



La comunicazione in MyPeBS

Francesca Di Stefano, Lina Jaramillo, Livia Giordano

CPO

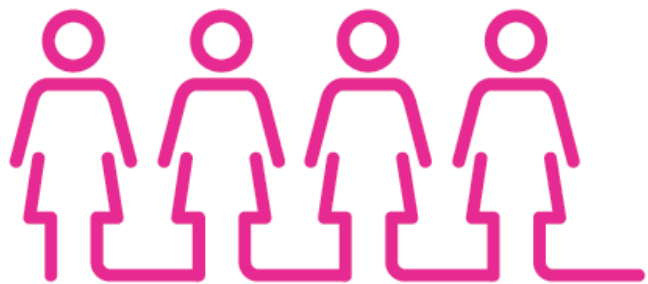
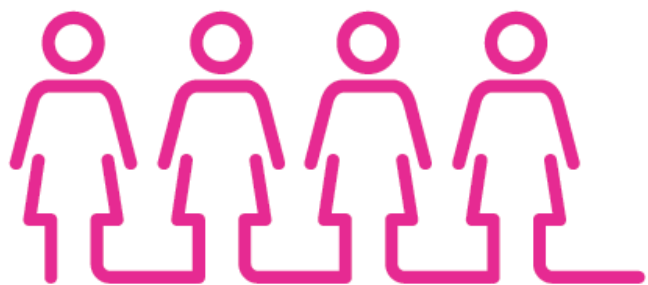
Prevenzione Serena – Screening mammografico – Workshop 2018

Torino, 6 dicembre 2018

Trial clinico randomizzato controllato multicentrico



**85,000
donne**

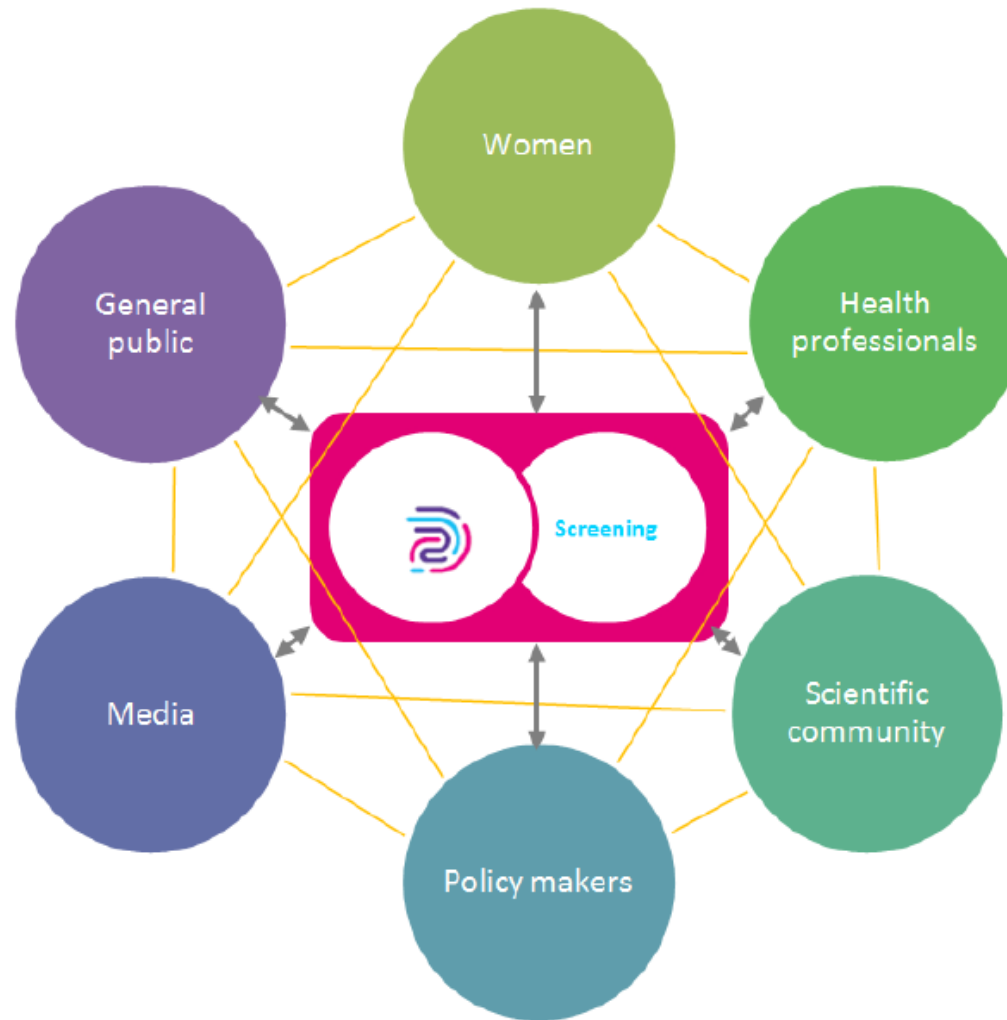


**STANDARD
SCREENING**

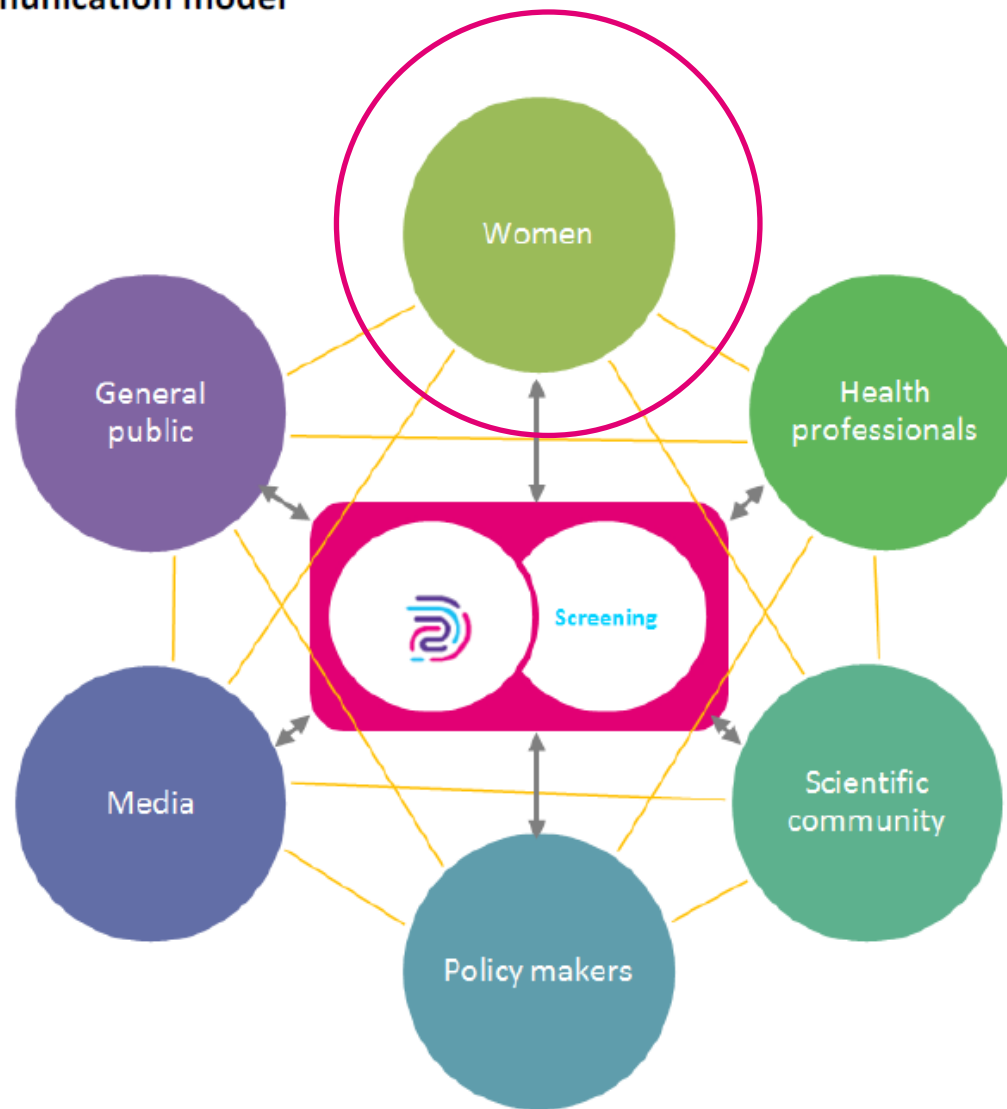


PERSONALISED SCREENING

MyPeBS Communication model





MyPeBS Communication model





Color
Brand palette



	MyPeBS Blue CMYK 68 - 0 - 0 - 0 RVB 0 - 210 - 255 Hex #00d2ff
	MyPeBS Pink CMYK 0 - 100 - 0 - 0 RVB 226 - 0 - 116 Hex #e20074
	MyPeBS Purple CMYK 76 - 90 - 0 - 0 RVB 117 - 59 - 189 Hex #753bbd
	MyPeBS Eggplant CMYK 80 - 92 - 30 - 24 RVB 73 - 43 - 93 Hex #492b5d



TOGETHER WE COULD IMPROVE **BREAST** SCREENING

You can join MyPeBS,
a unique trial on personalized
breast cancer screening



WHAT could be the benefits and risks of participation?

●● STANDARD SCREENING GROUP

For women in this group nothing will change compared with current screening practices. However, they will receive more information on breast cancer prevention and awareness than non-participants.

●●● PERSONALISED RISK-BASED SCREENING GROUP Compared to women in the standard group:

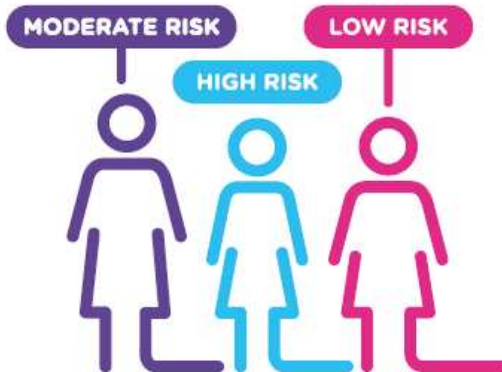
A woman who will have LESS FREQUENT mammograms

- will have a lower risk of incurring potential harms of mammography screening
- will have a higher risk of a cancer detected later (estimated risk of 1 woman per 1,000)

A woman who will have MORE FREQUENT mammograms

- will be more likely to have a cancer diagnosed earlier
- will have a higher risk of incurring potential harms of mammography screening

All women will receive information on how **to remain aware of their breast's health**. They will also be recommended to **periodically update their profile** on a secured area of MyPeBS portal. This will allow investigators to **eventually reassess a woman's risk and modify her screening schedule accordingly**.



ARE YOU INTERESTED?

Are you interested? To know how to participate, please call [local call centre number], or visit www.mypebs.eu



 **MyPeBS**
Personalising Breast Screening
www.mypebs.eu



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 755394



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 755394

[National / local logos as defined by national PIs]



TOGETHER
WE COULD
IMPROVE BREAST SCREENING

MyPeBS: the EU trial
on personalised
breast cancer screening

 **MyPeBS**
Personalising
Breast Screening

MyPeBS: the international, EU-funded trial on personalised breast cancer screening

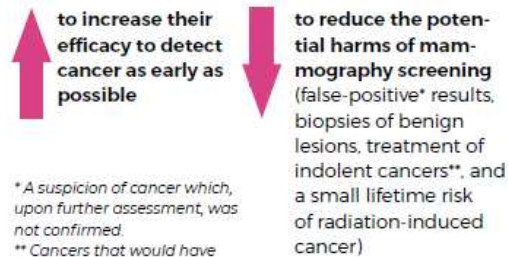
WHAT is MyPeBS?

MyPeBS (My Personal Breast Screening) is a research project, supported by the European Commission and run by leading international breast cancer prevention researchers and experts.

MyPeBS is a **clinical study** that will **compare the current practices of breast cancer screening to a personalised screening strategy**. It will involve **85,000 women** from Belgium, France, Israel, Italy and the United Kingdom.

WHY MyPeBS?

Organised breast cancer screening programmes set up in Western countries have played an important part in fighting breast cancer, but they can be improved further still:



*A suspicion of cancer which, upon further assessment, was not confirmed.

**Cancers that would have never caused problems during a woman's lifetime, if not detected by screening.

Scientific advances have provided us with **sufficient knowledge** to test a **new screening approach based on individual risk estimation of breast cancer**, assessed not only upon age, but also upon genetic factors, family history of cancer, and hormonal status. **This is the very goal of MyPeBS.**



WHO can participate in MyPeBS?

MyPeBS is open to women:

- between 40-70 years of age
- without a personal history of breast cancer
- without an already established very high risk of developing breast cancer
- who live in a participating region in one of the five countries involved in the trial

Participation is voluntary and can be withdrawn at any time. Women who cannot or do not want to participate will continue with their regular screening programme.

HOW does MyPeBS work?

A study investigator will describe the trial to interested women. Those who consent to participate will be asked a few questions about their health, family history and reproductive life, as well as knowledge and perception of breast cancer screening.

Then participants will be assigned **randomly** (by a computer) to one of the following **two study groups** (this will allow comparison of the two screening strategies):

●● **STANDARD SCREENING GROUP** Women's mammography screening schedule will continue according to the local/national screening programme. A mammogram will be needed after 4 years, at the end of the study.

●● **PERSONALISED RISK-BASED SCREENING GROUP** Each woman's individual risk score to develop a breast cancer in the next 5 years will be estimated based on:



Then each woman will receive a screening protocol for the next 4 years of follow-up, according to her own risk level:

RISK CATEGORY	YEAR 1	YEAR 2	YEAR 3	YEAR 4
LOW				1 mx
AVERAGE		1 mx 1us*		1 mx 1us*
HIGH	1 mx 1us*	1 mx 1us*	1 mx 1us*	1 mx 1us*
VERY HIGH	1 mx 1mri**	1 mx 1mri**	1 mx 1mri**	1 mx 1mri**

mx: mammogram
*us: ultrasound (**if breast density is high)*
*mri: Magnetic resonance Imaging (**until the age of 60)*

Participants will not receive remuneration, but all costs of exams will be covered by the study.



Everything you ever wanted to know about MyPeBS QUESTIONS & ANSWERS



Dear Madam,

In this booklet you will find answers to many of the questions you may have regarding your participation in MyPeBS. If you would like further clarification, please do not hesitate to contact study doctors / investigators or health professionals involved in the study.

INDEX

- 6 THE PROJECT
- 10 WHAT DO WE KNOW ABOUT BREAST CANCER SCREENING AND WHY DO WE NEED MYPEBS STUDY?
- 16 PARTICIPATING IN MYPEBS
- 33 USING MY PERSONAL AREA IN MYPEBS WEB PLATFORM
- 36 SAFETY, ETHICS AND TREATMENT
- 40 GLOSSARY

Through the document you will find some words with an "" You will find their definitions at the end of this booklet in the Glossary.

QUESTIONS TO BE ANSWERED BY THIS GUIDE

THE PROJECT

1. What does "MyPeBS" stand for?
2. What is the aim of MyPeBS?
3. Who leads MyPeBS?
4. Who funds MyPeBS?
5. Which countries participate in MyPeBS?
6. Which screening programmes participate in MyPeBS?

WHAT DO WE KNOW ABOUT BREAST CANCER SCREENING AND WHY DO WE NEED MYPEBS STUDY?

7. Why screen for breast cancer?
8. How is breast cancer screening implemented in participating countries?
9. What are the benefits of mammographic screening?
10. What are the limits and disadvantages of breast cancer mammography screening?
11. How may we estimate individual breast cancer risk towards potentially more effectively "targeted" screenings?

PARTICIPATING IN MYPEBS

12. What are the criteria for participating in MyPeBS?
13. Under which circumstances would a woman NOT BE ABLE to participate in MyPeBS study (exclusion criteria)?
14. How many women are expected to participate in MyPeBS?
15. How long is the participation of a woman in MyPeBS?
16. What would my participation in MyPeBS consist of?
17. Which questionnaires should I complete during my participation in MyPeBS?
18. Can I choose whether I participate in the standard screening group or in the personalised risk-based screening group?
19. How is a woman's breast cancer risk profile calculated (only for women allocated to the "personalised risk-based screening" group)?
20. If I am randomised to the standard group can I still be informed about my personal risk?
21. How does the analysis of genetic polymorphisms in the saliva DNA help estimate breast cancer risk?
22. Are any additional genetic analysis carried out for specific groups of women?
23. What happens with saliva sample residues that remain after the saliva test?

24. What breast cancer risk categories have been identified in MyPeBS?
25. What is the corresponding screening schedule for each risk category?
26. How can I be sure that I remember my test mammography?
27. Can my risk profile change during the duration of the project?
28. What should I expect from mammograms performed during the study?
29. What happens if I don't follow my screening examination schedule?

11. HOW MAY WE ESTIMATE INDIVIDUAL BREAST CANCER RISK TOWARDS POTENTIALLY MORE EFFECTIVE "TARGETED" SCREENING?

Our ability to identify women at higher or lower risk of developing breast cancer should make targeted breast cancer screening possible. This would result in offering more intensive screening for women at higher risk and reduced screening for those at lower risk. Reduced screening may lower the risk of the unintended adverse effects of breast cancer screening: false positives, overdiagnoses, and overtreatments, e.g. useless biopsies of benign lesions.

To do this, we need to estimate the individual risk influence the individual risk of developing breast cancer. At present, more than 300 of these polymorphisms have been described. Each individual variation only contributes a small amount of risk.

Over the last twenty years, European and American research teams have developed risk "scores", to estimate a woman's risk of developing breast cancer. These scores are now well-established and widely validated, especially in Europe. They use simple personal and clinical data like the woman's age, family history of cancer, personal history of benign/non-cancerous disease, and exposure to natural hormones (age of first period/menstrual cycle, pregnancy, age of menopause etc.) and medical hormones (hormone replacement treatments, the contraceptive pill etc.) and breast density score.

pregnancy, age of menopause etc.) and medical hormones (hormone replacement treatments, the contraceptive pill etc.) As part of every mammogram performed, the breast density is assessed in each woman and this "breast density score" also contributes to predicting individual risk.

In the last ten years, European and American researchers have been able to show that genetic polymorphisms (variations in the sequence of certain genes, in a substantial portion of the population) influence the individual risk of developing breast cancer. At present, more than 300 of these polymorphisms have been described. Each individual variation only contributes a small amount of risk. However, a score that includes about a hundred polymorphisms becomes much more predictive. Finally, by combining conventional clinical risk scores (created using data as described above) with the influence of polymorphisms we can identify women with different levels of breast cancer risk with more certainty.

BOX 5. ELEMENTS CONSIDERED FOR CALCULATING BREAST CANCER PERSONAL RISK-SCORES

PERSONALISED RISK-BASED SCREENING

Personal risk scores are based on:

- Woman's age
- Family history of cancer
- Personal history of benign/non-cancerous disease and exposure to natural hormones (age of first period/menstrual cycle, pregnancy, age of menopause etc.)
- Medical hormones (hormone replacement treatments, the contraceptive pill etc.)
- Breast density score
- Genetic polymorphisms

BOX 6. POTENTIAL BENEFITS OF PERSONALISED BREAST CANCER SCREENING.

WOMEN AT HIGH RISK

More intensive screening, possibly with earlier detection of cancer which is associated with more favourable outcome and less intensive treatments

WOMEN AT LOW RISK

Reduced frequency of screening, expected to lower unintended adverse effects of breast cancer screening (false positives, overdiagnosis, overtreatments).