

# Psychosexual consequences of risk-reducing salpingo-oophorectomy in BRCA1/2 mutation carriers.

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**Primary objective** The primary objective is to examine the effect of a MBSR intervention on the menopause-specific quality of life in BRCA1/2 mutation carriers who experience RRSO-induced menopausal complaints. **Secondary objective** The secondary...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Endocrine disorders of gonadal function
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40602

### Source

ToetsingOnline

### Brief title

PURSUE:Psychosexual consequences of risk-reducing salpingo-oophorectomy

### Condition

- Endocrine disorders of gonadal function
- Ovarian and fallopian tube disorders

### Synonym

menopausal transition., Menopause

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** BRCA1/2, Mindfulness, Psychosexual consequences, Salpingo-Oophorectomy

## Outcome measures

### Primary outcome

As the primary parameter, the MENQOL will be used to assess menopause-specific quality of life in the MBSR and control group at baseline to twelve weeks.

### Secondary outcome

As the secondary parameters, the MENQOL will be used to assess menopause-specific quality of life in the MBSR and control group at baseline to six and twelve months. Furthermore as secondary parameters the female sexual function index questionnaire (FSFI) and female sexual distress scale questionnaire (FSDS) will be used to assess sexual functioning and sexual distress in the MBSR and control group at baseline to twelve weeks, six months and twelve months.

## Study description

### Background summary

Risk-reducing salpingo-oophorectomy (RRSO) is a mainstay in preventing ovarian cancer in BRCA1/2 mutation carriers, as ovarian cancer screening is ineffective in detecting ovarian cancer in an early and curable stage. Although RRSO is very effective in decreasing the risk of developing ovarian cancer, women who underwent RRSO experienced bothersome menopausal symptoms and worsening of sexual functioning related to acute surgical menopause. Hormone replacement therapy (HRT) will mitigated some of the RRSO-induced menopausal complaints, however it does not reduce the complaints to a premenopausal level, and the sexual symptoms are not alleviated. Furthermore in BRCA1/2 mutation carriers a personal history of breast cancer is prevalent which contraindicates the use of HRT. As a possible alternative to HRT, Mindfulness interventions were found to improve sexual functioning and alleviate menopausal symptoms in various

populations. It has not been investigated whether mindfulness-based stress reduction (MBSR) is effective in mitigating the RRSO-induced menopausal complaints in BRCA1/2 mutation carriers and if this effect is sustained over a longer period of time.

## **Study objective**

### Primary objective

The primary objective is to examine the effect of a MBSR intervention on the menopause-specific quality of life in BRCA1/2 mutation carriers who experience RRSO-induced menopausal complaints.

### Secondary objective

The secondary objective is to examine the effect of a MBSR intervention on sexual functioning and distress in BRCA1/2 mutation carriers who experience RRSO-induced menopausal complaints.

## **Study design**

The study is a prospective, randomized controlled trial, with an intervention group that receives an eight-week MBSR training as well as care as usual and a control group that only receives care as usual. All participants will be asked to fill out questionnaires regarding menopausal and sexual complaints at baseline before randomization (T0) and at twelve weeks (T1), six (T2) and twelve months (T3) after randomization. The study will be conducted at the family cancer clinic of the UMCG.

## **Intervention**

eight week MBSR training consisting of a weekly class of two and a half hours and an eight hour training day. MBSR is a standardized psychosocial intervention developed by Dr. Jon Kabat-Zinn and is delivered by certified trainers. This program aims to train paying full attention to the present moment in a non-judgemental way through exercises as meditation, yoga and body scans.

The control group does not take this training. Both groups receive care as usual (see protocol, paragraph 5.2 care as usual).

## **Study burden and risks**

There are no risks associated with taking part in a MBSR intervention or filling in the questionnaires that will be used in this study. The content of the questionnaires concerns intimate matters and could be considered burdensome. A benefit for the participants of the MBSR intervention could be that they will be better able to cope with their complaints after RRSO. The

group relatedness is reflected in the fact that RRSO is specifically performed in women with a hereditary risk of ovarian cancer such as BRCA1/2 mutation carriers.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All women who underwent risk-reducing salpingo-oophorectomy (RRSO) at the UMCG and who were younger than 52 years at the time of RRSO, have no active cancer at the time of inclusion and report two or more moderate to severe menopause related complaints (see researchprotocol, paragraph 4.2).

## Exclusion criteria

Women will be excluded from the study if they have no sufficient mastery of the Dutch language, if they suffer from severe cognitive or psychiatric problems.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2015
Enrollment:	124
Type:	Actual

## Ethics review

Approved WMO	
Date:	14-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	18-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL46796.042.14