PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

What influence do information brochures have on the decision-making of women to take part in mammographic screening?

Trial Acronym

MaScE

URL of the trial

[---]*

Brief Summary in Lay Language

Since summer 2010 in Germany there is a new information brochure for mammography screening. While the old brochure did hardly contain any relevant information for screening (it was more promoting screening), the new brochure provides information to the reader that enables her to make an “informed decision”. We would like to find out if after reading the new brochure women have more knowledge on facts about screening than after reading the old brochure, and if this knowledge influences the willingness to attend screening. The study will be carried out in GP’s surgeries, and one group of women will read the old brochure, one group the new one. Both groups will fill out a questionnaire on comprehension of facts about mammography screening, and on the willingness for attending the screening. Women at the age oft 48-49y are included into the study, this is just before they are invited officially for screening for the first time.

Brief Summary in Scientific Language

Since September 2010 an information brochure is sent to women when they are invited for mammographic screening together with the invitation letter, which contains considerable more significant information regarding benefits and risks of the screening than previously sent brochures, thus offering a better basis for an informed decision.
There is no such information brochure in other countries yet that informs as comprehensively as ours. An argument against comprehensive information is the worry that the number of participants might decrease due to the small individual benefit. The aim of the study is to find out whether women are less interested in taking part in the screening after reading the “new” brochure than after reading the “old” brochure. Additionally, we would like to find out whether there is more knowledge about the screening in one group, and whether there are other influencing factors for or against the participation in the screening.

Organizational Data

- DRKS-ID: **DRKS00004271**
- Date of Registration in DRKS: **2012/08/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **3797 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**
- Free text: **Mammography screening, patient information**

Interventions/Observational Groups

- Arm 1: **Completion of a questionnaire after reading the new information brochure for mammography screening**
- Arm 2: **Completion of a questionnaire after reading the old information brochure for mammography screening**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, data analyst**
- Control: **Active control**
- Purpose: **Screening**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, data analyst**

Control: **Active control**

Purpose: **Screening**

Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Percentage of the expressed willingness of participation compared to the group with the new brochure (Group A) versus the group with the old brochure (Group B).

Secondary Outcome

Multivariable analysis of willingness to participate depending on knowledge, personal experience, the kind of brochure, demographic variables, and influences through the media

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Institut für Allgemeinmedizin, medizinische Fakultät, Düsseldorf**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/15**
- Target Sample Size: **350**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **48 Years**
- Maximum Age: **49 Years**

Additional Inclusion Criteria

women of the eligible age who are able to read and understand German.

Exclusion criteria

Women who are not oble to read or understand German or are mentally disordered, and women of whome it is known they have had breast cancer.

Addresses

- **Primary Sponsor**

  Institut für Allgemeinmedizin
  Universitätsklinikum Düsseldorf
  Ms. Dr. Elisabeth Gummersbach
  Moorenstr. 5
  40225 Düsseldorf
  Germany

  Telephone: **0211 8117771**
  Fax: **[---]***
  E-mail: **elisabeth.gummersbach at med.uni-duesseldorf.de**
  URL: **http://www.uniklinik-duesseldorf.de/allgemeinmedizin**
- **Contact for Scientific Queries**

  Institut für Allgemeinmedizin
  Universitätsklinikum
  Ms. Dr. Elisabeth Gummersbach
  Moorenstr. 5
  40225 Düsseldorf
  Germany

  Telephone: **0211 8117771**
  Fax: **[---]***
  E-mail: **elisabeth.gummersbach at med.uni-duesseldorf.de**
  URL: **http://www.uniklinik-duesseldorf.de/allgemeinmedizin**
- **Contact for Public Queries**

  Institut für Allgemeinmedizin
  Universitätsklinikum

Contact for Public Queries

Institut für Allgemeinmedizin
Universitätsklinikum
Ms. Dr. Elisabeth Gummersbach
Moorenstr. 5
40225 Düsseldorf
Germany

Telephone: **0211 8117771**
Fax: **[---]***
E-mail: **elisabeth.gummersbach at med.uni-duesseldorf.de**
URL: **http://www.uniklinik-duesseldorf.de/allgemeinmedizin**

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Institut für Allgemeinmedizin
Universitätsklinikum Düsseldorf
Moorenstr. 5
40225 Düsseldorf
Germany

Telephone: **0211 8117771**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/05/28**

Trial Publications, Results and other documents

- Abstract **DEGAM-Kongress 2014**
- Paper **Publikation im Deutschen Ärzteblatt**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*