My Home GMC: (online) Group Medical Consultations for breast cancer survivors.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23985

Source
Nationaal Trial Register

Brief title
My Home GMC

Health condition

Breast cancer; follow-up; empowerment; distress; eHealth

Sponsors and support

Primary sponsor: Radboud University Medical Centre, Nijmegen, The Netherlands
Source(s) of monetary or material Support: GlaxoSmithKline

Intervention

Outcome measures

Primary outcome

Psychological distress (SCL-90) and empowerment (Cancer Empowerment Questionnaire).

Secondary outcome

1. Fear of recurence - CWS;

2. QoL –EORTC-QLQ C30 + BR23;

3. Health outcome – EQ-5D;

4. Costs – TiC-P;

5. Satisfaction (patient & care provider);

6. Information need;

7. Medication adherence (MARS).

Besides questionnaires also the (online) GMCs will be observed and usage statistics from My Home GMC will be measured.

Study description

Background summary

During follow-up, breast cancer survivors (BCS) generally have a high need for psychosocial support and information, while the number of consultations decreases. Therefore, we have introduced specially programmed iPads (My Home GMC). Using this iPad, patients have access to information and videos and they can contact peer patients, as well as health care professionals by several communication channels, including virtual group meetings. A prerequisite for successful telecare is the existence of a relationship prior to online meetings. Therefore, patients first participate in a group medical consultation (GMC) in the hospital. GMCs provide individual medical visits conducted within a group. These (online) group-visits with ~8 patients allow patients to spend more time with their clinician and a behavioral health professional, as well as to learn from other patients who are dealing with similar issues. This approach provides a unique combination of both social support and professional education in an eHealth environment. However, it should be noted that (online) group sessions may increase distress and anxiety. Therefore, the effectiveness of GMCs and My Home GMC for BCS will be evaluated in a non-blinded multicenter randomized controlled trial. 130 BCS will be included. The intervention group will participate in a GMC once, followed by the provision of dedicated iPads (My Home GMC), while the control group will receive usual care (an individual visit). Changes in self-report questionnaires from baseline to 1 week, 3 months and 6 months after the consultation will be measured. Primary outcomes are empowerment (CEQ) and psychological distress (SCL-90). Besides questionnaires the use of My Home GMC and the content and frequency of communication will be measured.

The strength of My Home GMC is the additional attention for psychosocial related problems and interaction with other BCS, which will, as we hypothesize, lead to more empowerment and a decrease in distress.

Study objective

The research question is whether GMCs in combination with My Home GMC compared to usual care is effective in reducing psychological distress and/or improving empowerment.

Study design

Participants will be asked to fill out questionnaires at four time points: At baseline, 1 week after, 3 months and 6 months after the (group or individual) consultation.

Intervention

The intervention group will participate in a GMC once, followed by the provision of dedicated iPads (My Home GMC), while the control group will receive usual care (an individual visit). In principle, the content of a GMC is similar to an individual visit, except for the presence of maximally 8 other patients. The GMC will last for approximately 90 minutes. Physical examinations will be performed before the start of the group consultation. During a GMC a clinician and social worker or a nurse are collaborating.

Afterwards patients have access to My Home GMC (dedicated iPads), including several communication media with contact information of other participants from the GMC. Several virtual video group meetings will be organized, where patients can meet the other participants from the GMC in the presence of a nurse. During these virtual meetings, patients can address their own discussion topics. Additional documents (via iBooks) and 13 short videos with information concerning survivorship are available at My Home GMC. Also, suggestions for publicly available, survivorship relevant internet sites are given.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven breast cancer;

2. A minimum age of 18 years;

3. Completed primary treatment maximally five years ago.

Exclusion criteria

1. Currently involved in a diagnostic work-up because of a suspicion of breast cancer, either primary or metastatic;

2. Metastatic cancer;

3. Current psychiatric disorder precluding consultations in a group;

4. Insufficient command of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2012
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34236
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3612
NTR-old	NTR3771
CCMO	NL34511.091.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34236

Study results

Summary results
N/A