





Communication of breast cancer risk and a personalized screening protocol: experience within the MyPeBS Study

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The project

"My Personal Breast Screening"

Randomized Comparison Of Risk-Stratified versus Standard Breast Cancer Screening In European Women Aged 40-70



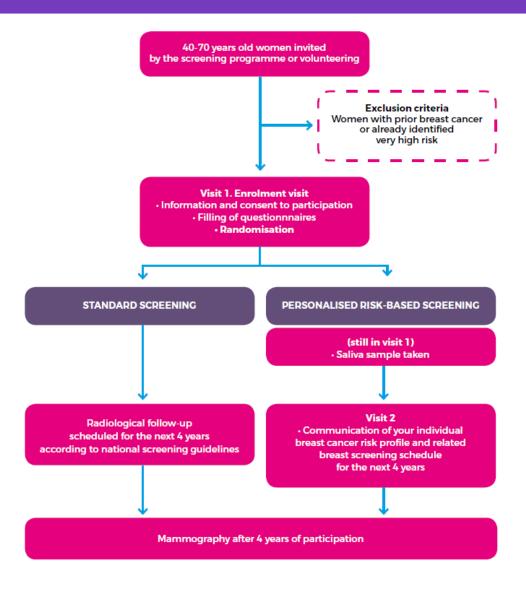
Study design

- International, multicentric EC-funded RCT
 - Belgium, France, Israel, Italy, Spain, UK
- Accrual target = 56.435 women
- Intention-to-treat analysis
- Main endpoints:
 - Non-inferiority in terms of incidence rate of breast cancer of stage 2 and higher
 - Superiority if non-inferiority is shown
 - Cost-effectiveness and acceptability

of risk-stratified breast cancer screening compared to standard screening

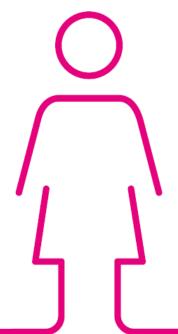


Trial flowchart





Risk estimation



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 replacements treatments, the contraceptive pill etc.)
- Breast density score
- Genetic polymorphisms





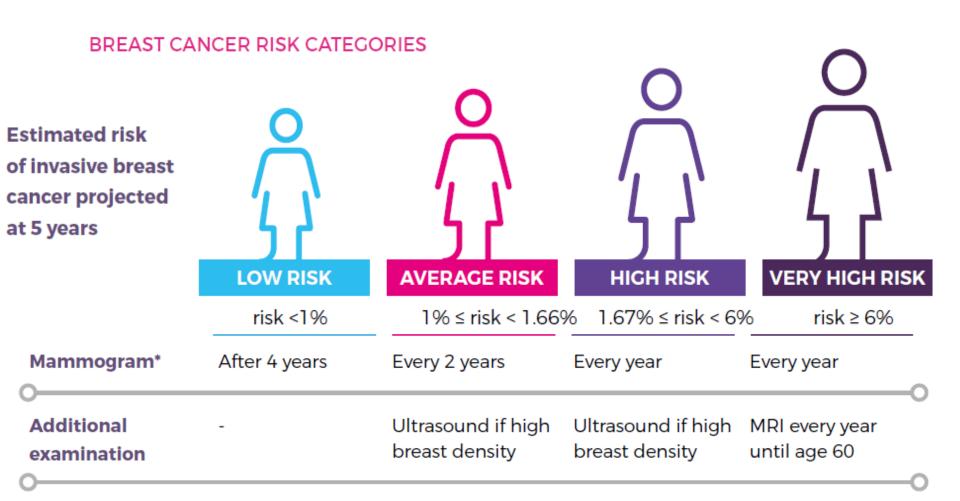


TYRER-CUZICK SCORE for participants with a family history of BC

BCSC SCORE for **general** screening population



Risk stratification and personalised protocols



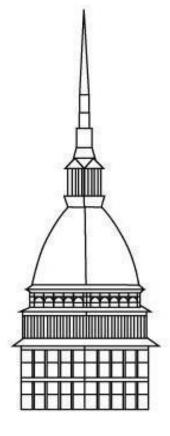


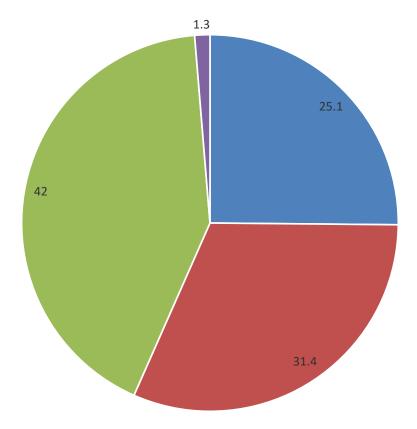
MyPeBS in Turin



4,461 participants
2,080 in the risk-based arm

RISK DISTRIBUTION 19/06/2023







Communication of individual risk and screening schedule





Risk communication



Interactive, bidirectional process
involving exchange of
information and
opinions related to
benefits and risks



Aims at improving risk comprehension and promoting informed choices



Communication of uncertain (statistical) data is critical



Risk communication in MyPeBS

- Specific visit dedicated to RC
- Video-tutorial distributed to all investigators as a part of the training programme
- Individual risk sheet
 - developed for helping women in understanding their risk condition and screening pathway
 - available on the participant's personal web account
 - delivered during the risk communication session



Individual risk sheet



Tube ID	XXXXX
Name:	

Personal Breast Cancer Risk Evaluation and Screening Programme

What is your breast cancer risk?

Compared to the average risk for women of your age, your breast cancer risk is



In this risk category, about 1 in 70 women may develop breast cancer within the next 5 years.

What personalised screening programme is proposed for you?

Mammogram	Ultrasound
✓	√
✓	✓
✓	✓
	Mammogram ✓

Ultrasound only if high breast density (D)

Basis of your risk estimation: This estimation was done using information you provided in your questionnaires + your breast mammographic density + your saliva test result (Polygenic risk score)

✓ Is there anything you need to be aware of?

- It is important that you update your personal data on your personal MyPeBS portal [http://portal.mypebs.eu] every year so that we can reevaluate your risk if required and eventually update your personal program.
- · And that you remain breast cancer-aware: please see a doctor if you identify something abnormal in one of your breasts (color change, mass, change in shape, discharge, etc.) [for more information: https://ww5.komen.org/BreastCancer/WarningSigns.html].

Is there anything you can do to reduce your risk?

Yes there are some things that you can do to reduce your risk of breast cancer:



Maintain a healthy body weight



Limit the amount of alcohol you drink



Eat a healthy diet with plenty of vegetables and fruits



Exercise regularly

Where can you get more information on risk reduction?

Institut National du cancer [to be adapted to each country]:

http://www.e-cancer.fr/Comprendre-prevenir-depister/Reduire-les-risques-de-cancer

You may find additional information on risk reduction measures on: https://cancer-code-europe.iarc.fr/index.php/fr/

You also need to know...

If you want more detailed information on your risk estimation Please ask your investigator who will be able to provide more details .

If you think your risk estimate may need re-evaluation Please enter new data that may change your risk estimation (new cancer in your family, new data on a breast biopsy, etc.) into your personal MyPeBS portal [http://portal.mypebs.eu]. Your risk level will be reestimated and a new sheet sent to you if your risk category has changed!

Queries about the MyPeBS study or result You will find information on your MyPeBS personal portal [http://portal.mypebs.eu]. For medical questions, please ask your MyPeBS investigator or personal physician.

If you have been diagnosed with breast cancer Please report this diagnosis in your personal MyPeBS portal. Being part of MyPeBS does not change your care.

For more information on MyPeBS trial and project www.mypebs.eu

Investigator / Center contacts

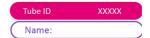


Individual risk sheet

Tube ID

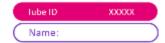
Name:





Personal Breast Cancer Risk Evaluation and Screening





What is your breast cancer risk?

Compared to the average risk for women of your age, your breast cancer risk is



	Mammogran
Now (if not done)	4
Oct 2019	✓
Oct 2020	✓
Oct 2021	✓
Oct 2022	✓

What personalised s

programme is propose

Ultrasound only if high b

Basis of your risk estimation: This estimation was done using information your questionnaires + your breast mammographic density + your saliva test r risk score)

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Personal Breast Cancer Risk Evaluation and Screening Programme

What is your breast cancer risk?

Compared to the average risk for women of your age, your breast cancer risk is



In this risk category, more than 1 in 17 women may develop breast cancer within the next 5 years.

What personalis

Now (If not done)

Oct 2020 Oct 2021

Oct 2022

A visit with a geneticist (genetic counselling) i

Basis of your risk estimation: This estimation was done using information questionnaires + your breast mammographic density + your salva test (score)

✓ Is there anything you need to be aware of?

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- * For you or a family member who had cancer. Your investigator will provide information and contacts for this visit.

Personal Breast Cancer Risk Evaluation and Screening Programme

What is your breast cancer risk?

Compared to the average risk for women of your age, your breast cancer risk is

Personalising

Breast Screening



In this risk category, **less than 1 in 120 women** may develop breast cancer within the next **5 years**.

What personalised screening programme is proposed for you?

XXXXX

	Mammogram
Now (if not done)	✓
Oct 2019	
Oct 2020	
Oct 2021	
Oct 2022	✓

Basis of your risk estimation: This estimation was done using information you provided in your questionnaires + your breast mammographic density + your saliva test result (Polygenic risk score)

✓ Is there anything you need to be aware of?

Your risk is low but you do not have no risk! You will not have a mammogram until 4 years after you joined the study but it remains important:

- That you update your personal data on your personal MyPeBS portal [http://portal.mypebs.eu] every year so that we can reevaluate your risk if required and eventually update your personal program.
- That you remain breast cancer-aware: please see a doctor if you identify something abnormal in one of your breasts (color change, mass, change in shape, discharge, etc.) [https://wwb.komen.org/BreastCancer/WarningSigns.html].



Riskbased screening sche<u>dule</u>

Frequencybased representation

of risk

Compared to the

of your age, you

Warning about

breast awareness and

update on relevant

information

isk Evaluation and Scree Programme

Tube

Name

What personalise reening programme is proposed for you?

	Mammograi	Ultrasound
Now (if not done)	✓	√
Oct 2019		
Oct 2020	✓	✓
Oct 2021		
Oct 2022	✓	✓

Ultrasound only if high breast density (D)

Basis of your risk
your questionnaires +
ammographic density + your saliva test result (Polygenic risk score)

✓ Is there anything you need to aware of?

for women

cer risk is

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Indivi

Primary prevention recommendations

Is there anything you can do to re

Yes there are some things that you can do to reduce



Maintain a healthy body weight



Eat a healthy diet with plenty of vegetables and fruits



Country-specific information

you d

Limit

Where can you get more information on risk red

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Instructions on the webplatform use

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What we have observed

WOMEN AT HIGH RISK



- Feel reassured by a more intensive screening
- Expectations towards the high score (relatives with cancer, frequent recalls)

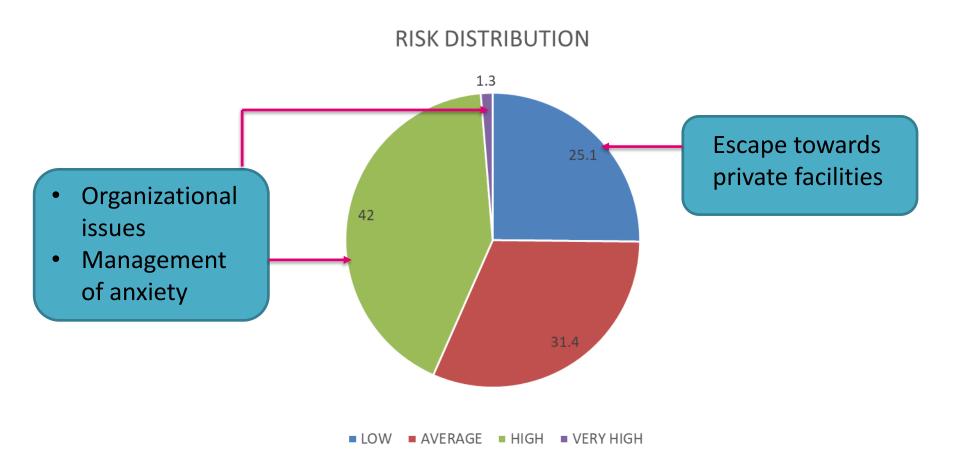
WOMEN AT LOW RISK



- Insecurity respect to the prolonged interval
- Drop out from the study (60% of withdrawn participants)
- Crucial to explain that low risk doesn't mean «no risk»



Critical points for possible implementation





Conclusions

Sensitization and training of HPs (also out of the screening)

Stakeholders' involvement

CULTURE CHANGE

Awareness and education campaigns

It's a long process: acceptability is an issue in the short term

