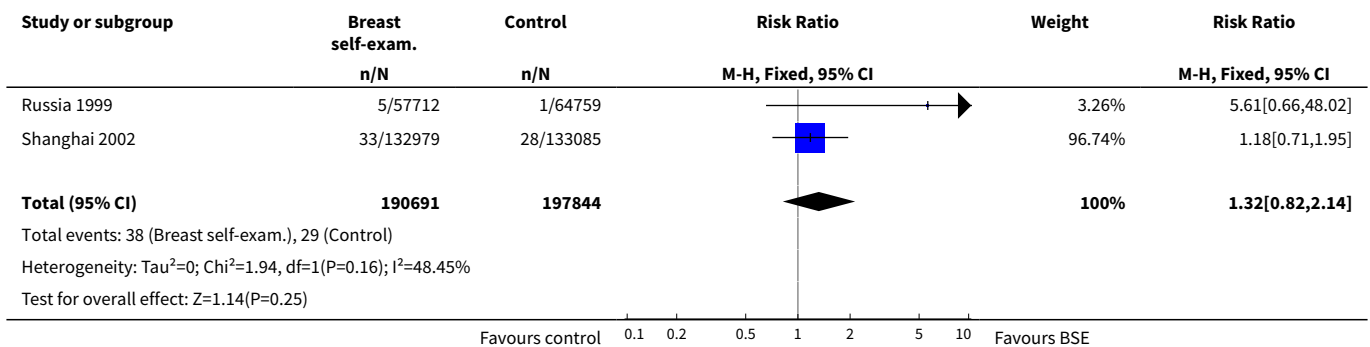
Analysis 1.1. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 1 Mortality from breast cancer.



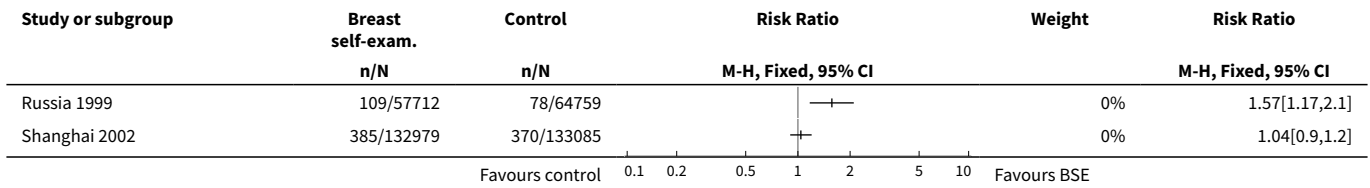
Analysis 1.2. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 2 Cancers identified.



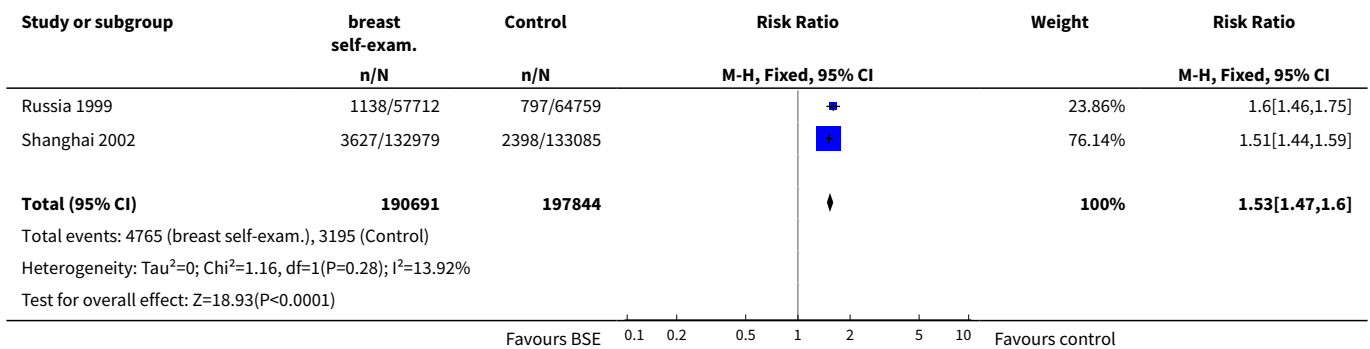
Analysis 1.3. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 3 Carcinoma in situ (Tis).



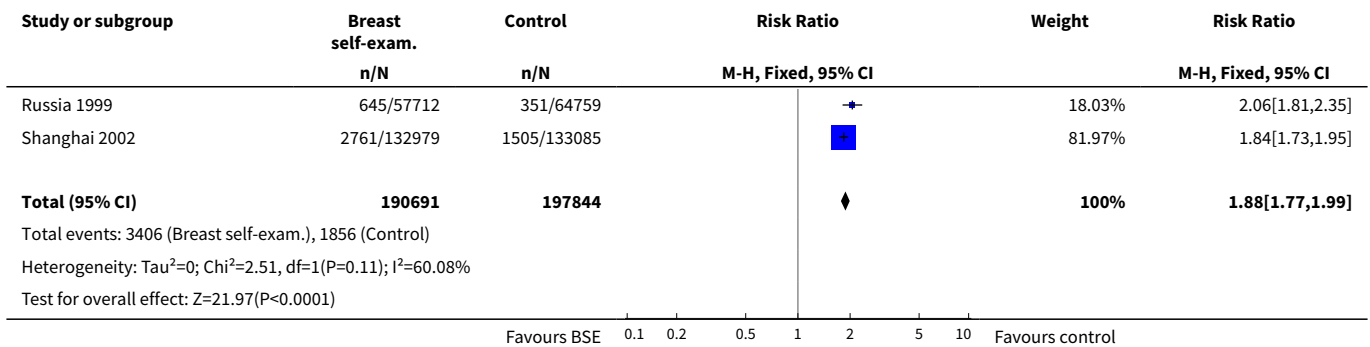
Analysis 1.4. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 4 T1-tumors (2 cm or less).



Analysis 1.5. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 5 Total number of biopsy examinations (both benign and cancer).



Analysis 1.6. Comparison 1 Breast self-examination versus no breast self-examination, Outcome 6 Total number of breast biopsies with benign histology.



APPENDICES

Appendix 1. Search strategy - Medline (PubMed: 1st September 2002 - 9th October 2007)

- #1 breast neoplasms
- #2 breast cancer
- #3 #1 OR #2
- #4 breast self-examination

#5 self-examination
#6 #3 AND #5
#7 #6 OR #4
#8 physical examination
#9 #3 AND #8
#10 random*
#11 "Clinical Trial"[Publication Type]
#12 "Clinical Trials"[MeSH]
#13 "Comparative Study"[Publication Type]
#14 #10 OR #11 OR #12 OR #13
#15 #9 AND #14
#16 #7 AND #14
#17 #15 OR #16
#18 #15 OR #16 Limits: Entrez Date from 2002/09/01 to 2008

Appendix 2. Search strategy - The Cochrane Library (1st January 2002 - 9th October 2007)

#1MeSH descriptor Breast Neoplasms explode all trees
#2breast cancer
#3(#1 OR #2)
#4MeSH descriptor Breast Self-Examination explode all trees
#5MeSH descriptor Self-Examination explode all trees
#6(#3 AND #5)
#7(#4 OR #6)
#8MeSH descriptor Physical Examination explode all trees
#9(#3 AND #8)
#10(#7 OR #9)
#11(#7 OR #9), from 2002 to 2007

Appendix 3. Search strategy - Medline (Ovid: 1966-October 2002)

1 explode "Breast-Neoplasms"/ all subheadings
2 "breast"
3 "cancer"
4 "breast cancer"
5 #4 or #1
6 explode "Breast-Self-Examination"/ all subheadings
7 explode "Self-Examination"/ all subheadings
8 #5 and #7
9 #8 or #6
10 explode "Physical-Examination"/ all subheadings
11 #10 and #5
12 random*
13 clinical-trial in pt
14 explode "Clinical-Trials"/ all subheadings
15 tg=comparative-study
16 #12 or #13 or #14 or #15
17 #16 and #11
18 #17 or #9

Appendix 4. Search strategy - The Cochrane Library (1966 - October 2002)

CLIB1=BREAST-NEOPLASMS*:ME
CLIB2=(BREAST next CANCER)
CLIB3=(#1 or #2)
CLIB4=BREAST-SELF-EXAMINATION*:ME
CLIB5=SELF-EXAMINATION*:ME
CLIB6=(#3 and #5)
CLIB7=(#4 or #6)
CLIB8=PHYSICAL-EXAMINATION*:ME
CLIB9=(#3 and #8)
CLIB10=(#7 or #9)

WHAT'S NEW

Date	Event	Description
12 May 2008	Amended	Converted to new review format.
14 February 2008	New search has been performed	New search - no change to conclusions or authors

HISTORY

Protocol first published: Issue 4, 2001

Review first published: Issue 2, 2003

Date	Event	Description
2 January 2008	New search has been performed	Central copyediting by Wiley/plain language summary drafted by members of CCNet for review by authors
1 February 2003	New search has been performed	First review publication

CONTRIBUTIONS OF AUTHORS

The draft protocol and draft review was written by Jan Peter Kösters; both authors contributed to the final versions and to the development of the search strategy. Jan Peter Kösters identified potentially eligible studies; the authors decided together on inclusion of studies. Data were extracted independently by both authors.

For the Updated review 2008 - The updated search was done by Jan Peter Kösters. Both authors decided on inclusion of studies and contributed to the revision of the review.

DECLARATIONS OF INTEREST

None

NOTES

A search for this update was performed on 9th October 2007.

A recently published, large population-based trial (Philippines 2006) of clinical breast examination combined with instructions in breast self-examination was retrieved and included. The intervention was discontinued because of poor compliance with follow up, and no conclusions could be drawn.

New data were not analysed.

INDEX TERMS

Medical Subject Headings (MeSH)

*Physical Examination; Breast Neoplasms [*diagnosis] [prevention & control]; Breast Self-Examination

MeSH check words

Female; Humans