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Effectiveness of case management as a cross-sectoral healthcare provision for women with breast cancer

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Abstract

***Objective*: Case management (CM) programs are intended to improve care coordination for cancer patients. This quasi-experimental, controlled study evaluated whether such a program was effective in improving health-related quality of life and reducing the psychological distress of breast cancer patients.**

***Methods*: For the study, 126 patients with CM and 118 patients with treatment as usual (TAU) were surveyed at baseline, a 6-month follow-up and a 12-month follow-up. Comparisons of the two groups with regard to quality of life (Short Form-8, European Organization for Research and Treatment of Cancer-11; primary outcome) and psychological distress (Hospital Anxiety and Depression Scale, distress thermometer; secondary outcome) were conducted.**

***Results*: Univariate *t*-tests regarding the primary and secondary outcomes demonstrated improvements in the relevant outcomes at the 6-month and 12-month follow-ups for the intervention group as well as for the control group. An analysis of covariance revealed that the controls showed a higher level of physical quality of life at the 12-month follow-up than the other time points and no differences at 6 months after the baseline.**

***Conclusions*: The tested CM model did not improve the quality of life or psychological well-being of the patients beyond treatment as usual. Possible reasons include that the treatment was already of high standards in the control group or that there are possibly different impacts than found in the literature regarding different forms of organization in CM. The need for and the tailoring of this CM model as well as the transfer of CM to other oncological indications remain to be clarified.**

Background

Cancer, which is often considered to be a chronic disease [1], is frequently associated with a high level of distress over the course of the disease [2]. In many cases, this requires a series of stressful, long lasting, and multidisciplinary treatments in different inpatient and outpatient clinics [1]. In addition to a primarily somatic treatment, psychosocial care is also offered, as reflected in different recent guidelines [e.g., 3,4]. Therefore, the challenge of providing *adequate assistance* for patients becomes evident. Moreover, the quality of treatment is endangered by potential problems concerning the coordination of care across healthcare services or settings. *Case management* (CM) [5] may be able to assist patients who are in severely stressful and/or chronic conditions find their way through the healthcare system by the trans-sectoral management of the pathways of care.

Unfortunately, only a few studies have analyzed CM models with heterogeneous target groups, interventions settings, and outcome measures; therefore, no reliable conclusions can be drawn regarding the effect of CM on cancer patient care [6]. In Germany, a limited number of *programs for the support for women with breast cancer* using the CM approach have been implemented in the clinical setting. The *counseling service of 'mammaNet' for women with breast cancer* that is based on the CM approach began in 2002 and aimed to provide integrative, cross-sectoral, and individually coordinated care for breast cancer patients in the region of Augsburg, a town in southern Germany (see also Supporting information). The main targets for this intervention were distressed patients (with regard to the physical, as well as the psychosocial, aspects). MammaNet has been conceptualized as a combination of an 'inpatient' and 'outpatient' model; thus, the case managers and their infrastructure are located close but separately from the participating clinical units. CM is meant to contribute to a better quality of life for the patients, less distress and the improvement of care by means of the individual coordination of treatment steps with patients and institutions. Its aim is to strengthen patients' self-efficacy and encourage their active cooperation (help

for self-help). A basic principle of CM relates to the concept that a comprehensive and, therefore, effective CM process can only be realized when it draws on the patient level (individual-based support), as well as the organizational level (i.e., coordination of all providers being involved in the patients' pathways). Therefore, the individual and continuous support of the patient (which provides the patient's personal resources) is performed by professional case managers; however, the individual patient pathway is embedded in a cross-sectoral and transdisciplinary, multiprofessional network of 170 partners who are involved in the patient's care and support (e.g., practitioners, outpatient facilities, physical therapists, cancer societies, self-help groups, counseling services, and municipal authorities).

The present paper introduces the *evaluation* of the effectiveness of this CM program. A prospective quasi-experimental, controlled study was conducted, which compared two catchment areas, that is, areas with and without mammaNet.

The primary outcome is health-related generic, as well as cancer-specific quality of life. Secondary outcomes include depression, anxiety, and distress. It is expected that the patients with CM have better short and long-term results than the patients with treatment as usual (TAU condition, cp. [7]).

Methods

Study design

The research question was analyzed in a quasi-experimental design, with the *CM program as the intervention condition* and the *TAU* as the control condition. The study was approved by the ethics committee of the responsible German medical association.

Over a period of 23 months, two consecutive samples of newly diagnosed breast cancer patients were recruited from two acute hospitals for breast cancer treatment in southern Germany (Klinikum Augsburg, intervention; Mammazentrum Klinikum Deggendorf, control). All of the patients had undergone routine treatment. Inclusion criteria for all of the study patients included the following: (a) 18 years or older; (b) a diagnosis of breast cancer; and (c) knowledge of the German language. Patients with severe physical or cognitive disabilities were excluded, as well as those with a severe acute emotional crises, who were thus not able to participate in a scientific study and had to be referred to specialized mental healthcare services.

The *control region* was chosen based on comparable structural and process characteristics. Randomization was not conducted due to ethical reasons (excluding eligible patients in Augsburg from an already implemented CM treatment).

Eligible patients were informed about the study and were asked to participate after a minimum of 10 days after the diagnosis disclosure. For all of the patients who agreed to participate, written informed consent was obtained.

Patients were asked to complete standardized questionnaires at three time points (baseline [t_0], six months after t_0 [t_1], and 12 months after t_0 [t_2, follow up]). Baseline assessment was conducted 10 days after the communication of the diagnosis, at the earliest, and no later than one day before the patient's discharge from an inpatient hospital. Baseline questionnaires and information materials, as well as the consent to participate in the study, were handed to the patient in person. Questionnaires were mailed at t_1 and t_2. Patients who did not send back their questionnaires within four to six weeks were reminded twice by mail or phone.

Measures

Demographic and basic medical data were collected from the patients at baseline. Additional medical data (the Classification of Malignant Tumours (TNM), disease stage and mode of surgery) were obtained from the medical records. The assessments (patient ratings) at t_0, t_1, and t_2 included the Short Form 8 Health Survey (1-week recall), which had both physical and mental component summary measures [SF-8; 8,9] (reliability for the physical component summary, $r=0.90$, and for the mental component summary, $r=0.85$) that indicated health-related *generic quality of life.* Additionally, the European Organization for Research and Treatment of Cancer-11 [EORTC-11; 10], which is a short form of the EORTC-QLQ-C30 [11] and includes the subscales of Global Quality of Life (Cronbach's $\alpha=0.90$), physical functioning ($\alpha=0.66$), emotional functioning ($\alpha=0.84$), and nausea ($\alpha=0.75$), was included in order to operationalize *cancer-specific quality of life*. Symptoms of *depression and anxiety* were evaluated with the German version of the Hospital Anxiety and Depression Scale [HADS-D; 12] (anxiety: $\alpha=0.80$, depression: $\alpha=0.81$). In addition, the Distress Thermometer [13,14] was used to assess *psychosocial distress,* as recommended by the National Comprehensive Cancer Network [15,16]. Primary outcomes are the mental component summary (SF-8) and Global Quality of Life (EORTC-11).

Statistical analyses and the power calculation

All of the statistical procedures were performed with SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

All of the data records that had more than 30% missing values per variable or case in the primary and secondary outcome parameters were excluded, and the remaining missing values were imputed with the Expectation-Maximization-Algorithm.

Baseline comparisons of the intervention and control groups and of the participants and non-participants, respectively, were conducted by means of *t*-tests for independent groups and chi^2 tests. For analyzing the change over time of the primary and secondary outcomes (i.e., the comparison of t_1 and t_0, as well as the comparison of t_2 and t_0), univariate *t*-tests for dependent samples were computed separately for the intervention group and the control group. To investigate the effectiveness of CM, analyses of covariance (ANCOVA) were conducted. Primary and secondary outcomes were compared at t_2, with their baseline values as covariates (e.g., the mental component summary (MCS) of the SF-8 at t_0 for the analysis of the primary outcome). To control for potential sociodemographic and medical confounding variables, we included those variables that significantly differ between the two groups at baseline as additional covariates (age, tumor size, neo-adjuvant chemotherapy, and mode of surgery).

Because studies concerning the long-term effectiveness of CM are missing to date, we cautiously expected a small to medium effect size in health-related generic (MCS of the SF-8), as well as cancer-specific, quality of life (GQoL of the EORTC-11), which is of sufficient clinical relevance. Accordingly, $f=0.10$ is classified as small, $f=0.25$ is classified as medium, and $f=0.40$ is classified as a large effect size. Given an alpha of 0.05 level of significance, a small to medium effect size ($f=0.20$), and a statistical power (1-β) of $p>0.80$, an a priori power analysis indicated that a sample size of 100 patients per study arm was necessary for the ANCOVA. An expected drop-out rate of approximately 30% at follow-up was taken into account; therefore, we aimed to include approximately $n=140$ patients per condition. Because of the more exploratory nature of the study, we analyzed per protocol.

Sample

In sum, 589 (intervention) and 332 (control) breast cancer patients were medically treated (Figure 1). The final sample consisted of $n=126$ (21%) for the intervention group and $n=118$ (36%) for the control group.

Results

Table 1 provides the demographic and clinical characteristics of the sample (see also supplementary Table 1). A statistical comparison between the intervention and control groups at t_0 revealed that participants of the intervention group were significantly older, and none of the controls lived in a large city. According to the medical records data, as well as the disease-related self-reports of the patients, participants of the intervention group feel less informed about the diagnosis (item: 'I am well informed about my diagnosis'), more frequently undergo mastectomy and less frequently neoadjuvant chemotherapy. The analysis of TNM classification based on the medical records revealed differences concerning the size of tumor, with a small effect size: tumor size categories of 1 and 3 occur more frequently with patients of the intervention

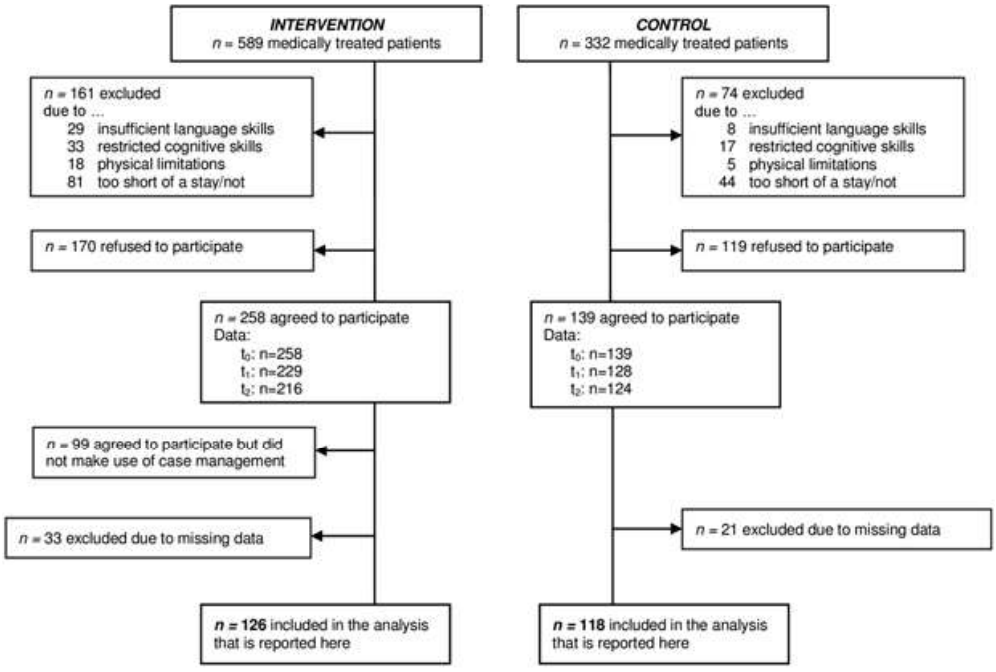

Figure 1. CONSORT diagram

Table 1. Baseline characteristics of the intervention and control patients

	Intervention ($n = 126$)	Control ($n = 118$)	t-test/χ^2
Age in years: mean (SD)	57.2 (11.2)	54.2 (9.9)	t (242) = 2.21 $p = 0.028$, $d = 0.28$
Education (%)			
Secondary general school	44.4	53.9	χ^2 (3, $n = 239$) = 3.81 $p = 0.282$, $\Phi = 0.126$
Intermediate secondary school	36.3	32.2	
Grammar school/specialized grammar school	17.7	13.9	
Other	1.6	0	
Tumor size (%)			
T0	0	1.7	χ^2 (4, $n = 238$) = 9.51 $p = 0.050$, $\Phi = 0.200$
T1	68.0	55.2	
T2	26.2	38.8	
T3	4.9	1.7	
T4	0.8	2.6	
Distant metastases (%)	1.6	4.2	χ^2 (1,$n = 243$) = 1.51 $p = 0.219$, $\Phi = 0.079$
Neoadjuvant chemotherapy (%)	4.1	13.7	χ^2 (1,$n = 240$) = 6.94 $p = 0.008$, $\Phi = 0.170$
Mode of surgery (%)			
Breast preservation surgery	56.3	77.8	χ^2 (1, $n = 243$) = 12.54 $p < 0.001$, $\Phi = 0.227$
Mastectomy	43.7	22.2	
Hours of case management (n)			
<4 h	40	–	
>4 h	86	–	

group, whereas tumor size category 2 and infiltrating tumors (T4) were more often found in the control group.

Comparisons of participants with non-participants (Supplementary Table 2) indicate that non-participants of the intervention group were more likely to live in the countryside, were older and had a higher physical burden (more often having neo-adjuvant chemotherapy, more infiltrating tumors, and increased distant metastases) than the participants of the study. Non-participants of the control group were significantly older and more likely to live in a village.

At first, univariate comparisons without an adjustment for the confounding variables in the short (t_0–t_1) and long-term course (t_0–t_2) were separately conducted for both of the groups concerning the primary (MCS of the SF-8 and GQoL of the EORTC-11) and secondary outcomes (supplementary Figure 1 and supplementary Table 3). The results demonstrated improvements in the mental component summary (SF-8), the global quality of life (EORTC-11), emotional functioning (EORTC-11), and the distress thermometer, with medium or close to medium effect sizes. Other improvements were for anxiety and depression (HADS), with small effect sizes for t_0–t_1, as well as for t_0–t_2, for both of the groups. No changes, neither after 6 months nor after 12 months, were found for the physical component summary (SF-8) or for nausea (EORTC-11).

Examination of the effectiveness of CM was implemented based on the ANCOVA. A comparison of the intervention and control groups concerning the *long-term* effect (t_2, Table 2 and supplementary Table 4) of CM revealed significant differences for two of the secondary outcomes, that is, the physical component summary (SF-8) and physical functioning (EORTC-11). These differences had small effect sizes and favored the control group. For all of the other generic and cancer-specific quality of life outcome variables, as well as mental health, no significant differences between the intervention and control groups were found.

A comparison of the intervention and control groups concerning the *short-term results* of CM (t_1, Supplementary Table 5) revealed no significant differences for the primary and secondary outcomes.

To summarize, the intervention group did not have significantly better results (neither for t_1 nor for t_2) in the primary or secondary outcome variables than the control group under statistical control of baseline levels and the covariates of age, tumor size, neo-adjuvant chemotherapy, and the mode of surgery.

Discussion

The present study analyzes the outcome of cross-sectoral care for cancer patients, who are either supported by CM or TAU. Strengths of the study include the evaluation of an already implemented complex intervention under clinically representative conditions with a control group, with a large sample and with an assessment of short and long-term outcomes, including a wide range of patient reported outcomes. Because of the already implemented CM, it was not possible to implement a randomized, controlled trial.

The results do not demonstrate that patients of the intervention group had a better outcome than the patients of the control group. The patients in both groups improved with regard to health-related quality of life and mental state one

Table 2. Comparison of intervention and control groups at a 12-month follow-up with regard to the primary outcomes

Outcome	Intervention ($n = 126$) marginal mean (s.e.)	Control ($n = 118$) marginal mean (s.e.)	ANCOVA group (IG versus CG)		Covariates (t_0)									
					Baseline		Age		Tumor size		Neoadjuvant chemotherapy		Lumpectomy versus mastectomy	
			p	η^2	p	η^2	p	η^2	p	η^2	p	η^2	p	η^2
SF-8 mental component summary	46.34 (0.94)	46.53 (0.97)	0.894	<0.001	<0.001	0.093	0.416	0.003	0.360	0.004	0.680	0.001	0.985	<0.001
EORTC-11 global quality of life	61.66 (1.96)	65.88 (2.02)	0.149	0.009	<0.001	0.083	0.367	0.004	0.591	0.001	0.822	<0.001	0.171	0.009

η^2 represents the estimation of effect size (partial η^2).
SF-8: Short Form of the SF-36 Health Survey
EORTC-11: European Organization for Research and Treatment of Cancer, a short form of the EORTC-QLQ-C30.

year after the diagnosis, compared with baseline levels, but no differences between the groups were found. Thus, the expected higher effectiveness of CM than TAU could not be confirmed. The question of why the outcomes of the two groups did not differ as expected will be discussed in the following sections.

A possible explanation for the counterintuitive findings relates to the chosen region of the *control group*. The region was selected according to the care structure, the number of treated patients, and the catchment area, which seemed to be suitable for a comparison group with the only difference in town status (less inhabitants in Deggendorf, but larger catchment area covering major cities). Nonetheless, it could be possible that patients of the control group receive a *higher quality treatment*, rather than the average standard treatment or routine care in Germany [7], to which the knowledge of taking part in a controlled study might have contributed. A further possible explanation could be that we were missing out on some of the most distressed potential participants that were not eligible for study participation and thus referred to specialized services.

Another important aspect may be the *organizational form* of the CM model that is evaluated in this study. An inpatient model underlies most of the efficacy studies of CM, whereas in the CM program evaluated in this study case managers were directly involved in the consultation hours of the breast center but were not part of the inpatient team. Additional studies need to directly compare different types of the organizational forms of CM.

Regarding possible *selection effects* at baseline, significant differences between the intervention and control groups were found concerning *age* (patients of the intervention group were three years older, on average, than the controls) and the *place of residence* (a higher percentage of patients in the intervention group lived in a city). With regard to age, it seems quite unlikely that a difference of three years in age, on average, would be of clinical significance. Furthermore, there were no differences between the two groups with regard to the primary and secondary outcomes at baseline, but the groups differed in a few of the clinical characteristics, including tumor size, use of neo-adjuvant chemotherapy, and mode of surgery. However, these variables were included as covariates (with the exception of place of residence, which was highly correlated with the group allocation and, thus, could not be statistically controlled) and were not able to significantly predict the variance in the outcome variables. Further methods like propensity scores weighting could have been applied, but given the small predictive power of the relevant covariates analyzed, we do not assume that the results would substantially vary. Therefore, it can be assumed that the described differences between the groups at baseline only had marginal effects on the outcome variables, which is notable because randomization was not feasible in this controlled trial. However, we could not

rule out possible effects of potential unknown confounders.

The consistent direction of the results across the outcomes could indicate that–regardless of the implementation of CM in the intervention group–*treatment dosages* (hours of psychosocial intervention) were comparable in both groups. This might be due to the available current guidelines, which include recommendations for psychosocial care [17]. Our study results, as well as complementary data from our survey of network partners and case managers [18], suggest that future studies should focus more on certain aspects of the implementation and the process of CM. However, the results of a current review provide only little evidence that CM interventions with a higher intensity or a longer duration result in better outcomes [19]. One reason for this may be that 'intensity' or treatment dosage in the sense of adequate care is difficult to determine and measure.

With regard to the *generalization of the results* of this study, older and seriously ill patients are somewhat underrepresented in the sample, which may lead to a slight underestimation of distress and an overestimation of (particularly physical) quality of life and, hence, to an underestimation of the need for CM or psychosocial care. The results of the analysis regarding the representativeness of our study indicate that *non-participants*, particularly those of the intervention group, are significantly *older* and have a *higher level of physical severity*. The observation that elderly breast cancer patients rarely participate in studies and are approached more cautiously in the recruitment process has been shown in previous studies [20–22]. Thus, the need for CM may be underestimated in previous research as well.

Our findings are consistent with the results of current systematic reviews comparing different models of integrated care [23], as well as CM models in patients with complex care needs [19] with TAU: The meta-analysis of Aubin *et al.* [23] could not show superiority of the included models (i.e., CM, shared care and interdisciplinary teams); their authors state that no conclusions can be drawn on the effectiveness of these interventions with regard to improvements in the continuity of care. Accordingly, the CM interventions that were reviewed by Hickam *et al.* [19] were only associated with small changes in patient-centered outcomes, the quality of care, and resource utilization. Regarding the subsample of eight studies on cancer patients, improvements in selected cancer-related symptoms and functioning were found, but there were no improvements in the overall quality of life. However, the strength of the evidence of these findings is low.

Conclusions and further directions

Before concluding that CM interventions are not helpful for cancer patients, future studies should focus on certain gaps in the current evidence base. First, it is necessary to gather information about the specific needs of cancer patients, as well as their providers, in order to successfully identify those patients who may substantially benefit from the better coordination of care and additional psychosocial support [e.g., 24,25]. Risk assessment tools must be developed and implemented in order to identify possible candidates for CM models and to be able to tailor the interventions to the needs of these patients. Because most previous studies have focused on breast cancer patients, it is necessary to include patients with different types of cancers and those who are in different phases of their cancer care. Second, until now, we did not sufficiently understand how long the CM interventions should last in order to achieve effectiveness and with what intensity, in terms of the frequency of contacts and the qualification, continuity, skills, and experience of the case manager. Little is known about the best type of delivery, including face to face or telephone based, or newer developments, such as the integration of e-health elements.

Thus, more rigorous, large-scale studies are warranted that focus on the duration and intensity of the components of CM as well as the contextual conditions, which are tailored to the needs of different patients. These studies should be based on theoretical models and should also focus more on the CM process. Additionally, there are lessons to learn from the replication of the results and studies that use randomized, controlled designs.

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Conflict of interest

None of the authors have a conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article at the publisher's web site.