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Effects of an Interprofessional Communication Approach on Support Needs, Quality of Life, and Mood of Patients with Advanced Lung Cancer: A Randomized Trial

Katja Krug [ID],[a] Jasmin Bossert [ID],[a,b] Nicole Deis,[b] Johannes Krisam [ID],[c] Matthias Villalobos [ID],[b] Anja Siegle [ID],[b] Corinna Jung [ID],[b,d] Laura Hagelskamp [ID],[b] Laura Unsöld,[b] Jana Jünger [ID],[e] Michael Thomas,[b] Michel Wensing [ID][a]

Departments of [a]General Practice and Health Services Research, [b]Thoracic Clinic, Thoracic Oncology, Translational Lung Research Center Heidelberg (TLRC-H), German Center for Lung Research (DZL), and [c]Institute of Medical Biometry and Informatics, University Hospital Heidelberg, Heidelberg, Germany; [d]Medical School Berlin, Berlin, Germany; [e]German National Institute for State Examinations in Medicine, Pharmacy, and Psychotherapy, Mainz, Germany
Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Lung cancer • Communication • Support • Needs • Quality of life

Abstract

Background. To address the support needs of newly diagnosed patients with lung cancer with limited prognosis, the Milestone Communication Approach (MCA) was developed and implemented. The main elements of the MCA are situation-specific conversations along the disease trajectory conducted by an interprofessional tandem of physician and nurse. The aim of the study was to evaluate the effects of MCA on addressing support needs, quality of life, and mood as compared with standard oncological care.

Patients and Methods. A randomized trial was conducted with baseline assessment and follow-up assessments at 3, 6, and 9 months in outpatients with newly diagnosed lung cancer stage IV at a German thoracic oncology hospital. The primary outcome was the Health System and Information Needs subscale of the Short Form Supportive Care Needs Survey (SCNS-SF34-G) at 3-month follow-up.

Secondary outcomes included the other subscales of the SCNS-SF34-G, the Schedule for the Evaluation of Individual Quality of Life, the Functional Assessment of Cancer Therapy lung module, the Patient Health Questionnaire for Depression and Anxiety, and the Distress Thermometer.

Results. At baseline, 174 patients were randomized, of whom 102 patients (MCA: $n = 52$; standard care: $n = 50$) provided data at 3-month follow-up. Patients of the MCA group reported lower information needs at 3-month follow-up (mean ± SD, 33.4 ± 27.5; standard care, 43.1 ± 29.9; $p = .033$). No effects were found for secondary outcomes.

Conclusion. MCA lowered patient-reported information needs but did not have other effects. MCA contributed to tailored communication because an adequate level of information and orientation set the basis for patient-centered-care. *The Oncologist* 2021;26:e1445–e1459

Implications for Practice: By addressing relevant issues at predefined times, the Milestone Communication Approach provides individual patient-centered care facilitating the timely integration of palliative care for patients with a limited prognosis. The needs of patients with lung cancer must be assessed and addressed throughout the disease trajectory. Although specific topics may be relevant for all patients, such as information about the disease and associated health care, situations of individual patients and their families must be considered. Additionally, using the short form of the Supportive Care Needs Survey in clinical practice to identify patients' problems might support individually targeted communication and preference-sensitive care.

Introduction

With the diagnosis of lung cancer, patients and family caregivers face challenges touching every part of their everyday lives, including physical symptoms like pain and fatigue,

organization of therapies, and changes in social relationships. Challenges are increased by the nature of the disease with its limited prognosis, a median survival time of

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12 months (stage IV) and a 5-year survival rate of 14%–19% in Germany (all stages) because of its late detection [1]. Thus, palliative care issues are of paramount importance during the whole disease trajectory. The early integration of palliative care in lung cancer care has shown positive effects on symptom management, quality of life, and quality of care of patients [2–4].

Because of the complex care situation, patients (and family caregivers) need to be constantly informed about the current situation, care options, and consequences, especially with the rapid development of new therapeutic approaches in oncology care [5, 6]. Because therapeutic goals and preferences for care are also influenced by the burden of the disease [7, 8], health care professionals have a crucial role of eliciting patient preferences using communication skills appropriate to the individual patient's needs as they evolve along their disease trajectory [9].

At a thoracic oncology clinic, an interprofessional communication concept, the Milestone Communication Approach (MCA) [10], was developed and implemented, aiming both at strengthening communication skills of health care professionals and providing needs-oriented and goal-concordant care for patients. The MCA intends to achieve preference-sensitive shared decisions, continuity of care, and early recognition, integration, and therapy of palliative care needs.

Addressing patient information needs in a timely fashion is of paramount importance for preference-sensitive decisions and patient-centered care. Thus, the aim of our study was to evaluate MCA care with respect to addressing information support needs compared with standard oncological care from the patients' perspective (primary outcome). Additionally, effects on addressed physical and psychological support needs and on quality of life, distress, and mood (depression and anxiety) were examined.

MATERIALS AND METHODS

Study Design
This randomized trial was part of a larger multiphase mixed-method study focusing on the implementation and evaluation of the MCA concept in a thoracic oncology clinic [11]. Publications on the MCA concept development [10], implementation fidelity [12], and patient and caregiver experiences [13] are available. The present publication follows the recommendations of the Consolidated Standards of Reporting Trials (checklist available as supplemental online Table 1).

Primary outcome of the study was patient information needs on the Health System and Information Needs subscale of the German version of the Short Form Supportive Care Needs Survey (SCNS-SF34-G) measured 3 months after inclusion in the study. This was compared between patients receiving MCA and patients receiving standard oncological care. Secondary outcomes included physical and psychological supportive care needs (as measured by the SCNS-SF34-G), quality of life (assessed by the Schedule for the Evaluation of Individual Quality of Life [SEIQoL] and

the Functional Assessment of Cancer Therapy–lung module [FACT-L]), distress (assessed by the Distress Thermometer), and depression and anxiety (assessed by the Patient Health Questionnaire for Depression and Anxiety [PHQ-4]).

Patients included in the study were randomized to either the MCA pathway or standard oncological care using blocked randomization with sealed opaque envelopes provided by the Institute of Medical Biometry and Informatics (which was not involved in the data collection or interventions; concealed allocation).

After inclusion in the study, participating patients were asked by a study nurse to fill in questionnaires at the time of recruitment (baseline [t0]), after 3 (t1), 6 (t2), and 9 months (t3). Data for t3 were assessed at 9 months instead of the planned 12 months (as described in the study protocol [11]) because of organizational aspects and a high dropout rate. Randomization took place after the baseline assessment and before the first appointment with the physician (and nurse for the MCA patients). Patients and health professionals were aware of the group assignment.

Selection and Description of Participants
To be eligible for inclusion in the study, patients had to be 18 years or older and being treated at the Department of Thoracic Oncology in Heidelberg with newly diagnosed metastatic lung cancer (stage IV). They needed to have a sufficient command of German and to be able to fill in the questionnaires. Patients were invited to participate while waiting for an outpatient appointment about diagnostic test results or after having received the diagnosis. Patients unwilling to participate and unable to give consent were excluded from the study.

The hospital is one of the largest thoracic oncology clinics in Germany, providing care for about 600 patients newly diagnosed with metastatic lung cancer per year (about 1% of incident yearly lung cancer cases in Germany).

Interventions
For an overview, the published study protocol (with supplements) includes a detailed description of the intervention following the template for intervention description and replication [14]. In summary, the MCA concept consists of three key features: structured, interprofessional (physician-nurse tandem) milestone conversations, follow-up phone calls by the nurse, and an interprofessional communication training [10].

For the conversations, milestones were defined at specific points in the disease trajectory (diagnosis, stable phase, progression, transition to best supportive care). Previously identified (information) needs specific to the milestones [15–17] were addressed in face-to-face conversations between patients (and family caregivers) and an interprofessional tandem of nurse and physician (with experience in oncology and palliative care). Particularly, milestone 1 focused on the disclosure of diagnosis and prognosis, and milestone 2 addressed the stable phase treatment with response under cancer-specific treatment. At milestone 3, disease progression with reassessment of options and change or stop of disease-modifying

Table 1. Baseline sociodemographic factors of patients (MCA randomized controlled trial)

Sociodemographic factor	MCA intervention (n = 79), n (%)	Standard oncological care (n = 78), n (%)	p value
Age, mean ± SD, years	67.2 ± 8.5	65.3 ± 9.2	.194[a]
Gender[b]			.831[c]
Female	34 (43.0)	34 (43.6)	
Male	45 (57.0)	42 (53.8)	
Residence[b]			.381[c]
City ≥100,000 inhabitants	10 (12.7)	6 (7.7)	
Town up to 100,000 inhabitants	20 (25.3)	26 (33.3)	
Rural up to 15,000 inhabitants	48 (60.8)	44 (56.4)	
Marital status[b]			.316[c]
Single	2 (2.5)	4 (5.1)	
Married/ with partner	61 (77.2)	51 (65.4)	
Separated/divorced	6 (7.6)	12 (15.4)	
Widowed	9 (11.4)	9 (11.5)	
Living situation[b]			.170[c]
Living alone	13 (16.5)	22 (28.2)	
Living with partner	62 (78.5)	50 (64.1)	
Other	2 (2.5)	2 (2.6)	
Children[b]			.035[c]
Yes	59 (74.7)	66 (84.6)	
No	20 (25.3)	9 (11.5)	
Educational level[b]			.076[c]
None	—	1 (1.3)	
8th/9th grade	47 (59.5)	38 (48.7)	
10th grade	18 (22.8)	22 (28.2)	
12th/13th grade	10 (12.7)	5 (6.4)	
Other	2 (2.5)	9 (11.5)	
Working status[b]			.574[c]
Yes	17 (21.5)	19 (24.4)	
>40 hr/week	7 (41.2)	9 (47.4)	
20–40 hr/week	5 (29.4)	6 (31.6)	
<20 hr/week	5 (29.4)	4 (21.1)	
No	61 (77.2)	55 (70.5)	
Homemaker	3 (4.9)	5 (9.1)	
Unemployed	2 (3.3)	1 (1.8)	
Retired	49 (80.3)	44 (80.0)	
Other	5 (8.2)	4 (7.3)	
Primary language[b]			.583[c]
German	77 (97.5)	75 (96.2)	
Other	2 (2.5)	1 (1.3)	
Self-reported smoking status[b]			.784[c]
Yes	10 (12.7)	13 (16.7)	
No	31 (39.2)	32 (41.0)	
Occasionally	9 (11.4)	7 (9.0)	
Ex-smoker	29 (36.7)	24 (30.8)	
Physical activity/sports[b]			.617[c]
Never	50 (63.3)	42 (53.8)	
Once a week or less	17 (21.5)	19 (24.4)	

(continued)

Table 1. (continued)

Sociodemographic factor	MCA intervention (n = 79), n (%)	Standard oncological care (n = 78), n (%)	p value
Several times a week	8 (10.1)	10 (12.8)	
Daily	3 (3.8)	1 (1.3)	
Health care insurance[b]			.575[c]
Statutory	75 (94.9)	74 (94.9)	
Private	2 (2.6)	1 (1.3)	
Chronic diseases[b]			.181[c]
No	13 (16.5)	21 (26.9)	
Yes	54 (68.4)	51 (65.4)	
Hypertension	39 (72.2)	37 (72.5)	
Diseases of the joints	16 (29.6)	13 (25.5)	
Chronic back pain	15 (27.8)	12 (23.5)	
Coronary heart disease	13 (24.1)	13 (25.5)	
Asthma/bronchitis	14 (25.9)	10 (19.6)	
Diabetes mellitus	15 (27.8)	7 (13.7)	
Allergies/ skin diseases	11 (20.4)	4 (7.8)	
Depression/anxiety	3 (5.6)	7 (13.7)	
Chronic gastrointestinal disease	3 (5.6)	3 (5.9)	
Other	14 (25.9)	10 (19.6)	
No. of current medications[b]			.913[c]
None	3 (3.8)	2 (2.6)	
1–2	15 (19.0)	18 (23.1)	
3–4	19 (24.1)	19 (24.4)	
5–6	16 (20.3)	13 (16.7)	
≥7	24 (30.4)	20 (25.6)	

[a]t test.
[b]Percentages do not add up to 100 because of missing values.
[c]Chi-square test.
Abbreviation: MCA, Milestone Communication Approach.

interventions were discussed, and milestone 4 introduced the transition to best supportive care leading to an end-of-life consensus [18]. Milestones 2 and 3 could be repeated or omitted depending on the individual development of the disease. A physician and a nurse conducted the milestone conversations together as a nurse-physician tandem. The conversations were structured using SPIKES [19] and prepared and debriefed by the tandem. Physicians and nurses used a shared electronic documentation system that was also used for assessing implementation fidelity [12].

The nurse also conducted additional phone calls about a week after each conversation and at least once a month to follow up on the patients, to clarify questions occurring after the conversations, and to sustain communication. In detail, follow-up calls included the assessment of symptoms and palliative care needs using the Integrated Palliative Outcome Scale [20], prognostic awareness [21], resuming main topics of the milestone conversations, and providing information about and contact to other health care professionals (e.g., general practitioner, psycho-oncologist, social worker). For the nurses, contact to other physicians involved in the treatment was possible and even encouraged.

Physicians and nurses of the tandems received an interprofessional communication training before implementation

of the MCA in practice. The training consisted of four training days (one day a month) with days 1 and 3 covering communication theories, MCA content, and communication training with standardized patients. Days 2 and 4 were trainings on the job: real-life communications as a physician-nurse tandem with patients were observed, and feedback was provided.

Standard oncological care was not explicitly oriented on the disease trajectory (i.e., general issues were addressed but not systematically trajectory-specific), appointments were scheduled with patients and the physician alone (without involving a nurse), and there were no follow-up calls. Patients receiving standard oncological care had contact with nurses in the ambulatory setting for the application of chemotherapy and on the ward during treatment of complications. Conversations were unplanned and unstructured, and there were no assessments of palliative needs on a regular basis. The standard procedure of communication among oncologists (e.g., in meetings) was not changed for the intervention. Patients not included in the study received standard oncological care.

The incremental resources contained additional working time of nurses and physicians of up to six MCA conversations (about 45–60 minutes) and up to 12 follow-up

conversations (about 20 minutes) per patient per year. At the same time, there were possibly working time savings through fewer unplanned, uncoordinated (between physicians and nurses), and unstructured conversations with multiple stakeholders.

Measures

Patient support needs were assessed by the German Version of the Short Form Supportive Care Needs Survey (SCNS-SF34-G) [22, 23]. The questionnaire includes 34 items on a response scale of 1 (no need), 2 (need sufficiently addressed), and 3–5 (low to high need), combined in five subscales: Physical and Daily Living Needs (five items, e.g., tiredness, pain), Psychological Needs (10 items, e.g., feelings of sadness, uncertainty about the future), Sexuality Needs (three items, e.g., changes in sexual feelings), Patient Care and Support Needs (five items, e.g., choice of hospital), and Health System and Information Needs (11 items, e.g., receiving timely information about test results, availability of one team member to discuss all aspects of the disease). The subscales are analyzed separately. Standardized Likert sum scores of each subscale lead to values between 0 (no need) and 100 (high need) [24]. The questionnaire has been validated and showed good psychometric properties (i.e., [22, 23, 25, 26]).

Quality of life was assessed by the SEIQoL [27] and the FACT-L [28, 29]. The SEIQoL covers 12 areas of quality of life, which patients rate in importance and satisfaction on five-point percentage scales (0, 25, 50, 75, 100). A quality-of-life index score with values between 0 (lowest quality of life) and 100 (highest quality of life) is calculated from satisfaction scores weighted by the respective importance. The FACT-L comprises the basic module, FACT–General (FACT-G), with 27 items covering four domains (physical well-being, social well-being, emotional well-being, functional well-being) and seven additional questions on lung cancer–specific symptoms on five-point Likert scales. Domain sum scores take values between 0 designating low well-being and 24 (emotional well-being) and 28 (other domains and additional questions) designating high well-being, leading to a FACT-G total score of 0 to 108 and a FACT-L total score of 0 to 136. Additionally, the FACT trial outcome index can be combined from the physical, functional, and additional questions subscales (0–84).

Mood (depression and anxiety) was assessed by the PHQ-4, [30] consisting of two questions addressing depression (PHQ-2) and two questions addressing anxiety (Generalized Anxiety Disorder two-item questionnaire [GAD-2]), with four-point response scales leading to a sum score of 0–12 for the PHQ-4 and transformed sum scores of 0–6 for the subscales. Values ≥3 in the subscales are considered elevated [30].

Furthermore, psychosocial distress was assessed with the German version of the National Comprehensive Cancer Network (NCCN) Distress Thermometer [31] taking values between 0 (no distress) and 10 (extreme distress) on an 11-point scale with values ≥5 considered needing attention. On the accompanying problem list, 36 distress-related issues can be identified (physical, emotional, practical, family, spiritual problems, e.g., fatigue, worry, living situation).

As the patients in our study completed the baseline questionnaire before or up to 1 week after their first appointment (and thus in some cases without knowing the diagnosis), baseline assessment focused on physical (five items of the SCNS-SF34-G), psychological (six items of the SCNS-SF34-G), and information needs (10 items of the SCNS-SF34-G), on quality of life (SEIQoL), distress (Distress Thermometer), and depression/anxiety (PHQ-4). Follow-up assessments included all questionnaires in full. Because of the limited prognosis of the disease and the palliative situation, only item 28 of the SCNS-SF34-G (to be informed about cancer that is under control or diminishing, i.e., remission) was removed from all assessments. Sociodemographic characteristics were also assessed from patients at baseline (age, gender, residence, marital status, living situation, children, educational level, working status, primary language, smoking status, physical activity/sports, health care insurance, chronic diseases, number of medications).

Data Analysis

SCNS-SF34-G subscales, SEIQoL index score, FACT subscales and total scores, PHQ-4 sum score, and Distress Thermometer were described as means ± SD for both groups at all assessments. Categorical data (sociodemographics, PHQ-2, GAD-2, distress) were described as absolute and relative frequencies.

Between-group differences in addressed information needs between MCA and standard care at t1 (primary outcome), at t2 and t3, for psychological and physical support needs, for quality of life (SEIQoL), patient health (PHQ-4), and distress (secondary outcomes) were analyzed for the intention-to-treat population including all randomized patients using linear models including the baseline (t0) value as independent variable. Missing values of the primary outcome were replaced by multiple imputation (fully conditional specification method [32]). A complete case analysis was done for sensitivity analysis. Between-group differences at t0 and for follow-up scores without t0 values were analyzed descriptively using the nonparametric Mann-Whitney U test. Categorical data were analyzed using chi-square independence tests for t0 data and logistic regression with an adjustment for the baseline value if assessed. Values of $p < .05$ were considered statistically significant.

A sample size of 82 patients was planned to detect a relevant difference of five points on the SCNS-SF34-G information subscale in the linear model between groups at t1 with an SD of $\sigma = 7.4$ [33] (effect size of d = 0.676). The initially proposed dropout rate of 18.5% (based on prognoses of metastatic lung cancer and the experiences at the Department of Thoracic Oncology, University Hospital Heidelberg) had to be adjusted 6 months after starting patient recruitment because of a higher dropout rate (including mortality) at t1 of 57%; we therefore aimed at including 190 patients in the study.

For analyses, SAS version 9.4 (SAS Institute, Cary, NC) and IBM SPSS Statistics 25 were used.

Ethics Approval

The study was approved by the Ethics Committee of the University Hospital Heidelberg, Germany (protocol no. S-561/2017) and performed in accordance with the ethical standards as laid down in the Declaration of Helsinki as revised in 2013. All patients gave written informed consent before enrolling in the study. The trial was prospectively registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien, trial registration no. DRKS00013469).

RESULTS

Between May 2018 and July 2019, 171 patients were included in the study and randomized (Fig. 1). Fourteen patients did not provide data; thus, baseline data of 157 patients were analyzed (MCA: $n = 79$, standard care: $n = 78$). Patients were on average aged 66.3 ± 8.9 years and predominantly male ($n = 87$, 55.4%). There were no differences between MCA and standard care group in sociodemographic factors, except that in the MCA group fewer patients had children (Table 1). For 154 patients, baseline information on support needs was available, with 102 patients also providing data at 3-month follow-up (t1; Fig. 1).

Health System and Information Needs

Patients in both MCA and standard care group had similar information needs at baseline (MCA: $n = 78$; mean $\pm$ SD, 53.8 ± 33.3; standard care: $n = 76$; 54.5 ± 31.3). At t1, patients receiving MCA care reported lower information needs ($n = 52$, 33.4 ± 27.5) than patients receiving standard oncological care ($n = 50$, 43.1 ± 29.9; $p = .033$; effect size: Cohen's d $= -.0.37$). The sensitivity analysis using complete cases ($n = 102$) showed similar results ($p = .043$). At t2 and t3, no differences in addressed information needs were observed between the groups (Table 2).

Other Support Needs

At all assessment points, patients in both groups did not differ in their mean physical and daily living care needs and in their psychological care needs (Table 2). Patient care and support needs and sexuality needs were not assessed at baseline; group differences were only analyzed descriptively (Table 2).

Quality of Life

The SEIQoL quality-of-life index score showed a similar quality of life in both patient groups at baseline and follow-up assessments (Table 3). The various FACT scores were not assessed at baseline; they showed no differences between MCA and standard oncological care group at follow-up assessments (Table 3).

Mood (Depression/Anxiety)

Generally, depression and anxiety as measured with the four-item PHQ-4 did not show differences between the treatment groups at any time (Table 4). For depression measured with the two-item PHQ-2, patients in standard oncological care reported higher scores at baseline (MCA:

mean $\pm$ SD, 2.0 ± 1.5; standard oncological care: 2.6 ± 1.6; $p < .05$). There were no differences at other assessment times adjusted for baseline. Neither did patients report elevated scores for anxiety (GAD-2) at any point in time.

Distress

More than 50% of patients in both groups reported increased distress across assessments. There were no differences between groups in the proportion of patients reporting critical distress (at least five points on the Distress Thermometer; Table 4). At baseline, patients identified a median of 8.0 (interquartile range [IQR], 4.0–12.0) issues (MCA: median, 8.0; IQR, 5.0–12.0; standard oncological care: median, 9.0; IQR, 5.0–12.3) and at 3-month follow-up a median of 4.0 (IQR, 0.0–10.0) issues (MCA: median, 4.0; IQR, 0.0–10.0; standard oncological care: median, 5.0; IQR, 0.0–11.0) on the problem list. The most frequently marked issues referred to physical and emotional problems. Fatigue remained a problem for more than 60% of the patients throughout the study; however, emotional problems like worry and fear became less important (Table 5).

DISCUSSION

The structured Milestone Communication Approach more effectively managed patients' health system and information needs compared with standard oncological care. Needs were high in the patient population related to the predefined primary outcome of the randomized trial. Following the milestone structure, patients received necessary information about diagnosis and prognosis when they needed it. Patients with standard oncological care also experienced decreasing information needs over time but with a delay of at least 3 months behind the MCA group. Addressing information needs in a timely patient-centered way is one important aspect of facilitating prognostic awareness and advance care planning.

With the primary focus on meeting information needs after receiving the diagnosis of stage IV lung cancer, the MCA addressed the most pressing questions determined by patients at time. Nevertheless, other issues were not neglected but were only touched upon (so as not to overwhelm patients unless they voiced the need to discuss those as well). The MCA provides a method to find a balance between sufficiently meeting information needs and inundating patients with information that they cannot process in due time [34].

Information needs assessed by the SCNS-SF34 covered issues like receiving timely information about test results, having access to professional counseling if needed, being informed about benefits and side effects of treatments, and the availability of one team member to discuss all aspects of the disease. The MCA addressed those needs, not only by structured conversations but also by providing continuity of care.

A stronger role was given to oncology nurses in the MCA. They were in closer contact with the patients, kept the contact up through regular conversations (not only within the milestone conversations) and phone calls, and
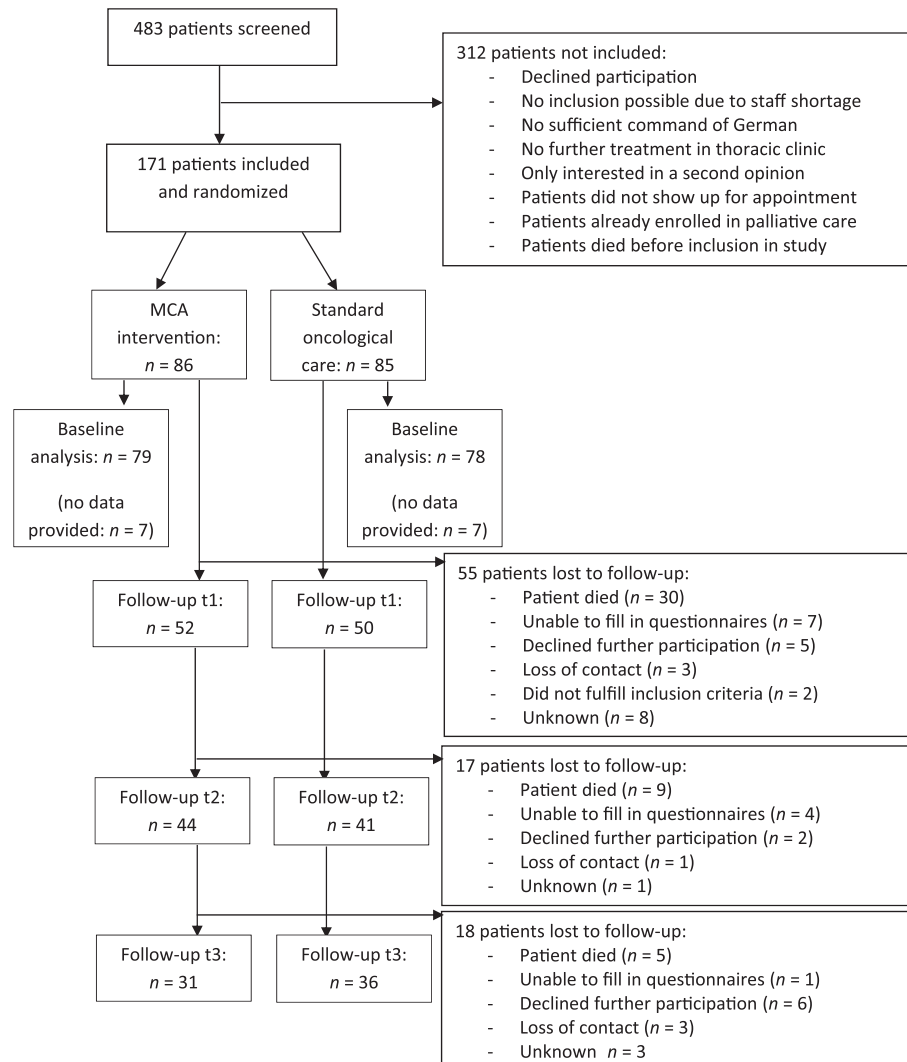
Figure 1. Flowchart of MCA randomized controlled trial.
Abbreviations: MCA, Milestone Communication Approach; t1, 3-month follow-up; t2, 6-month follow-up; t3, 9-month follow-up.

built a trusting relationship to the patients, often being the first health care professional to whom patients reported their concerns. Nurses responded to individual needs of patients, including giving information about treatment and symptom management and sharing information with the interprofessional team by documentation. There was significantly increased contribution to patient-centered care within the MCA by the nursing team members.

Health system and informational needs have been reported as key issues for patients with cancer in various studies [35–41], including the German validation study of the SCNS-SF34 [23]. In this study, the decision to choose information needs as the primary outcome related to the problem of uncertainty in the decision-making process. Cancer therapeutics develop rapidly and the constantly changing treatment algorithms challenge the clinician-patient communication. In addition, the trend for shared decision-making and the need for timely information by patients were strong influences. Being informed constitutes the necessary basis for realistic prognostic awareness and patient-centered shared decisions during treatment and at the end of life.

For the SCNS-SF34, no minimally important difference indicating a clinically relevant change or difference between treatment groups has been published. For planning our study, we considered a mean difference of five points on the 0–100 scale as sufficient for a relevant difference between MCA and standard care groups. The observed mean difference of 10 points in our study was in line with the results reported for known-groups validity in the original validation study (mean difference: 11.5 points [22]) and international translations [42–44].

Although the average reported needs in other studies are similar to our findings, our patient sample reported a larger deviation in individual needs. Thus, at first glance this homogeneous patient group (only patients with stage IV lung cancer) had heterogeneous needs, which must be considered when planning individualized patient care. New treatment regimens, such as targeted therapy and immunotherapy, may further trigger individualized approaches to distinct disease trajectories with

Table 2. Differences in supportive care needs (German version of the Short Form Supportive Care Needs Survey) between MCA and standard oncological care

Supportive Care Needs subscale	MCA intervention	Standard oncological care	p value
Health System and Information Needs			
t0			
n	78	76	
Mean ± SD	53.8 ± 33.3	54.5 ± 31.3	.899[a]
t1			
n	52	50	
Mean ± SD	33.4 ± 27.5	43.1 ± 29.9	.033[b]
			.043[c]
t2			
n	44	41	
Mean ± SD	34.5 ± 30.9	34.7 ± 30.7	.620[d]
t3			
n	31	35	
Mean ± SD	34.3 ± 33.7	25.6 ± 25.4	.378[d]
Physical and Daily Living Needs			
t0			
n	74	71	
Mean ± SD	32.5 ± 28.2	36.4 ± 25.7	.396[a]
t1			
n	52	50	
Mean ± SD	33.1 ± 23.7	36.1 ± 25.2	.840[d]
t2			
n	44	41	
Mean ± SD	28.8 ± 22.3	34.5 ± 28.1	.409[d]
t3			
n	31	35	
Mean ± SD	26.4 ± 27.1	30.3 ± 28.1	.824[d]
Psychological Needs			
t0			
n	74	70	
Mean ± SD	39.2 ± 31.2	45.9 ± 29.6	.190[a]
t1			
n	52	50	
Mean ± SD	37.2 ± 29.7	42.2 ± 29.2	.662[d]
t2			
n	44	41	
Mean ± SD	43.4 ± 27.3	34.8 ± 26.8	.063[d]
t3			
n	31	35	
Mean ± SD	40.9 ± 32.7	29.1 ± 23.6	.053[d]
Patient Care and Support Needs			
t1			
n	52	50	
Mean ± SD	25.5 ± 27.7	30.2 ± 28.1	.489[a]
t2			
n	44	41	
Mean ± SD	24.3 ± 29.6	22.8 ± 28.0	.785[a]

(continued)

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Table 2. (continued)

Supportive Care Needs subscale	MCA intervention	Standard oncological care	p value
t3			
n	31	35	
Mean ± SD	26.5 ± 32.2	16.4 ± 23.2	.190[a]
Sexuality Needs			
t1			
n	47	44	
Mean ± SD	17.1 ± 22.9	15.4 ± 18.4	.608[a]
t2			
n	42	39	
Mean ± SD	17.0 ± 23.1	14.4 ± 19.1	.975[a]
t3			
n	29	34	
Mean ± SD	14.0 ± 20.7	11.2 ± 20.0	.302[a]

[a]Mann-Whitney U test.
[b]Linear model with multiple imputation and adjustment for baseline value.
[c]Complete case linear model (sensitivity analysis).
[d]Linear model with adjustment for baseline value.
Abbreviations: MCA, Milestone Communication Approach; t0, baseline assessment; t1, 3-month follow-up; t2, 6-month follow-up; t3 9-month follow-up.

varying needs. Communication interventions aiming at patient values and goals, such as the Serious Illness Care Program [45], could be combined with the longitudinal perspective. The Milestone Communication Approach may be a concept to assist in navigating the complex balance between individual needs and trajectory-specific challenges.

Patients who are newly diagnosed with metastatic lung cancer are confronted with a very challenging situation. Getting timely and tailored information about the disease and what to expect in the future supports them in maintaining a sense of control [46]. Structured communication and having a responsive member of the health care team following up on patients assist in patient coping [13] and reducing uncertainty in a highly uncertain situation [47]. Interprofessional collaboration (notably physicians and nurses) and a longitudinal communication approach (including aspects of illness understanding, prognostic awareness, coping, and advance care planning) are key features for effectiveness in early palliative care according to cancer care guidelines [48]. MCA integrated these aspects into patient-centered oncological care pathways. Trials evaluating early palliative care focused on health-related quality of life, depression, symptom intensity, and survival [49].

Similar to other trials, the communication approach showed no effects on patient-reported quality of life. Generally, quality-of-life scores were comparable to those of other study samples [50]. Other studies addressing patients with advanced cancer did not report change in quality of life either [51, 52], although the integration of early palliative care has led to improved quality-of-life scores [2, 49]. In our study, potential changes in quality of life were analyzed using the SEIQoL, which considers shifts in relevance of areas of life. In a life-changing situation, patients adapt their priorities of what is important for them in life to cope with the challenges of the situation and thus to maintain quality of life.

Symptoms, anxiety, and depression are relevant patient-reported outcomes for which no differences were found for patients in MCA care and patients in standard oncological care. Other studies fostering the early integration of palliative care could also not detect advantages of early palliative care for physical functioning and symptom management [49] but reported a higher satisfaction of patients, especially with physicians' attention and information given [53]. With our study, the MCA highlighted the importance of communication between health care professionals and patients using an individualized approach. However, patients in both groups of our study reported elevated scores of depression and distress that call for further attention. Other studies reported similar levels of distress and depression in patients with lung cancer [50]. The regular use of short screening tools like the PHQ-4 and the NCCN Distress Thermometer should be considered in clinical practice to identify patients in need of specific support [54].

Limitations

Patients in the intervention and the control group were cared for by the same oncologists. Thus, it cannot be excluded that the communication training possibly had effects on their interactions with both patient groups. Still, the main intervention—the conversation with a physician-nurse tandem and continuity of care by the nurse—was only given to patients in the intervention group. The reported difference between the patient groups in addressing information needs was observed despite possible contamination and might thus be underestimated.

Group allocation could not be blinded for patients and health care providers. The information given to all patients for informed consent to participate in the study

Table 3. Differences in quality of life (SEIQoL, FACT) between MCA and standard oncological care

Quality of life (sub-)scale	MCA intervention	Standard oncological care	p value
SEIQoL quality of life index			
t0			
n	56	50	
Mean ± SD	61.6 ± 17.6	61.0 ± 17.7	.922[a]
t1			
n	34	33	
Mean ± SD	59.6 ± 17.7	56.8 ± 17.3	.832[b]
t2			
n	29	32	
Mean ± SD	62.4 ± 17.6	65.0 ± 16.8	.238[b]
t3			
n	25	29	
Mean ± SD	59.2 ± 17.8	62.5 ± 15.8	.473[b]
FACT-G total score			
t1			
n	50	48	
Mean ± SD	73.5 ± 16.7	69.1 ± 16.8	.361[a]
t2			
n	41	39	
Mean ± SD	72.5 ± 16.3	72.6 ± 16.1	.765[a]
t3			
n	31	36	
Mean ± SD	70.2 ± 20.0	75.4 ± 16.7	.230[a]
FACT-L total score			
t1			
n	50	48	
Mean ± SD	93.9 ± 18.9	88.7 ± 20.3	.301[a]
t2			
n	41	39	
Mean ± SD	93.1 ± 19.2	93.1 ± 19.8	.904[a]
t3			
n	31	36	
Mean ± SD	89.9 ± 23.7	96.1 ± 20.4	.266[a]
FACT physical well-being			
t1			
n	52	50	
Mean ± SD	20.0 ± 5.8	19.4 ± 6.1	.673[a]
t2			
n	43	41	
Mean ± SD	20.7 ± 5.5	19.8 ± 6.5	.723[a]
t3			
n	31	36	
Mean ± SD	19.3 ± 7.4	20.3 ± 6.3	.619[a]
FACT social/family well-being			
t1			
n	50	49	
Mean ± SD	22.4 ± 4.7	20.4 ± 5.8	.064[a]

(continued)

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Table 3. (continued)

Quality of life (sub-)scale	MCA intervention	Standard oncological care	p value
t2			
n	42	41	
Mean ± SD	22.0 ± 4.4	21.4 ± 4.8	.661[a]
t3			
n	31	36	
Mean ± SD	21.0 ± 5.4	21.8 ± 4.0	.739[a]
FACT emotional well-being			
t1			
n	52	50	
Mean ± SD	17.1 ± 4.8	15.8 ± 5.5	.280[a]
t2			
n	42	40	
Mean ± SD	16.1 ± 5.3	16.8 ± 4.8	.707[a]
t3			
n	31	36	
Mean ± SD	15.5 ± 6.4	17.1 ± 5.1	.341[a]
FACT functional well-being			
t1			
n	52	50	
Mean ± SD	13.4 ± 6.6	14.0 ± 6.0	.555[a]
t2			
n	42	41	
Mean ± SD	13.2 ± 5.9	14.7 ± 5.7	.301[a]
t3			
n	31	36	
Mean ± SD	14.4 ± 6.7	16.2 ± 6.5	.287[a]
FACT additional concerns			
t1			
n	52	50	
Mean ± SD	20.4 ± 4.0	19.7 ± 4.7	.540[a]
t2			
n	43	41	
Mean ± SD	20.5 ± 4.4	20.4 ± 4.5	.816[a]
t3			
n	31	36	
Mean ± SD	19.7 ± 5.2	20.7 ± 4.7	.610[a]
FACT trial outcome index			
t1			
n	52	50	
Mean ± SD	53.8 ± 14.0	53.1 ± 14.4	.963[a]
t2			
n	42	41	
Mean ± SD	54.2 ± 13.5	54.9 ± 15.0	.820[a]
t3			
n	31	36	
Mean ± SD	53.3 ± 16.9	57.2 ± 15.5	.443[a]

[a]Mann-Whitney U test.
[b]Linear model with adjustment for baseline value.
Abbreviations: FACT, Functional Assessment of Cancer Therapy; FACT-G, FACT general module; FACT-L, FACT lung module; MCA, Milestone Communication Approach; SEIQoL, Schedule for the Evaluation of Individual Quality of Life; t0, baseline assessment; t1, 3-month follow-up; t2, 6-month follow-up; t3, 12-month follow-up.

Table 4. Differences in depression, anxiety, and distress between MCA and standard oncological care

Mood scale	MCA intervention	Standard oncological care	p value
PHQ-4 sum score			
t0			
n	79	74	
Mean ± SD	4.1 ± 3.1	5.0 ± 3.4	.129[a]
t1			
n	50	50	
Mean ± SD	3.5 ± 2.9	3.9 ± 2.9	.565[b]
t2			
n	43	40	
Mean ± SD	3.4 ± 2.9	4.1 ± 3.1	.724[b]
t3			
n	31	36	
Mean ± SD	4.2 ± 3.6	3.6 ± 3.1	.284[b]
PHQ-2 sum score			
t0			
n	79	74	
Mean ± SD	2.0 ± 1.5	2.6 ± 1.6	.041[a]
≥3, n (%)	26 (32.9)	31 (41.9)	.251[c]
t1			
n	50	50	
Mean ± SD	1.8 ± 1.6	1.9 ± 1.4	.421[b]
≥3, n (%)	12 (24.0)	13 (26.0)	.446[d]
t2			
n	43	40	
Mean ± SD	1.7 ± 1.4	2.1 ± 1.6	.555[b]
≥3 n (%)	7 (16.3)	15 (37.5)	.236[d]
t3			
n	31	36	
Mean ± SD	2.1 ± 1.8	2.0 ± 1.6	.256[b]
≥3, n (%)	10 (32.3)	12 (33.3)	.867[d]
GAD-2 sum score			
t0			
n	79	74	
Mean ± SD	2.1 ± 1.8	2.4 ± 2.0	.361[a]
≥3 n (%)	28 (35.4)	28 (37.8)	.759[c]
t1			
n	50	50	
Mean ± SD	1.7 ± 1.5	2.1 ± 1.8	.814[b]
≥3, n (%)	9 (18.0)	15 (30.0)	.833[d]
t2			
n	43	41	
Mean ± SD	1.7 ± 1.7	1.9 ± 1.7	.889[b]
≥3, n (%)	7 (16.3)	11 (26.8)	.964[d]
t3			
n	31	36	
Mean ± SD	2.1 ± 1.9	1.6 ± 1.6	.300[b]
≥3, n (%)	10 (32.3)	8 (22.2)	.120[d]

(continued)

Table 4. (continued)

Mood scale	MCA intervention	Standard oncological care	p value
Distress Thermometer			
t0			
n	72	74	
Mean ± SD	5.9 ± 2.4	6.3 ± 2.6	.416[a]
≥5, n (%)	55 (76.4)	50 (67.6)	.236[c]
t1			
n	51	46	
Mean ± SD	4.9 ± 2.5	5.5 ± 2.4	.146[b]
≥5, n (%)	33 (64.7)	31 (67.4)	.357[d]
t2			
n	38	38	
Mean ± SD	5.2 ± 2.7	4.7 ± 2.6	.309[b]
≥5, n (%)	26 (68.4)	21 (55.3)	.551[d]
t3			
n	27	36	
Mean ± SD	5.8 ± 3.2	5.2 ± 2.6	.473[b]
≥5, n (%)	17 (63.0)	23 (63.9)	.837[d]

[a]Mann-Whitney U test.
[b]Linear model with adjustment for baseline value.
[c]Chi-square independence test.
[d]Logistic regression with adjustment for baseline value.
Abbreviations: GAD-2, Generalized Anxiety Disorder two-item questionnaire; MCA, Milestone Communication Approach; PHQ-2, Patient Health Questionnaire (two depression items); PHQ-4, Patient Health Questionnaire for Depression and Anxiety (PHQ-2 and GAD-2); t0, baseline assessment; t1, 3-month follow-up; t2, 6-month follow-up; t3, 12-month follow-up.

Table 5. Most frequently reported problems (Distress Thermometer)

Problem (whole sample)	t0	n (%)	t1	n (%)	t2	n (%)	t3	n (%)
Physical problem: fatigue	1	109 (72.7)	1	65 (65.0)	1	51 (63.7)	1	40 (62.5)
Emotional problem: fears	2	92 (61.3)	2	54 (54.0)	4	38 (46.3	14	22 (33.8)
Physical problem: getting around	3	91 (60.3)	3	53 (53.5)	3	41 (49.4)	2	33 (50.0)
Emotional problem: worry	4	87 (59.6)	4	49 (49.5)	2	44 (52.4)	10	25 (39.1)
Physical problem: pain	5	82 (54.3)	5	49 (49.5)	7	33 (40.7)	4	28 (43.1)
Physical problem: skin dry/itchy	12	47 (31.3)	9	39 (39.4)	10	30 (37.0)	3	33 (49.3)
Physical problem: memory/concentration	13	44 (29.3)	16	32 (31.4)	5	35 (41.7)	6	28 (42.4)

Abbreviations: t0, baseline assessment; t1, 3-month follow-up; t2, 6-month follow-up; t3, 12-month follow-up.

concentrated on the structure of the intervention (additional contacts for patients, training for physicians and nurses to promote interprofessional communication) and did not reveal actual contents of the intervention conversations. Higher expectations in the group of patients receiving standard oncological care might have led to reporting bias. Patient-reported topics addressed in conversations could have been compared with topics in the documentation file filled in by the physicians. For communication with patients, it is more important, however, which information the patient remembers from the conversation than what was objectively addressed [55]. An underreporting caused by poor recollection of the conversation would also provide further aspects for improvement in patient communication.

Differences between the groups observed in secondary outcomes have to be interpreted with caution. The study was powered to detect a difference in information needs—which could be shown—but other observed differences would need to be confirmed in future studies. For further evaluation and improvement of the concept, other aims, such as prognostic awareness and advance care planning, should be focused on in addition to quality-of-life and palliative care outcomes.

An additional limitation is the high dropout rate. The large amount of loss to follow-up was largely due to high mortality, which was higher than expected. The median survival in our study was lower than in the general population of patients with lung cancer with a median survival of 12 months. All included patients had stage IV

lung cancer. Other clinical characteristics were not assessed in the study, so these patients may have had a more severe type of cancer.

Implications for Future Research

Involving patients in their care, including making decisions about treatments, especially for patients with life-threatening diseases and a limited prognosis (e.g., stage IV lung cancer), is increasingly important. Patients should have the ability to determine their care and treatment according to their individual wishes. Therefore, identifying support needs of patients and ways to address them early in the disease trajectory must have a focus in oncology care and research [4]. Future studies should also analyze if and how the concept of structured communication along the disease trajectory addresses individual advance care planning for the benefit of patients and their families.

Conclusion

Patients reported decreased (unmet) information needs after having received MCA care in comparison with patients offered standard oncological care. Balancing information flow and occasions for communication in the disease trajectory according to patient's own self-determined readiness led to well-informed patients better able to understand their situation and the limited prognosis. The MCA intervention is a worthwhile tool for improving the communication processes at key stages of the patient journey for newly diagnosed patients with cancer with limited prognosis.

Author Contributions

Conception/design: Katja Krug, Jasmin Bossert, Johannes Krisam, Matthias Villalobos, Anja Siegle, Jana Jünger, Michael Thomas, Michel Wensing
Provision of study material or patients: Matthias Villalobos, Michael Thomas
Collection and/or assembly of data: Nicole Deis, Matthias Villalobos, Anja Siegle, Corinna Jung, Laura Hagelskamp, Laura Unsöld, Michael Thomas
Data analysis and interpretation: Katja Krug, Jasmin Bossert, Nicole Deis, Johannes Krisam, Matthias Villalobos, Anja Siegle, Corinna Jung, Laura Hagelskamp, Laura Unsöld, Jana Jünger, Michael Thomas, Michel Wensing
Manuscript writing: Katja Krug, Jasmin Bossert, Nicole Deis, Johannes Krisam, Matthias Villalobos, Anja Siegle, Corinna Jung, Laura Hagelskamp, Laura Unsöld, Jana Jünger, Michael Thomas, Michel Wensing
Final approval of manuscript: Katja Krug, Jasmin Bossert, Nicole Deis, Johannes Krisam, Matthias Villalobos, Anja Siegle, Corinna Jung, Laura Hagelskamp, Laura Unsöld, Jana Jünger, Michael Thomas, Michel Wensing

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