MyPeBS

Personalising
Breast Screening

Breast cancer:
better detection for a better cure

MyPeBS: A European project towards personalised breast Screening

Press kit
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"All women have a different risk of developing breast cancer. At the moment, except for women at very high risk (with the mutation known as BRCA1/2), the screenings carried out in Europe, which vary from one country to another, do not take into account these differences. Is there a need to change screenings and adapt them to each individual's risk? Is it more efficient in limiting the number of cancers detected at an advanced stage? The goal of MyPeBS is to answer these questions and provide specific solutions to the problems raised by current screenings, such as false positives, the risk of overdiagnosis and overtreatment, repeated needless exposure to ionising radiation, interval cancers, etc.

If we succeed in proving the medical relevance of personalized screening, its acceptance by women and its economic sustainability, then MyPeBS will make it possible to unify European practices in a large revision of breast cancer screening.

And we hope that this will make it possible to save the lives of more women. Today, the success of this important study depends on the commitment of healthcare professionals and, above all, the women themselves who will choose to participate in this ambitious venture. This is why we are counting on you to pass on information."

Dr Suzette Delaloge,

Oncologist at Gustave Roussy, Villejuif, France and president of French Breast Cancer Intergroup, Unicancer, France
MyPeBS coordinator

Breast cancer:
better detection for a better cure

MyPeBS: A European project towards personalized breast screening

About MyPeBS

The context

AWith 360,000 new cases diagnosed and 92,000 deaths in Europe every year, breast cancer is the most frequently occurring cancer among women. Current screening campaigns target all women[1] using a single selection criterion: age. But these bring with them a certain number of pitfalls: false positives on mammograms, risk of overdiagnosis[2], even over-treatment or, on the other hand, the risk of certain women developing an interval cancer that is detected too late[3].

The study

MyPeBS (My Personal Breast cancer Screening) is the first European randomised clinical study, conducted on a European scale, that aims to evaluate the benefits of a screening programme where the frequency will be adapted to the individual risk of breast cancer for each woman. This study is conducted across multiple centres, in which 85,000 female volunteers between 40 and 70 years old will participate and be randomly placed in one of two groups:

- a group following standard screening, currently ongoing in the participating countries
- a group evaluating a new personalised screening strategy based on the individual risk of breast cancer.

unicancer

MyPeBS is coordinated by Unicancer, the main European academic sponsor in oncology

1 Excluding those who have been identified as being at a particularly increased risk, e.g. gene mutation BRCA1 or BRCA2

2 Overdiagnosis: a cancer detected following a screening but that develops so slowly that it never causes symptoms over the life of the woman concerned; however, it leads to other non-necessary examinations (e.g. biopsy), even needless cancer treatments. This is also referred to as over-treatment. This concerns approximately 1 breast cancer in 10 detected by screening.

3 An interval cancer is a cancer that appears between two negative screening exams

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About MyPeBS (continuation)

The main objectives

- To demonstrate that, in comparison to standard screening, personalised screening is at least as efficient in terms of detecting advanced cancers at diagnosis (stage two and above).
- In the long run, to save more women by reducing the number of breast cancers diagnosed at an advanced stage.

The other objectives

The study will compare both screening strategies in terms of the rate of false positives and overdiagnosis, but also the psychosocial impact on the participants and the cost-effectiveness ratio.

funding

MyPeBS project has received 12.4 million Euros of funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 755394. Coordinated by Unicancer, MyPeBS brings together seven countries and 26 European and American partners.

The participants

Seven countries are involved in the project: France, Italy, Israel, Belgium, the United Kingdom, the Netherlands, USA.

Five recruiting countries:

- France (20,000 female volunteers expected)
- Italy (30,000 female volunteers expected)
- Israel (15,000 female volunteers expected)
- Belgium (10,000 female volunteers expected)
- United Kingdom (10,000 female volunteers expected)

Study duration: six years

What is the personalised screening in MyPeBS?

MyPeBS intends to assess the value in screening based on the individual risk of developing breast cancer in the next 5 years.

This risk will be calculated using various personal details from each woman, such as her age, family history of cancer (which is strongly linked to genetic factors), hormonal "status" (e.g. age when first period occurred), breast density.

This personalised screening will suggest carrying out mammograms at a frequency adapted to this individual risk level: the higher the risk, the more important frequent screenings are. This should make it possible to **detect breast cancer as early as possible in women who are at the most risk and to reduce exposure to the harmful effects of mammograms for women who are at low risk,** such as false positives, over-diagnosis, over-treatment, anxiety due to over-diagnosis and over-treatment, (rare) radiation-induced cancers.

In some cases, a magnetic resonance imaging (MRI) scan and an additional ultrasound may be suggested.

What are the objectives of the MyPeBS study?

The aim of the MyPeBS study is to evaluate whether screening that is personalised according to the individual risk of breast cancer is at least equally effective as, or even more so than, standard screening to detect breast cancer before it is advanced.

MyPeBS will also assess if this strategy of personalised screening can reduce the potentially negative consequences of standard screening using mammograms, notably needless biopsies following "false positives" or over-diagnosis (2), leading to over-treatment.

Furthermore, the study will compare the socio-psychological and socio-economic impact of the two screening strategies by evaluating women's satisfaction, anxiety, etc.

After analysing all the results of the study, **the MyPeBS European project will offer general recommendations for the best possible breast cancer screening in Europe.**

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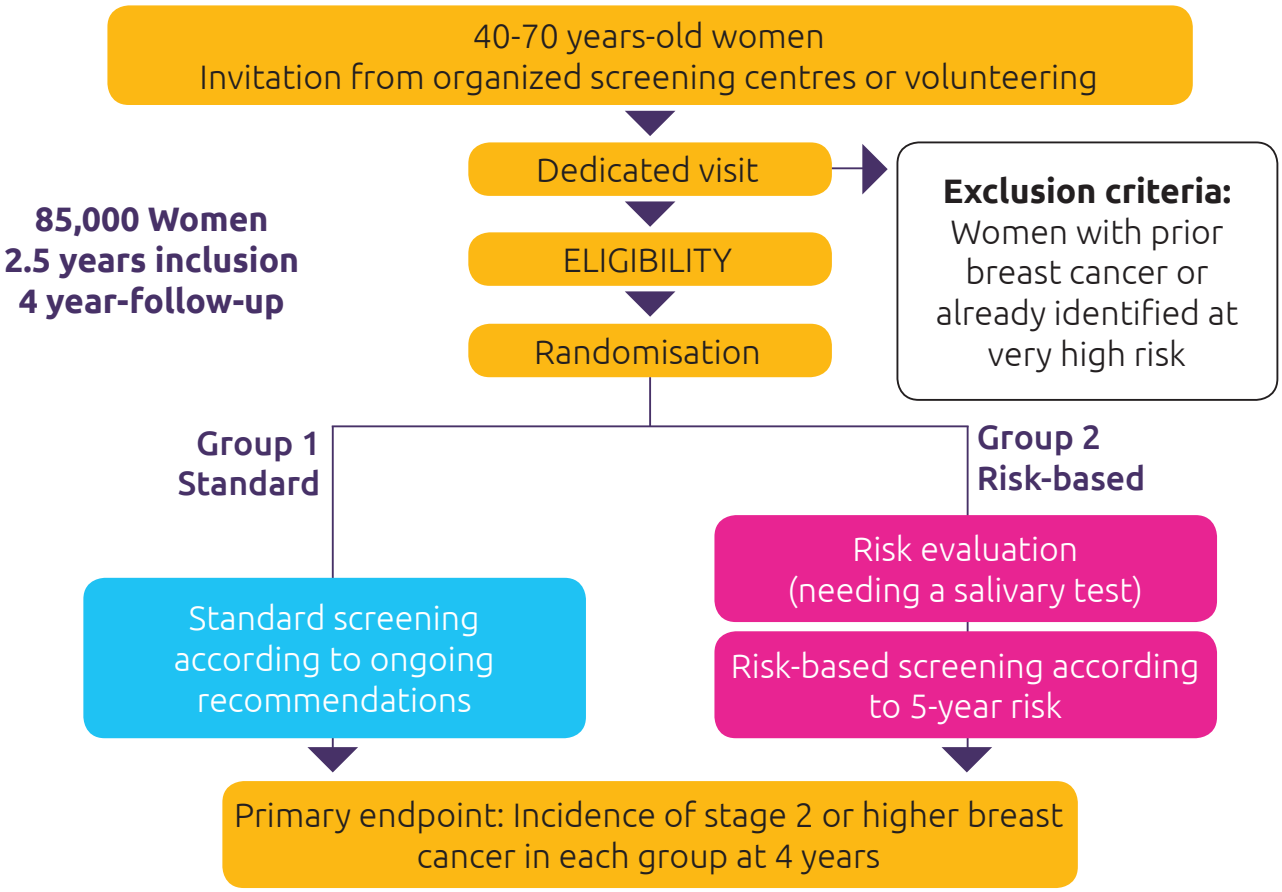
MyPeBS: Study scheme



What is a randomised study?

MyPeBS is a randomised study, which means that women who want to take part will be assigned at random (random draw by a computer) to one of two screening programmes: either standard screening (group 1) or screening based on risk (group 2).

Randomisation makes it possible to create comparable groups.

In MyPeBS, women will have a one in two chance (50%) of being allocated into one or the other group.

- In group 1, they will follow the standard course of screening.
- In group 2, they will have a screening programme that is personalised according to their individual risk of developing breast cancer in the next 5 years.

How to get involved with the study

www.mypebs.eu

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How to get involved with the study (continuation)

Step 1: Eligibility test

Women who would like to take part in the study must verify if they check the "administrative" criteria to do so: are they the required age and do they live in a participating area?

The pre-eligibility test can be found online at www.mypebs.eu

Step 2: Introductory appointment

Pre-eligible women will then contact one of the investigating doctors (radiologists, GPs, gynaecologists), a list of which is available on the website.

They will then meet for an introductory appointment, during which the women will be given more information and the doctors will verify their medical histories and provide the information documents on the subject of the study.

After having read the information and asked their doctors all their questions, the participants will then be asked to sign a consent form to participate in the study.

Step 3: Entering data

All of the information on the study will be entered by the participants and the investigators into an online platform dedicated to the MyPeBS study via personal and secure access.

The women taking part can also access their own online space in which they can find their screening programme, their questionnaires and letters to be printed for their various doctors, if needed, etc.

The participant women's clinical information will be anonymised, as required by regulations on clinical trials.

How to get involved with the study (continuation)

Step 4: Separation into groups

The participants will then be randomly placed in one of two groups:

- **Either the "standard screening group":** their screening schedule, or the schedule for their mammograms, will follow the standard screening programme in place for the four years of participating in the study. There will not be any other appointments as part of the MyPeBS study.
- **Or the "personalised screening based on risk" group:** during the introductory appointment, participants will be asked to provide a sample of saliva, which will be used to analyse their DNA. This analysis will look into a group of factors (genetic polymorphisms) that are associated with an increased risk of breast cancer. The saliva samples will be sent to a specialist analysis lab in France and analysed there. Their level of risk, based primarily on this genetic analysis, will be sent to them after a few weeks.

Step 5: Second visit ONLY for the women in the "personalised screening based on risk" group

The second visit will take place around 12 weeks after the introductory appointment, by which time the genetic analyses will be complete.

In the run up to the date of the scheduled visit(s)/scan(s), the participants will receive a reminder by letter, e-mail or text message.

They will be told their risk level, which will be explained by their investigator, during this second visit, and will also receive their personalised screening programme, which is the schedule of their mammograms (and other radiological examinations, if this is the case) for the next four years.

What are the potential consequences for the women who participate in the MyPeBS study?

For women in the standard screening group, nothing will change with regard to the current screening practices; on the other hand, these women will receive more information on preventing breast cancer than those who have not participated in the study.

For women in the "personalised screening based on risk" group:

- Participants whose risk level is associated with **less frequent exams** than the standard screening schedule in place in their area will have fewer risks of being exposed to the harmful effects linked to screenings using mammograms. In order to reduce the risk of detecting cancer later than with the standard screening schedule (this risk is estimated to be around 1 women in 1,000), these women will be "followed" closely: they will receive regular recommendations aimed at warning about and detecting breast cancer (e.g. self-examination, appointments with gynaecologists or GP if it is suspected) and they will be asked to periodically update their personal information to reevaluate their risk profile if needed and, if need be, their screening schedule.
- For participants whose higher risk will be combined with **more frequent exams,** breast cancer should be detected earlier than with standard screening, which will enable a decline in the associated morbidity and mortality. On the other hand, the risk of being exposed to the harmful effects of screenings by mammogram will potentially be higher. Mammograms will be carried out in accordance with the organised screening standards with a very high level of technology and a second systematic analysis.

Testimonies of volunteers

"Being in a so-called 'monitored age group', I wonder if age is the sole criterion on which this should be based? Apart from women identified as being at risk. I was convinced by this MyPeBS study because of the fact that it is personalised. 'No more standardisation'. In addition, I am proud to make my contribution to this major public health study."

Mariem • France

"I've been wondering about breast cancer screening for several years. Several articles cause doubts and I wonder if the way we screen today is the best way. When I heard about this scientific study, I was immediately interested because a robust scientific study is the only indisputable way to answer this question. Therefore, I have committed to participate in this study, even if I know that I have only a 50% chance of benefiting from individual screening since it will be randomised, as is the rule for any well-conducted scientific study. The results of the study will benefit all women in the following generations and this is sufficient motivation for me."

Karine • Belgium

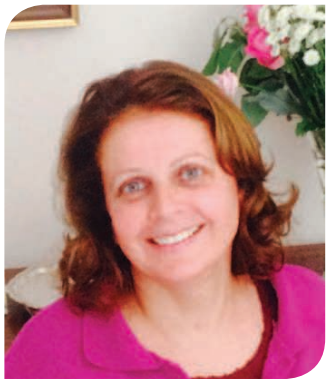
"Every two years, I participate in the Italian screening programme. Every time I am in the clinic, waiting for my mammogram, I see how different we are and I wonder if the 'one size fits all' approach is really the only solution. Finally, someone seriously wants to test if personalization can improve prevention."

Elisabetta • Italy

Testimonies of volunteers (continuation)

"I always have a breast cancer screening and am very pleased that my local health service has such a well-organised programme. Since I am a firm believer in screening and in public health, I would be happy to participate in a trial that aims to improve screening."

Jacqueline • Italy



"It is extremely encouraging to see that MyPeBS, a European study, is looking at personalising breast screening. It evaluates the necessity of how frequently mammograms should be offered to women, particularly women like myself who are encouraged to have one every three years. Should my mammograms be more or less frequent? What is even more interesting is the personalisation of screening women who fall into different categories, from low to high-risk groups."

Sarah • United Kingdom

"My hope is that personalized medicine will improve the early detection of breast cancer in the general population of women being screened. I find it exciting that with the help of new, non-invasive technology we can potentially improve detection and quality of life for many women. A diagnosis of breast cancer has so many ramifications for a woman. For many, their breasts are a part of their self-image and an earlier diagnosis can affect the choices a woman may have. If breast cancer is diagnosed, personalized screening and detection will hopefully become a part of the continuum which already includes personalized treatments today. "

Clarit • Israel

France

67 million
inhabitants

54,000
new cases per year

12,000
deaths per year

Current screening: inviting women between 50 and 74 years old to have a mammogram every two years.

MyPeBS: 20,000 female volunteers expected

Principal investigator:
Dr Corinne Balleyguer
(Gustave Roussy, Villejuif)

"By offering women personalised breast cancer screening, MyPeBS will make a notable contribution to homogenizing screening for women between 40 and 50 years old. In fact, at the moment most of these women have had at least one mammogram, even if this does not conform to French national recommendations. MyPeBS will undoubtedly also contribute to making improvements for women taking part in national screenings. Currently, barely more than one in two participate."

Press contact:

Claire Parisel (Gustave Roussy)
+ 33 6 17 66 00 26 / claire.parisel@gustaveroussy.fr

Véronique Simon (Fondation ARC pour la recherche sur le cancer – ARC Foundation for Cancer Research)
+ 33 6 73 14 38 79 / vsimon@fondation-arc.org

MyPeBS
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Italy

60 million
inhabitants

50,000
new cases per year

12,700
deaths per year

Current screening: as a rule, inviting women between 50 and 69 years old (up to 74 years old in certain regions) to have a mammogram every two years. In some regions, screening takes place annually.

MyPeBS: 30,000 female volunteers expected

Principal investigator:
Dr Paolo Giorgi Rossi (Reggio Emiliae)

"In most Italian regions, including Piedmont, Lombardy, Veneto, Emilia-Romagna and Tuscany, screening programmes are very well organised and have had a positive impact on breast cancer mortality. Even if the current screening programmes have a positive benefit-risk ratio, they nevertheless have limits in terms of the benefits and causing side effects. Personalising screening on the basis of individual risk for each woman, which is assessed through state-of-the-art molecular and imaging technologies, might increase benefits and reduce the risk. Our goal is an improved screening programme that is developed on the basis of scientific evidence and made available to the entire population. The challenge is to provide all women with access to optimal prevention."

Press contact:

Federica Gazzotti
+ 39 522 335296 / 329 2104811 / federica.gazzotti@ausl.re.it

United Kingdom

66 million
inhabitants

55;000
new cases per year

11,500
deaths per year

Current screening: inviting women between 50 and 73 years old to have a mammogram every three years.

MyPeBS: 10,000 female volunteers expected

Principal investigator:
Pr Fiona Gilbert (University of Cambridge)

"We need to change the model of breast cancer screening used in the United Kingdom and recognise that women are individuals with different risks and lifestyles. Therefore, they should be offered customised screening tailored to their own profile."

Press contact:

Craig Brierley (Université de Cambridge)
+ 44 (0)1223 332300 / craig.brierley@admin.cam.ac.uk

MyPeBS
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Belgium

11,5 million
inhabitants

10,500
new cases per year

2,500
deaths per year

Current screening: inviting women between 50 and 69 years old to have a mammogram every two years.

MyPeBS: 10,000 female volunteers expected

Principal investigator:
Dr Jean-Benoît Burrion
(Institut Jules Bordet, Bruxelles)

"In Belgium, the breast cancer screening programme started in 2001. Its implementation is organised by the regional authorities. Just like in other countries, the programme is currently being questioned, given the limits and inconveniences it may have. Past simplistic promotion has been turned into a communication-based approach on the risks and benefits. For many decision makers, stakeholders and beneficiaries, a screening programme that takes into account only age is unsatisfactory. We now have validated tools to evaluate individual risk in a standardised, reliable and reproducible manner. The MyPeBS study is an excellent opportunity to test cancer screening that is based on individual risk, together with a quality control policy. The key to MyPeBS is more efficient screening, with fewer disadvantages for women. For public authorities, it is the prospect of qualitative and quantitative progress."

Press contact:

Ariane van de Werve (l'institut Jules Bordet)
+ 32 48617 33 26 / ariane.vandewerve@bordet.be

Israel

8,8 million
inhabitants

4,500
new cases per year

900
deaths per year

Current screening: excluding those at a very high risk, inviting women between 50 and 74 years old to have a mammogram every two years.

MyPeBS: 15,000 female volunteers expected

Principal investigator:
Dr Michal Guindy
(Assuta Medical Centers,Tel-Aviv - Jaffa)

"Israel has a very high incidence of breast cancer. Consequently, screening in Israel is widespread and current guidelines for breast cancer screening in place do not offer a solution for women aged 40-50 who are at risk for developing the disease in a more severe and deadly instance. The study may offer a practical method for a new balance between doing too much and not enough. This collaborative research supported by the EU empowers winning global partnerships that will have potential to create real policy change worldwide, as well as facilitate other partnerships beyond this study."

Press contact:

Yonit Amar (Assuta Medical Centers)
+ 972 54-8170115 / yonita@assuta.co.il

The 26 partners

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

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contact@mypebs.eu