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Nurse-led telephone follow-up and an educational group programme after breast cancer treatment: Results of a 2 × 2 randomised controlled trial

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ABSTRACT

Objective: To investigate whether frequent hospital follow-up in the first year after breast cancer treatment might partly be replaced by nurse-led telephone follow-up without deteriorating health-related quality of life (HRQoL), and whether a short educational group programme (EGP) would enhance HRQoL.

Patients and methods: A multicentre pragmatic randomised controlled trial (RCT) with a 2 × 2 factorial design was performed among 320 breast cancer patients who were treated with curative intent. Participants were randomised to follow-up care as usual (3-monthly outpatient clinic visits), nurse-led telephone follow-up, or the former strategies combined with an educational group programme. The primary outcome for both interventions was HRQoL, measured by EORTC QLQ-C30. Secondary outcomes were role and emotional functioning and feelings of control and anxiety.

Results: Data of 299 patients were available for evaluation. There was no significant difference in HRQoL between nurse-led telephone and hospital follow-up at 12 months after

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treatment ($p = 0.42$; 95% confidence interval (CI) for difference: −1.93–4.64) and neither between follow-up with or without EGP ($p = 0.86$; 95% CI for difference: −3.59–3.00). Furthermore, no differences between the intervention groups and their corresponding control groups were found in role and emotional functioning, and feelings of control and anxiety (all p-values >0.05).

Conclusion: Replacement of most hospital follow-up visits in the first year after breast cancer treatment by nurse-led telephone follow-up does not impede patient outcomes. Hence, nurse-led telephone follow-up seems an appropriate way to reduce clinic visits and represents an accepted alternative strategy. An EGP does not unequivocally affect positive HRQoL outcomes.

1. Introduction

After curative treatment for breast cancer women commonly attend regular follow-up examinations. In most countries, follow-up is rather frequent (2–4 times annually) in the first 2–3 years; thereafter frequency is reduced to once a year.[1,2] The aim of these follow-up examinations is not only to detect local disease recurrence or a second primary breast cancer, but also to provide information and psychosocial support.[1,2] However, there has been much debate regarding the value of this routine follow-up of women with breast cancer. Current follow-up patterns depend heavily on expensive and scarce specialised knowledge for routine history taking and for physical examinations, but do not always provide optimal care for patients.[3–6]

Alternative follow-up strategies have been proposed, such as follow-up by general practitioners,[7] nurse-led follow-up[8] or telephone follow-up.[9,10] Although studies have shown that these alternative follow-up models can be equally effective as traditional hospital follow-ups, measured by a variety of outcomes, these models are not yet widely applied in clinical practice. It could be that the results are not sufficiently convincing or lack generalisability to other settings. Other reasons may be that medical specialists believe that patients need frequent reassurance, or that patients still have the misconception that frequent follow-up will improve their prognosis.[11]

Psychosocial support and education of patients could be improved and may lead to wider acceptance of a reduced follow-up policy by both patients and health professionals.[12] We therefore developed a short educational group programme (EGP) to be offered after completion of primary treatment. In this programme patients were educated about the aims of follow-up and possible psychosocial and physical sequelae of breast cancer treatment. In addition, breast care nurses were trained to perform telephone follow-up. Importantly, in contrast to most other studies investigating alternative strategies, we focused specifically on the period immediately following primary treatment. A pragmatic randomised controlled trial (RCT) with a 2×2 factorial design was performed to test whether the EGP would increase health-related quality of life (HRQoL) of patients after treatment and whether nurse-led telephone follow-up could replace hospital visits without deteriorating HRQoL.

2. Methods

2.1. Trial design, sample and interventions

Details of the trial design and protocol execution have been reported previously (ISRCTN 74071417).[13] In sum, the study was a multicentre RCT with a 2×2 factorial design. Between 2005 and 2008, 320 females were recruited through seven hospitals and two radiotherapy clinics in the South of the Netherlands. Participants were eligible for inclusion if they had completed curative breast cancer treatment with a curative intent less than six weeks prior to randomisation, with a WHO performance score between 0 and 2, and were fluent in speaking and reading Dutch. Exclusion criteria were distant metastases and/or participation in another clinical trial or medical illness requiring more frequent follow-up. Participants were randomly assigned to one of four follow-up arms for the first 18 months after treatment. These arms were (1) hospital follow-up as usual: five outpatient clinic visits in the first 18 months (at 3, 6, 9, 12 and 18 months), including a mammography at 12 months; (2) nurse-led telephone follow-up: a mammography at 12 months combined with an outpatient clinic visit, and telephone interviews by a breast care nurse (BCN) at the same time points as for the usual follow-up (i.e. 3, 6, 9 and 18 months); (3) arm 1 plus educational group programme (EGP); (4) arm 2 plus EGP. Study arms were combined for analysis as follows: hospital follow-up (arms 1 and 3) compared to nurse-led telephone follow-up (arms 2 and 4); and EGP (arms 3 and 4) compared to no EGP (arms 1 and 2).

For patients randomised to hospital follow-up (arms 1 and 3), care was provided by a surgeon, medical oncologist, radiation oncologist and/or a BCN. Follow-up visits consisted of medical history taking and physical examination. For patients randomised to telephone follow-up (arms 2 and 4), follow-up was provided by a BCN specifically trained for this study. Follow-up consisted of a semi-structured interview including screening for physical and psychological symptoms, treatment side-effects, compliance with hormonal therapy plus open discussion of these issues. An additional appointment to come to the hospital was made if the patient or BCN was not reassured.

The EGP consisted of two interactive group sessions of 2.5 h each and was attended by the patient +/− her partner within three months after treatment. The BCN provided

information on possible treatment side-effects, signs and symptoms of a possible recurrence, prostheses and fatigue. A health care psychologist addressed psychological and social consequences of breast cancer, particularly anxiety, depression, changes in family and social role patterns and discussed psychological coping strategies.

Randomisation by minimisation[14] was performed by the independent Comprehensive Cancer Centre Limburg using a computerised randomisation programme (ALEA). Patients were pre-stratified by hospital and treatment modality (surgery, surgery + radiotherapy, surgery + chemotherapy, and surgery + radiotherapy + chemotherapy).

The study protocol was approved by the Medical Ethical Review Board of MAASTRO Clinic (Netherlands). All participating centres signed local feasibility declarations, according to Dutch law and regulations, prior to inclusion of the first patient.

2.2. Outcome measures

The primary outcome for both interventions was HRQoL at 12 months after randomisation, measured by EORTC QLQ-C30. This self-administered disease-specific HRQoL questionnaire is validated for oncological clinical research[15,16] and has a validated Dutch version available.[17] The EORTC QLQ-C30 consists of 30 items and provides scores on multi-item functional subscales (e.g. role, emotional functioning), multi-item symptom scales (e.g. fatigue, pain), a HRQoL (global health) subscale and a number of single items (e.g. sleep disturbance). The HRQoL subscale was used as the primary outcome measure in this study and consists of two items: (1) How would you rate your overall health during the past week? and; (2) How would you rate your overall quality of life during the past week? Items are rated on a 7-point Likert-scale, ranging from "very bad" to "excellent". Scores on HRQoL and functional subscales range from 0 to 100, with higher scores representing higher levels of functioning and HRQoL.

Secondary outcome measures were emotional and role functioning (EORTC QLQ-C30 subscales),[17] anxiety (State-Trait Anxiety Inventory (STAI))[18] and perceived feelings of control (Mastery Scale).[19] Furthermore, details on the number of visits to the hospital, telephone contacts with medical specialists and breast care nurses, as well as general practitioner visits were collected using patient records and cost diaries.

Patients were sent questionnaires by post before randomisation at baseline, and at 3, 6, 12 and 18 months after treatment. The 18 months data were collected for a subsample of patients to be used in an economic evaluation, but were not used for the analyses presented in this paper.

2.3. Statistical analysis

Sample size calculations were based on HRQoL measured by the global health subscale of the EORTC QLQ-C30.[17] A baseline score of 64 with a standard deviation of 17 was considered as a starting point.[20,21] An analysis of the clinical significance of HRQoL changes showed that patients indicate a change between 5 and 10 to be small, between 10 and 20 to be moderate, and of more than 20 to be large.[22] Consequently, we considered a change smaller than 5 to mean no change. A power analysis on our study design required 320 breast cancer patients in order to demonstrate that HRQoL of patients with nurse-led telephone follow-up would be at least similar (i.e. <5 points difference) to patients in the hospital follow-up (non-inferiority analysis; power 80%, α 0.05). Also, with 320 patients, a moderate improvement in HRQoL (i.e. >10 points difference) in patients attending the EGP could be detected (superiority analysis; power 95%, $\alpha < 0.01$). A dropout rate of 10% was accounted for in these calculations. Sample size was calculated for main effects only and assumed no interaction between the two interventions.

Data were entered in a database by a professional centre for data and information management and analysed using SPSS version 17.0. Missing data were imputed by means of Rubin's multiple imputation procedure using the defaults in SPSS 17.0, generating five datasets.[23] All analyses were performed with each of the five data sets, and results were pooled.

Differences in patient characteristics and number of contacts with health professionals were compared using the X^2 test and independent sample *t*-test. The primary analysis assessed the above pre-defined effects of both interventions. Patients remained in the study arm to which they were assigned, whether or not they complied with the protocol. Additionally, we included an interaction effect to test for interaction/mutual effect modification between interventions. Regression analyses were used to predict primary and secondary outcome differences at 12 months after randomisation by including or excluding interventions. Linear mixed models were fitted with EGP (yes/no) and telephone follow-up (yes/no) as fixed factors and patient as the random factor. In addition, recruitment hospital, age, education, time since end of treatment and treatment modality were included as covariates. Primary and secondary outcomes were adjusted for baseline differences.

Since protocol violation may bias the trial (in either direction), per protocol analyses including only patients who properly followed the study protocol were also performed, as recommended by Piaggio and colleagues.[24] Furthermore, explorative subgroup analyses were performed according to level of anxiety, age, level of education, use of chemotherapy and level of support from partner. Analyses were performed by creating an interaction term between the intervention and subgroup and testing the significance of the interaction in the regression model.

3. Results

3.1. Patients

Between June 2005 and March 2008, 320 of 881 eligible patients (36.4%) agreed to participate in the study (Table 1 and Fig. 1). All patients were included within 6 weeks after the end of their final treatment (excluding hormonal treatment). Time since diagnosis was not recorded separately but all treatment modalities had rather fixed durations in participating hospitals. The average time periods since diagnosis were 10 weeks for patients who had received surgery, 22 weeks for surgery and radiotherapy, 29 weeks for surgery and

Table 1 – Baseline and sociodemographic characteristics of participants in intervention (telephone follow-up or educational group programme (EGP)) and control arms. Values are numbers (percentages) unless stated otherwise.

	Hospital follow-up (n = 149)	Telephone follow-up (n = 150)	EGP (n = 149)	No EGP (n = 150)	All participants (n = 299)
Age at recruitment (in years)					
Mean (SD)	56.2 (10.7)	55.5 (9.0)	55.3 (10.4)	56.3 (9.4)	55.8 (9.9)
Range	23–78	34–75	23–76	34–78	23–78
Level of education					
Low	45 (30.2)	57 (38.0)	51 (34.2)	51 (34.0)	102 (34.1)
Middle	62 (41.6)	56 (37.3)	60 (40.3)	58 (38.7)	118 (39.5)
High	42 (28.2)	37 (24.7)	38 (25.5)	41 (27.3)	79 (26.4)
Marital status					
Married	109 (73.2)	103 (68.7)	104 (69.8)	108 (72.0)	212 (70.9)
Unmarried	16 (10.7)	17 (11.3)	17 (11.4)	16 (10.7)	33 (11.0)
Cohabiting	9 (6.0)	20 (13.3)	13 (8.7)	16 (10.7)	29 (9.7)
Widowed	15 (10.1)	10 (6.7)	15 (10.1)	10 (6.7)	25 (8.4)
Tumour stage					
Stage I	91 (61.1)	90 (60.0)	85 (57.0)	96 (64.0)	181 (60.5)
Stage IIa	35 (23.5)	34 (22.7)	36 (24.2)	33 (0.22)	69 (23.1)
Stage IIb	8 (5.4)	13 (8.7)	13 (8.7)	8 (5.3)	21 (7.0)
Stage III	13 (8.7)	11 (7.3)	12 (8.1)	13 (8.7)	24 (8.0)
Unknown	2 (1.3)	2 (1.3)	3 (2.0)	–	4 (1.3)
Treatment modality					
Surgery	15 (10.1)	14 (9.3)	13 (8.7)	16 (10.7)	29 (9.7)
Surgery + radiotherapy (RT)	89 (59.7)	89 (59.3)	91 (61.1)	87 (58.0)	178 (59.5)
Surgery + chemotherapy (CH)	7 (4.7)	8 (5.3)	8 (5.4)	7 (4.7)	15 (5.0)
Surgery + RT + CH	38 (25.5)	39 (26.0)	37 (24.8)	40 (26.7)	77 (25.8)
Hormonal therapy (yes)	50 (33.6)	44 (29.3)	48 (32.2)	46 (30.7)	94 (31.4)
Health scores (mean (SD))					
Health-related quality of life	70.5 (17.8)	67.2 (19.0)	70.5 (18.9)	67.3 (17.9)	68.9 (20.1)
Emotional functioning	77.7 (20.4)	69.9 (25.7)	75.8 (23.6)	71.8 (23.3)	73.8 (23.5)
Role functioning	68.6 (29.3)	62.6 (27.8)	67.2 (29.9)	64.0 (27.4)	65.6 (28.7)
Anxiety	39.3 (11.3)	40.9 (11.8)	39.0 (11.5)	41.2 (11.6)	40.1 (11.6)
Feelings of control	2.6 (0.8)	2.6 (0.8)	2.5 (0.7)	2.6 (0.8)	2.58 (0.8)

chemotherapy, and 38 weeks for surgery and chemotherapy and radiotherapy.

Two-hundred and forty non-participants agreed to fill out the baseline questionnaires for comparison with participants. At the baseline, participants did not differ from non-participants with respect to education, marital status, HRQoL, emotional functioning and levels of anxiety (all p-values >0.05). However, participants were significantly younger than non-participants (mean age 60 years (SD = 10.2), $p < 0.001$).

Throughout the trial, 21 patients (6.5%) were lost to follow up for various reasons (e.g. development of metastases, recurrence, or three or four missing questionnaires) and were not included in the analysis (Fig. 1).

3.2. Protocol compliance

Ten patients randomised to telephone follow-up preferred to receive hospital follow-up instead, and 20 patients with telephone follow-up received only one telephone follow-up contact, which was considered as protocol violation. Hence, 120 out of 150 patients (80%) in the telephone follow-up arms, received telephone follow-up according to protocol. Protocol violators did not differ from protocol compliers regarding age, education, treatment modality, role functioning and feelings of control at baseline (all p-values >0.05). However, their HRQoL and emotional functioning were significantly lower and feelings of anxiety higher than protocol compliers (p-values of respectively 0.02, 0.01, and 0.01).

Ten out of 149 patients randomised to EGP did not attend the meetings. These patients did not differ from those attending the EGP with respect to age, education, treatment modality and all outcome measures (p-values all >0.05). One-hundred and twenty-one patients (87%) attended both meetings and 78 patients (52%) were accompanied by their partner at one or both meetings.

Table 2 shows the mean number of hospital visits and telephone contacts with the BCN, medical specialist and general practitioner in one year. In the telephone group patients had on average 2.4 telephone contacts with the BCN and 3.4 visits to the hospital, of which one hospital visit was conform protocol and 2.4 were additional visits. In the hospital group patients had on average 5.9 visits to the hospital, of which four visits were conform protocol and 1.9 were additional visits. The mean number of general practitioner visits did not differ between groups.

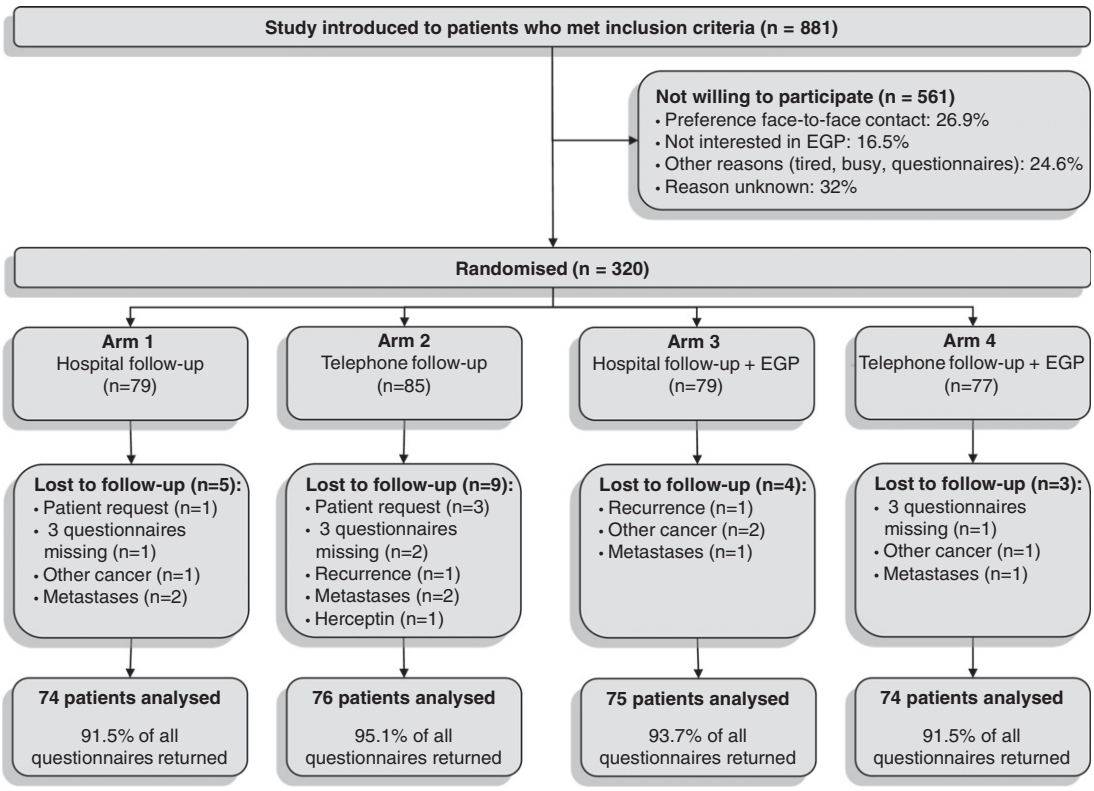

Fig. 1 – Flow of participants through trial.

Table 2 – Number of contacts per patient in one year with medical specialist (MS), breast care nurse (BCN) and general practitioner (GP) in one year, according to follow-up group (hospital and telephone). Numbers are means and standard deviations.

	Hospital follow-up Total contacts	Telephone follow-up Total contacts	*p*-value
Visits hospital (MS or BCN)	5.9 (2.2)	3.4 (2.4)	<0.001
Telephone contact BCN	0.1 (0.4)	2.4 (1.1)	<0.001
Visits to GP	1.6 (2.7)	1.2 (2.4)	0.228
Telephone contact GP	0.3 (0.9)	0.3 (1.0)	0.906

3.3. *Primary outcome: health-related quality of life (HRQoL)*

At 12 months after treatment, mean HRQoL scores were 78.4 (SD = 16.2) and 77.7 (SD = 16.2) respectively for telephone follow-up and hospital follow-up. The small difference between the groups was not significant ($p = 0.42$). The 95% confidence interval for the estimated difference between mean HRQoL scores at 12 months after treatment was −1.93–4.64. A positive mean difference indicates higher levels of functioning for nurse-led telephone follow-up, whilst a negative difference indicates higher levels of functioning in the hospital follow-up. Yet, HRQoL significantly improved over time ($p = 0.01$), but without significant differences in slope of improvement between both follow-up groups ($p = 0.41$) (Fig. 2).

Similarly, there was no significant difference in HRQoL between follow-up with or without EGP ($p = 0.86$). At 12 months, mean HRQoL scores were 82.4 (SD = 17.4) and 81.9 (SD = 17.6) respectively for EGP and no EGP. The 95% confidence interval for the estimated difference between mean HRQoL scores at 12 months was −3.59–3.00. Again, there was no significant difference in slope of improvement between follow-up groups ($p = 0.10$) (Fig. 2). Finally, there was no significant interaction effect between EGP and nurse-led telephone follow-up with respect to HRQoL ($p = 0.50$).

3.4. *Secondary outcomes*

Role and emotional functioning, and feelings of control and anxiety improved over time, but there were no significant differences between patients randomised to telephone and hospital follow-up (Table 3). Similarly, differences between having participated in the EGP or not with respect to role and emotional functioning and feelings of control and anxiety, were not significant at 12 months after treatment.

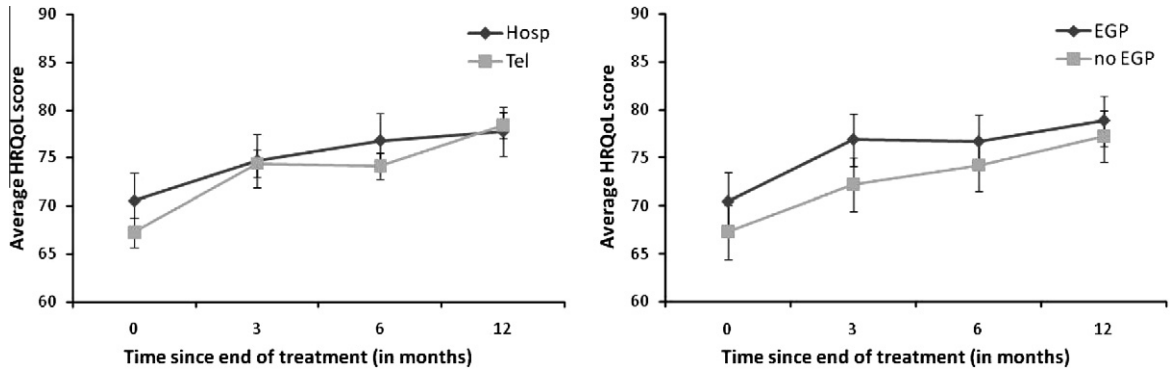

Fig. 2 – Average health-related quality of life (HRQoL) scores on the EORTC QLQ-C30 questionnaire at baseline, and 3, 6 and 12 months after treatment: telephone versus hospital follow-up (left hand) and an educational group programme (EGP) versus no EGP (right hand). Error bars represent the 95% confidence interval.

Intention to treat and per protocol analyses showed almost identical results (data not shown).

3.5. *Subgroup analyses*

Explorative subgroup analyses according to level of anxiety, age, education, use of chemotherapy, and level of support from partner did not identify specific subgroups of patients for whom the interventions may be more effective than for others (data not shown).

4. Discussion

Frequent follow-up of breast cancer patients continues to be controversial despite almost two decades of research. This multicentre RCT showed that some hospital clinic visits in the first year after treatment could well be replaced by nurse-led telephone follow-up without a loss of HRQoL, a decrease in role and emotional functioning and feelings of control, nor an increase in feelings of anxiety. It was also found that an educational group programme (EGP) did not lead to a significant improvement in HRQoL, or any other psychological outcome measures.

The present positive findings regarding nurse-led telephone follow-up are similar to those reported in earlier studies.[9,25,26] A recently published RCT by Beaver and colleagues comparing nurse-led telephone follow-up with hospital follow-up, showed that telephone follow-up significantly improved satisfaction and did not produce excess anxiety compared with hospital follow-up. Women were on average 20 months after end of treatment when entering the trial.[9] Since in the present study women entered immediately after treatment both trials may be seen as complementary and provide evidence that telephone follow-up appears appropriate for patients in different phases after treatment. Moreover, our study found high patient satisfaction scores for both nurse-led telephone as well as hospital follow-up, regarding access of care, technical competence, interpersonal aspects and general satisfaction.[27] Satisfied patients in general have better HRQoL and less anxiety and depression.[28] Hence, the high HRQoL and patient satisfaction scores found in this study lend further support for the acceptability and feasibility of nurse-led telephone follow-up.

With respect to HRQoL and feelings of control and anxiety, the EGP did not meet our initial expectations. No additional gains in HRQoL or feelings of control or a reduction in anxiety were found due to participation in the EGP. Possibly two group sessions of education were not sufficient to significantly improve health outcomes. Another reason may be that since most patients tend to adjust well to their disease,[29] it may have been difficult to achieve additional gains in HRQoL. Interestingly, whilst multiple observational studies found a positive relation between appropriate information provision and HRQoL in cancer survivors, most interventional studies did not identify positive effects of information interventions on HRQoL, as was demonstrated recently in a review by Husson and colleagues.[28] Another review on psychosocial interventions as part of breast cancer rehabilitation programmes, by Fors and colleagues, also reported limited evidence on the efficacy of psychosocial interventions both during as well as after treatment. In addition, this review could not identify selected groups with specific characteristics who would benefit more than others from psychosocial interventions.[30] Also in our study, explorative analyses were not able to find subgroups of patients (e.g. with a higher level of anxiety or lower level of education) who may benefit from the EGP. Hence, based on our results and the literature we would not recommend implementation of the present EGP with the sole aim to improve HRQoL. However, implementation of some kind of EGP may still be justified to satisfy information needs. Beaver and colleagues found that many patients still report the need for more information even after several years of follow-up.[9] Furthermore, Koinberg and colleagues found that a short multidisciplinary educational programme similar to the EGP developed in our study could replace some hospital visits, without negative effects on wellbeing or coping abilities.[12] Hence, the EGP might be able to meet information needs and reduce hospital visits.

Some concerns may exist regarding the use of EORTC QLQ-C30 in this RCT, loss of follow-up, participation rate and protocol adherence. This study provides evidence for equal effectiveness of nurse-led telephone follow-up and the EGP, compared to their respective control groups. It is

Table 3 – Outcome findings by study group at baseline, 3, 6 and 12 months. Scores are based on the imputed datasets and intention to treat analysis: *n* = 150 for telephone follow-up (f-up), *n* = 149 for hospital f-up; *n* = 149 for EGP, *n* = 150 for no EGP. EGP = Educational Group Programme.

	Baseline scores mean (SD)		3 months scores mean (SD)		6 months scores mean (SD)		12 months scores mean (SD)		Estimate of difference at 12 months[e]	95% CI for difference[a]	Sig.
Telephone versus hospital f-up	Hospital	Telephone	Hospital	Telephone	Hospital	Telephone	Hospital	Telephone			
Health-related quality of life	70.5 (17.8)	67.2 (19.0)	74.7 (16.9)	74.4 (17.4)	76.8 (17.5)	74.1 (16.9)	77.7 (16.2)	78.4 (16.2)	1.35	−1.93–4.64	0.42
Emotional functioning	77.7 (20.4)	69.9 (25.7)	75.6 (21.7)	73.9 (20.9)	79.8 (19.4)	76.5 (20.8)	82.6 (16.9)	81.7 (18.0)	2.23	−1.50–5.96	0.24
Role functioning	68.6 (29.3)	62.6 (27.8)	76.6 (23.2)	74.5 (25.8)	80.4 (24.1)	78.4 (22.9)	82.9 (23.2)	83.4 (21.4)	2.56	−2.12–7.24	0.28
Anxiety[c]	39.3 (11.3)	40.9 (11.8)	39.1 (11.5)	39.6 (10.9)	38.8 (11.7)	40.2 (11.3)	37.9 (10.5)	37.8 (10.2)	−0.84	−2.78–1.11[b]	0.40
Feelings of control[d]	2.6 (0.8)	2.6 (0.8)	2.6 (0.8)	2.6 (0.7)	2.6 (0.8)	2.6 (0.8)	2.6 (0.8)	2.5 (0.7)	−0.07	−0.22–0.07	0.32
% returned questionnaires	100	100	88.4	88.6	84.8	85.8	81.8	81.0			
EGP versus no EGP	No EGP	EGP	No EGP	EGP	No EGP	EGP	No EGP	EGP			
Health-related quality of life	67.3 (17.9)	70.5 (18.9)	72.2 (17.3)	76.9 (16.7)	74.2 (17.0)	76.7 (17.4)	77.2 (16.6)	78.9 (15.8)	−0.29	−3.59–3.00	0.86
Emotional functioning	71.8 (23.3)	75.8 (23.6)	72.6 (21.9)	76.9 (21.3)	76.5 (20.8)	79.8 (19.4)	81.9 (17.6)	82.4 (17.4)	−1.66	−5.32–2.00	0.37
Role functioning	64.0 (27.4)	67.2 (29.9)	74.7 (23.9)	76.4 (25.2)	78.8 (23.9)	80.1 (23.1)	81.7 (23.0)	84.6 (21.5)	1.23	−3.45–5.92	0.61
Anxiety[c]	41.2 (11.6)	39.0 (11.5)	40.6 (11.3)	38.1 (11.0)	40.5 (11.8)	38.5 (11.1)	38.6 (11.0)	37.1 (9.7)	−0.10	−2.07–2.15[b]	0.92
Feelings of control[d]	2.6 (0.8)	2.5 (0.7)	2.6 (0.8)	2.6 (0.8)	2.6 (0.8)	2.6 (0.8)	2.6 (0.8)	2.5 (0.8)	0.00	−0.15–0.15	0.99
% returned questionnaires	100	100	89.8	89.0	83.6	87.0	84.2	78.6			

a Positive differences imply a higher level of functioning in the telephone and EGP group.

b Negative differences imply less anxiety in the telephone and EGP group.

c Scores range from 20 to 80, a higher score indicating greater anxiety.

d Scores range from 0 to 5, with higher scores representing higher perceived feelings of control.

e Scores are adjusted for recruitment hospital, age, level of education, time since end of treatment and treatment modality as well as baseline differences.

therefore relevant to explore whether the EORTC QLQ-C30 was sensitive enough to changes in this specific setting and whether a ceiling effect may have been present. Baseline HRQoL scores found in this study were a little higher than HRQoL reported in other studies, when taking the treatment received and time since diagnosis into account.[20,31–33] Nevertheless, the distribution of scale values did not indicate the presence of a strong ceiling effect (4% of patients reported baseline HRQoL scores lower than 40, 28% reported scores between 41 and 60, 31% reported scores between 61 and 80, and 35% reported scores between 81 and 100). Importantly, a ceiling effect would not have concealed possible deterioration in health as a result of a reduced follow-up strategy (i.e. nurse-led telephone follow-up). Regarding responsiveness of the EORTC QLQ-C30 in breast cancer patients after treatment, a full investigation of responsiveness was beyond the scope of our study. However, individual change scores revealed sufficiently large subgroups of patients with clinically relevant small, moderate and large changes in HRQoL (12% of patients reported a moderate or large deterioration in health, 8% reported a small deterioration, 25% reported no change, 14% reported a small improvement in health and 41% reported a moderate to large improvement in health), to support a reasonable responsiveness of the EORTC QLQ-C30 in this setting.[34]

Twenty-one (6.5%) patients were lost to follow up in early stages of the trial. Missing data in clinical trials is inevitable and specifically for these patients imputation would have required strong assumptions that were hard to justify.[35] As a result, strictly speaking, our analysis was not an intention to treat. However, the frequency and the causes of dropping out did not differ between intervention and control groups. Also, in our sample size calculations a dropout rate of 10% was taken into account. Nevertheless, this may have resulted in a final sample that was doing relatively well after one year.

The participation rate of 36% in our study is relatively low when compared to the rates of 50–60% in other studies investigating alternative follow-up strategies.[7,9] This low participation rate was anticipated for a number of reasons. First, patients were asked to forego hospital visits with physical examinations whilst this is currently clinical practice. It is known that, in general, people have a preference for the status quo.[36] Second, patients were accrued in the first two weeks after completion of their primary treatment. This transitional period can be highly stressful for patients, losing a sense of protection.[37,38] Therefore, introducing a study immediately after completion of treatment is particularly difficult. Importantly, participants did not appear to differ from a large sample of non-participants regarding health outcomes after treatment. Nevertheless, loss to follow-up and some eligibility criteria for this trial may have induced a selection of a 'healthy' sample. It is unknown to what extent these factors may have contributed to the fact that no difference between hospital and telephone follow-up was detected and no additional improvement in HRQoL was seen from the EGP. All possible efforts were made to minimise loss to follow up and the pragmatic and multicentre nature of the trial did enable us to include a broad sample of breast cancer patients in the Netherlands.

A final concern was that all patients received some follow-up in the hospital, including patients randomised to telephone follow-up, which may have contributed to the fact that no differences between the telephone and hospital follow-up were found. A limitation of the study was that the reasons for the additional hospital visit were not recorded routinely. It may be that, since patients who violated the protocol reported lower HRQoL and higher levels of anxiety at baseline, additional visits were related to this poorer health status or that telephone follow-up provided insufficient reassurance. It could also be speculated that some hospital visits in the telephone group were inherent to introducing a new type of follow-up, i.e. logistic difficulties and the new responsibility of providing telephone follow-up for breast care nurses. A learning effect might reduce the number of additional hospital visits in the future. Nevertheless, this pragmatic trial aimed to reflect clinical practice and it seems that patients will visit the hospital with breast cancer related problems no matter what type of follow-up is offered. This in itself supports the introduction of a reduced follow-up strategy, since it still leads to fewer hospital visits than current practice, making more efficient use of scarce specialised resources.

Importantly, the low participation rate and protocol violations in the telephone follow-up may suggest that instead of a one-size-fits-all approach, more individualised follow-up may have to be applied, taking into account specific patient preferences.[39] For example, for anxious patients hospital follow-up may be better suited. A decision-support tool could assist doctor and patient in a shared-decision making process for an appropriate follow-up strategy and has the potential to improve satisfaction and compliance to the chosen follow-up strategy.[40] The tool should incorporate a range of characteristics of the patient, including tumour characteristics, treatments received, quality of life and preferences for follow-up. Future studies could develop and test such a tool. Nevertheless, it must be realised that implementation of a reduced or individualised follow-up strategy asks for a paradigm shift, requiring attitude change among both medical specialists and patients and efforts to prevent false expectations of follow-up efficacy. Education of patients, which may be in the form of the EGP, is extremely important for successful implementation of reduced strategies.

In conclusion, replacement of most hospital follow-up visits in the first year after treatment by nurse-led telephone follow-up does not impede patient outcomes. Hence, nurse-led telephone follow-up seems an appropriate way to reduce clinic visits and represents an accepted alternative strategy. An EGP may be appropriate to address information needs but it does not unequivocally affect positive HRQoL outcomes.

Conflict of interest statement

None declared.

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