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Informed shared decision making supported by decision coaches for women with ductal carcinoma in situ

Submission date 04/06/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/06/2015	**Overall study status** Completed	
Last Edited 26/06/2019	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Women with breast cancer want to participate in treatment decision making. SDM includes a mutual decision making process between patients and healthcare professionals considering all relevant information on treatment options and patients´ preferences. It enables patients to make informed decisions. Up to now implementation of SDM has failed due to e.g. limited resources of physicians and lack of evidence-based decision aids. We developed an SDM programme for women with primary ductal carcinoma in situ (DCIS). It includes an evidence-based patient decision aid, training of specialized breast care and oncology nurses, workshop for physicians, and decision coaching for women. The programme aims at supporting involvement in decision making and informed choices.
In this study we investigate if women receiving evidence based decision aids and decision coaching by specialised nurses will be more involved in treatment decision making than women receiving standard care.

Who can participate?
Women are eligible if they are at least 18 years old, have no known BRCA1/2-mutation, are not pregnant and have a primary DCIS. All participants need sufficient German language skills.

What does the study involve?
The trial compares the SDM programme with standard care. 16 certified breast care centres will be included recruiting 192 women with primary DCIS. Two study groups (intervention and control group) are compared. The intervention includes a four day training programme in SDM for specialised nurses, a two hour-lasting workshop in SDM for physicians and an evidence-based patient decision aid and decision coaching for women. Women in the control group receive standard care.

What are the possible benefits and risks of participating?
It is expected that the provision of an evidence-based patient decision aid combined with

decision coaching will increase women´s involvement in decision making and informed choices. The intervention will reduce women's decisional conflicts and the duration of physician encounters. We expect no harm for participating women.

Where is the study run from?
The study will include 16 certified breast care centres in the following federal states of Germany: Schleswig-Holstein, Hamburg, Bremen, North Rhine-Westphalia, Hessen, Saxony-Anhalt, Mecklenburg-West Pomerania and Lower Saxony.

When is the study starting and how long is it expected to run for?
October 2014 to March 2016

Who is funding the study?
German Ministry of Health

Who is the main contact?
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Study website
www.spupeo.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Informed shared decision making supported by decision coaches for women with ductal carcinoma in situ: a cluster-randomized-controlled trial

Acronym
SPUPEO

Study objectives
The main hypothesis is that patients facing a primary treatment decision on ductal carcinoma in situ (DCIS) who receive an evidence-based decision aid combined with decision coaching by specialized nurses are more involved in treatment decision making compared to patients receiving standard care. The extent of physicians', patients' and nurses' shared decision making-behaviour will be assessed using the observer-based rating of the `multifocal approach to the sharing in shared decision making´ (MAPPIN-SDM). In addition, we hypothesize that in the intervention group informed choices will increase, decisional conflict will decrease and the duration of physician consultations will be shortened.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the German Society of Nursing Science - Witten, 19/05/2015, ref: EK 15-003

Study design
Superiority cluster-randomized-controlled trial with a parallel group design and with 1:1 allocation ratio.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format and only in German language. Please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Breast cancer, ductal carcinoma in situ, primary treatment decision, shared decision making

Interventions
1. Intervention group: SPUPEO programme comprising:
1.1. Evidence-based decision aid on the primary treatment of ductal carcinoma in situ
1.2. Nurse training (four days divided into two modules)
1.3. Workshop for physicians (two hours) and
1.4. At least one decision coaching session for the participating patients.
2. Control group: The health care professionals in the control group receive no intervention and will deliver standard care.

Intervention Type
Other

Primary outcome measure
The primary outcome is defined as the extent of informed shared decision making-behaviour (SDM-behaviour) of physicians, nurses and patients during the consultations and the decision coaching sessions. We will measure SDM-behaviour using the observer based instrument MAPPIN-O of the “multifocal approach to the ‘sharing’ in shared decision-making” (MAPPIN). It assesses the mutual SDM-behaviour of health care professionals and patients based video-recordings. In the control group the physician consultations will be rated, whereas in the intervention group nurse and physician encounters will be summed up. All ratings will be performed independently by two trained observers.

Secondary outcome measures
1. Observer based rating of SDM-behaviour of patients alone (MAPPIN-Opatient)
2. Observer based rating of SDM-behaviour of physicians alone (MAPPIN-Ophysician)
3. Observer based rating of SDM-behaviour of nurses alone (MAPPIN-Onurses)
4. Patient based judgment about perceived SDM-behaviour
5. Nurse based judgment about perceived SDM-behaviour (only in the intervention group)
6. Physician based judgment about perceived SDM-behaviour
7. Concordance between professionals (nurses or physicians) and patient based judgment of SDM-behaviour
8. Informed choice (including the three subdimensions attitude, knowledge and uptake)
9. Decisional conflict
10. Duration of consultations

Overall study start date
01/10/2014

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Breast care centres are eligible if they are certified according to a German or European certification body (e.g. Onkozert, Äkzert or EUSOMA)

Nurses are eligible if they have a one- or two-year long advanced training as breast care or oncology nurses or if they have been entrusted with the breast care nurses´ tasks for at least 6 months

Women are eligible if:
1. they are aged 18 years or older
2. they have a primary, histologically confirmed DCIS
3. don't have invasive breast cancer or lobular carcinoma in situ
4. are facing a primary treatment decision
5. have sufficient language skills in German

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
16 clusters (breast care centres) will be recruited and randomized. Each cluster will include 12 participants. The total sample size comprises 192 participants.

Total final enrolment
67

Key exclusion criteria
Women who:
1. are pregnant
2. have a known BRCA 1/2 mutation
3. had a previous history of breast cancer or DCIS (irrespective if ipsi- or contralateral)
4. have a contra-indication for radiotherapy
5. are seeking a second opinion

Date of first enrolment
01/07/2015

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
Germany

Study participating centre
University of Hamburg
Faculty of Mathematics

Informatics and Natural Sciences
Unit of Health Sciences and Education
Martin-Luther-King-Platz 6
Hamburg
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Sponsor information

Organisation
German Aerospace Centre Project Management Agency

Sponsor details
Heinrich-Konen-Str. 1
Bonn
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Sponsor type
Government

ROR
https://ror.org/04bwf3e34

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Health

Results and Publications

Publication and dissemination plan
We intend to publish and disseminate the results of the study after the study ended.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/10/2015		Yes	No
Basic results		26/06/2019	26/06/2019	No	No
Other publications	development and pilot testing of the intervention	06/12/2017	26/06/2019	Yes	No
Results article	results of the cluster randomized controlled trial	01/05/2019	26/06/2019	Yes	No