
Executive summary

Health Council of the Netherlands. Population Screening Act: research into familial risk in the screening programme for breast cancer. The Hague: Health Council of the Netherlands, 2014; publication no. 2014/23

In this advisory report the Committee on Population Screening of the Health Council of the Netherlands assesses a license application for scientific research by the Radboudumc in Nijmegen. The study aims to ascertain if (extra) anxiety is associated with an online questionnaire form familial risk for breast cancer within the regular population based screening programme for breast cancer. At the request of the Minister of Health, Welfare and Sport the committee advises about the license application for this study within the framework of the Population Screening Act.

According to the guideline (www.oncoline.nl) familial breast cancer (depending on risk and age) more intensive screening can be advisable for women with increased familial or hereditary risk for breast cancer than in the regular national population based screening programme. The use of an online questionnaire can standardise and facilitate the detection of these families, but could also cause extra anxiety. The committee finds it useful to examine this. However, on the condition, that the control group is omitted, as it has no added value for this research.

The committee finds that the provision of information, the informed consent procedure and the complaints procedure correspond with the requirements of the WBO, on the condition that it will be clearly explained that there can be consequences for nearest family members as well.

The burden of the study is limited to filling out a questionnaire on two occasions. More intensive screening with mammography means a higher

radiation burden for the women who conform to the guideline, but the risks involved remain relatively limited. And according to the committee, the expected benefits of more intensive screening would outweigh these risks for women with at least a two times higher risk for breast cancer than the average risk. Therefore the benefit risk ratio is considered positive.

The committee has one final condition, that will be registered at least how many women (female participants and family members) with an increased familial risk for breast cancer are detected by this research and how many of them conform to the guideline.

The committee recommends the Minister of Health, Welfare and Sport to grant the license under the three conditions:

- 1 the control group will be omitted
- 2 it will be clearly explained that there can be consequences for nearest family members as well
- 3 it will be registered how many women (female participants and family members) with an increased familial risk for breast cancer are detected by this research and how many of them conform to the guideline.