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Improving the efficiency and quality of follow-up after curative treatment for breast cancer

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 27/01/2011	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR121; 2

Study information

Scientific Title

Acronym
MaZorg studie/MaCare trial

Study objectives
1. Regular physical follow-up can partly be replaced by nurse-led telephone follow-up, with at least similar Quality of Life (QoL), in breast cancer patients treated with curative intent (change in QoL less than five points)
2. An informative/educational group intervention (Info-Care-Programme) in the first three months of follow-up improves the QoL in breast cancer patients treated with curative intent (change in QoL more than ten points)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised, active controlled, factorial multicentre trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Breast cancer

Interventions
The first arm is the standard arm, and consists of usual follow-up as described in the regional guidelines. The patient has an appointment with the medical specialist and/or nurse-practitioner every three months during the first year, every six months during the second year, and thereafter once a year until at least five years. A mammography will be taken once a year, if needed supplemented by a breast ultrasound.

In arms two and four, where the effect of 'telephone follow-up' is studied, follow-up will consist of a first follow-up visit two to six weeks after treatment as usual, to evaluate the acute treatment related side effects. Thereafter, patients will only once a year be seen by either the medical oncologist/surgeon/Nurse-Practitioner (NP) or the radiation oncologist. This visit will be combined with the annual mammography. At the regular follow-up times (i.e. at three, six, nine, and 18 months), the NP will have a telephone interview with the patients. This telephone interview will be done by open discussion, and a semi structured questionnaire, including screening for physical and psychosocial symptoms, and compliance to hormonal therapy (if applicable). In addition, data about the side effects of treatment are collected during this telephone interview.

In the arms three and four, with an additional group intervention, the patients and their partners will follow the Info-Care Programme (ICP) led by two NPs, within three months of the end of the treatment. This programme, given at a central location in the region, consists of two interactive group sessions of about two to three hours of psycho-education, including mutual contact between participants for sharing. The ICP intervention is aimed at improving perceived behavioural control, and reduction of anxiety. To improve the feeling of self control and self reliance, information will be given about being alert to physical and psychosocial symptoms

related to breast cancer and the (side) effects of the treatment. Information is given about the actions (e.g. call for professional help) that may be undertaken when symptoms occur, and about the scale of health care workers and interventions that are available. Discussions will also be conducted addressing issues such as how to deal with anxiety, mood changes, and changes in intimacy (i.e. altered feminity, body image, sexuality).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cancer-specific QoL at 12 months after randomisation, measured by the global health status /QoL scale of the EORTC QLQ-C30.

Key secondary outcome(s))
1. Other QoL scales, including breast cancer specific items, EuroQoL, perceived behavioural control, anxiety, and patients' satisfaction with follow-up
2. Costs will be determined based on standardised cost-diaries filled out by the patients over a predefined period, at the same time points.
3. The incidence of local recurrences and distant metastases, by whom these recurrences are detected, and whether they are detected with or without symptoms

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Female patients with breast cancer without distant metastases
2. World Health Organisation (WHO) performance scale zero to two
3. No concomitant/previous malignant disease or psychiatric disorders
4. Treated with curative intent (i.e. lumpectomy or mastectomy, with or without radiotherapy and/or chemotherapy)
5. Treatment completed less than eight weeks prior to randomisation
6. Not included in another trial, requiring frequent follow-up
7. Able to read and speak fluently in Dutch
8. No medical diseases (treatment-related side-effects, concomitant tumours) requiring frequent follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/06/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
MAASTRO Clinic
Maastricht
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Sponsor information

Organisation
Maastro Clinic (Netherlands)

ROR
https://ror.org/059wkzj26

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/02/2009		Yes	No
Results article	results	30/04/2010		Yes	No
Results article	economic evaluation results	01/05/2011		Yes	No
Protocol article	study protocol	02/01/2007		Yes	No