








BMJ Open Effectiveness of interprofessional communication skills training for oncology teams: study protocol for a three-arm cluster randomised trial (KommRhein Interpro)

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ABSTRACT

Introduction Patient–provider communication is an important factor influencing the quality of care in oncology. The study examines the comparative effectiveness of a 10-hour interprofessional communication skills training (CST) programme for physicians and nurses in cancer centres.

Methods and analysis KommRhein Interpro is a cluster-randomised trial sponsored by the German Cancer Aid (Deutsche Krebshilfe, DKH) and conducted at the cancer centres of the university hospitals of Aachen, Bonn, Cologne and Düsseldorf. Thirty oncology teams of four cancer centres are randomly assigned to three study arms, providing healthcare professionals with either (a) only written information on patient-centred communication or (b) written information plus CST for physicians or (c) written information plus interprofessional CST for physicians and nurses. For summative evaluation, standardised surveys from three measurement points for patients (T0pat: study enrollment; T1pat: after discharge; T2pat: 3 months' follow-up) and two measurement points for physicians and nurses (T0hpc: before the intervention; T1hpc: after the intervention) are used. N=1320 valid patient cases are needed for data evaluation. The primary endpoint is fear of progression in patients with cancer after discharge. Data will be analysed according to the intention-to-treat principle using a mixed model for repeated measurement. Secondary outcome is the providers' self-efficacy in patient centeredness. Individual confounders and possible moderating effects of organisational factors will be considered. Secondary analysis will be performed by means of multilevel analysis and structural equation modelling.

Ethics and dissemination A vote of approval has been obtained from the ethics committees of the medical faculties of RWTH Aachen University (EK325/20), University of Bonn (391/20), University of Cologne (20–1332) and Heinrich Heine University Düsseldorf (2019–796). Data protection regulations are adhered to for all processed data. The conduct of the study will be monitored. Dissemination strategies include a transfer workshop with

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Large cluster-randomised trial of a short communication skills training at four cancer centres in German university hospitals.
- ⇒ Evaluation of an interprofessional communication skills training (CST) for oncology teams.
- ⇒ Complex multivariate and multilevel models, which take organisational factors into account.
- ⇒ No observational measures for the CST programmes.

cancer teams and distribution of the final study report to participants.

Trial registration number DRKS00022563; DRKS (German Clinical Trials Register).

INTRODUCTION

Patient–provider communication is a significant factor influencing the outcome of medical treatment^{1–3} and is considered to be an important quality indicator in oncology.⁴ While communication skills are part of the curriculum of medical schools and other healthcare professional programmes, they have not yet been included in postgraduate medical education, despite recommendations by the National Cancer Plan.^{5 6} It has been shown that communication skills can be improved by communication skills training (CST) for healthcare professionals.^{7–9} However, positive effects on patient-reported outcomes (e.g., anxiety or distress) have yet to be proven.¹⁰ As most CST programmes are very lengthy, CST for healthcare professionals faces the problem of insufficient implementation into clinical practice.^{11 12}

High-quality communication between healthcare professionals and patients

requires patient centeredness in addition to communication skills. Patient centeredness is understood as a consistent focus of healthcare professionals on the needs of the patient.¹³ This concept requires taking into account not only the patients' perspective but also the patients' self-management abilities and the continuity of care throughout the treatment.¹⁴ Also organisational and structural aspects of treatment planning and process¹⁵ have to be taken into account. The quality of communication and, thus, of the treatment are directly influenced by the hospital's internal processes and organisational procedures as well as the workload and satisfaction of its subsystems, namely the healthcare professionals.^{15 16} Communication between providers from different healthcare professions within a hospital or ward is as important as communication between providers and patients.¹⁵ Hence, interprofessional learning might increase the effectiveness of CST.^{17–20}

Currently available CST programmes differ in design in terms of duration, target groups, learning objectives or didactic methods.^{6 21} The moderating effects of training duration and length remain unclear.^{10 22} While some studies report that shorter interventions have a smaller positive effect on communication skills,^{7 23} other studies could not replicate this finding.¹⁰ Shorter interventions might have the advantage of more efficient implementation in clinical practice²⁴ and are associated with high acceptability and a low drop-out rate.²⁵ Therefore, they may be more feasible and, due to greater utilisation, more effective than extensive and more time-consuming interventions.

Aims

The present study aims to evaluate the effectiveness of an interprofessional CST programme for oncology teams. It is hypothesised that patients with cancer treated by healthcare professionals who underwent the interprofessional CST show less fear of progression than patients treated on wards where only physicians underwent CST or where healthcare professionals were exclusively provided with written information on provider–patient communication (primary endpoint). Furthermore, CST is assumed to lead to a greater increase in providers' self-efficacy in patient centeredness (secondary endpoint). Individual confounders and possible moderating effects of organisational factors are considered.

METHODS AND ANALYSIS

Study design

KommRhein Interpro is a three-arm cluster randomised trial. Thirty cancer ward units are assigned to three intervention groups: (a) healthcare professionals receive written information on patient-centred communication, (b) healthcare professionals receive written information and physicians participate in a CST, (c) healthcare professionals receive written information and participate in an interprofessional CST. The study will be

conducted between July 2019 and December 2022 at the cancer centres of the university hospitals of Aachen, Bonn, Cologne and Düsseldorf (Centre for Integrated Oncology, CIO ABCD).

Sample

Thirty cancer ward units of the CIO ABCD are randomly assigned to the three study arms. Randomisation is performed using a parallel block randomisation approach with computer-generated random numbers. Size and regional location of the wards are blocking criteria. Blinding of the investigators and healthcare professionals is not practicable. Patients will not be informed about study arm allocation. To be included in the study, ward units must be part of a participating cancer centre and have an identifiable team of physicians and nurses, that is, two-thirds of the staff must be permanently assigned to the ward. Oncological wards count as trained if more than 65% of the team participated in the intervention. Inclusion criteria for physicians and nurses are a license to practice medicine or nurse registration, assignment to the ward unit, age ≥ 18 years, sufficient German language skills and written informed consent. Inclusion criteria for patients are age (at least 18 years old), confirmed cancer diagnosis (International Classification of Diseases, Tenth Revision, ICD-10), inpatient treatment on a participating oncological ward, sufficient German language and cognitive skills and written informed consent.

Recruitment

Local study coordinators initiate contact to the respective heads of department and nursing management to recruit oncology ward units for participation. On the participating ward units, trained study nurses establish contact with healthcare professionals and patients. Furthermore, they initially screen all healthcare professionals for eligibility. Patient recruitment starts when training is finished on a ward unit (see *Samples* for specifics). A two-step screening process is performed for patient enrolment. First, study nurses use the hospital information system to electronically screen all patients admitted to one of the participating wards for a cancer diagnosis. Second, patients with a cancer diagnosis are screened face to face for the remaining inclusion criteria. Details of recruitment are illustrated in [figure 1](#).

The study nurse informs eligible patients and healthcare professionals about the aim of the study, the course of the study and data protection (a copy of the *guideline for study nurses* is found in online supplemental materials). After respondents agree to participate in the study, they complete and sign the informed consent form and receive a copy for their records. Screened data from non-participants are anonymously collected for non-responder analysis.

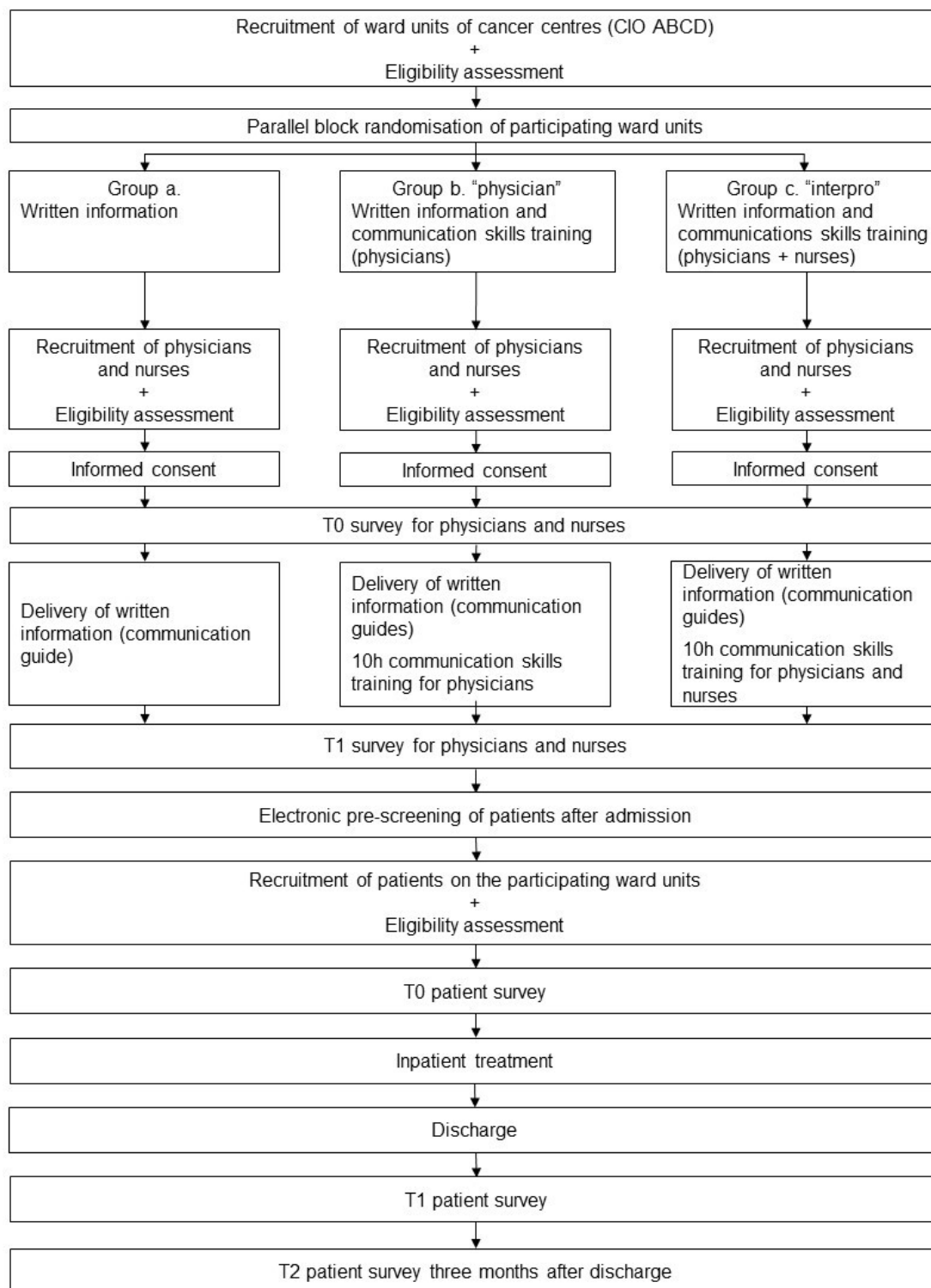


Figure 1 Overview of study procedure and study measures for healthcare professionals and patients in the KommRhein Interpro study.

Intervention

All groups receive written information (communication guide) on patient-centred communication for physicians and other healthcare professionals.^{26 27}

The CST programme includes learner-centred elements, which take into account participants' clinical experiences and problems, and it is based on role play sessions with

standardised patients (portrayed by professional actors). It further includes a high proportion of rapid cycle deliberate feedback²⁸ and is conducted in small groups of four to eight people. The overall duration is 10 hours, of which at least 8 hours are necessary for a participant to be considered as trained. The 10 hours can be split into two or three sessions during normal working days.

Session length is based on the needs and preferences of participating ward units. The CST programme consists of four modules: breaking bad news (4 hours), dealing with difficult emotions (death and dying) (2 hours), interprofessional hand-over (2 hours) and interprofessional case discussion (2 hours). Taking into account elements of the KOMSKILL²⁹ modular CST programme for oncology, two new training manuals for physicians and the interprofessional group have been developed for the KommRhein Interpro intervention.^{30 31} Depending on group size and training conditions, CST sessions are led by one or two trainers qualified through a train-the-trainer course (7.5 hours) based on the KommRhein Interpro manuals. The training sessions are primarily organised as face-to-face events. However, if such events are not feasible due to hygiene regulations in the context of the COVID-19 pandemic, CST will be conducted as an online intervention (via Microsoft Teams,³² Zoom³³ or Webex,³⁴) without any changes in terms of content or methods.

Measures and sample size calculation

Healthcare professionals' survey

For the secondary endpoint, healthcare professionals are asked to rate their communication skills using the German version of the Self-Efficacy in Patient Centeredness Questionnaire-27.³⁵ Using a 5-point Likert scale (0='to a very low degree' to 4='to a very high degree'), participants rate their self-efficacy in patient-centred communication via 27 items in three subscales.³⁵ The internal consistency of the original instrument is deemed very good, at $\alpha=0.92-0.95$ ³⁵. The Job Content Questionnaire (JCQ)³⁶ is used to assess physical and psychological work demands via 10 items rated on a 4-point Likert scale (1='strongly disagree' to 4='strongly agree').³⁶ The overall internal consistency of the JCQ is sufficient, at $\alpha=0.74$.³⁶ Social capital is measured with the 6-item, 4-point Likert scale SOCAPO-E instrument (answer categories from 1='strongly disagree' to 4='strongly agree'), which exhibits an excellent internal consistency of $\alpha=0.93$.³⁷ The wording of the items was adapted to hospital wards. Process organisation (six items) and open communication (four items) within the ward, scored on a 4-point Likert scale (1='strongly disagree' to 4='strongly agree'), are assessed with the Employee Questionnaire for Cancer Centers.³⁸ The internal consistency for each of the scales is deemed very good, at $\alpha=0.86-0.88$ ³⁸. Additionally, the questionnaires comprise self-developed single-item measures regarding sociodemographics, the received intervention and burden due to the COVID-19 pandemic.

Patient survey

The primary endpoint 'fear of progression' is collected with the Fear of Progression Questionnaire—Short Form (FoP-Q-SF).³⁹ This is a 12-item instrument with four subscales. Patients are asked to rate questions on a 5-point Likert scale (1='never' to 5='very often'). The FoP-Q-SF shows good internal consistency, at Cronbach's $\alpha=0.87$.³⁹ Anxious/depressive symptoms are assessed using the

Hospital Anxiety and Depression Scale (German version, HADS-D).³⁸ The HADS-D consists of two subscales 'anxiety' and 'depression', with seven items for each subscale. Patients are asked to rate their answers on a 4-point Likert scale. The internal consistency for both subscales is $\alpha=0.80$.⁴⁰ Patients' quality of life is assessed with the Core Quality of Life Questionnaire-C30.⁴¹ The questionnaire consists of 30 items, of which 28 are answered on a 4-point Likert scale (1='not at all' to 4='totally') and two items on a 7-point Likert scale (1='very bad' to 7='excellent'). The questionnaire shows internal consistencies of $\alpha=0.65-0.89$ for the nine subscales.⁴² Patients' need for information is assessed using the subscales 'medical examination results and treatment options' and 'side effects and medication' of the Cancer Patient Information Needs⁴³ scale, consisting of six dichotomous items (1='yes' or 0='no'). This scale shows an excellent internal consistency of $\alpha=0.90$.⁴³ Patients' trust in their physicians and nurses is assessed with five items from the Cologne Patient Questionnaire (KPF), scored on a 6-point Likert scale (1='never' to 6='always').⁴⁴ Perceived support from physicians and nurses is measured with three items that are also based on the KPF and are rated on a 5-point Likert scale (1='not at all' to 5='totally'). The measures show an excellent internal consistency of $\alpha=0.92-0.95$ ⁴⁵. Patient enablement is assessed by two items of the Patient Enablement Instrument (PEI)⁴⁶ to be answered using an adapted 5-point Likert scale (1='not at all' to 5='totally'). The questionnaire shows an overall internal consistency of $\alpha>0.90$.⁴⁶ The two items show an internal consistency of $\alpha=0.88$.⁴⁶ The wording of the items concerning patients' trust in healthcare professionals, patients' perceived support of healthcare professionals and the PEI instrument was adapted to hospitals. The perceived empathy of healthcare professionals is assessed with the 10-item Consultation and Relational Empathy⁴⁷ questionnaire. Patients are to rate the items on a 5-point Likert scale (1='totally agree' to 5='totally disagree'). It shows an internal consistency of $\alpha=0.92-0.94$.⁴⁷ The wording of the items was adapted to refer to all physicians involved in the treatment, while the original wording refers to only one physician. Patients' individual health literacy is assessed using the Health Literacy Questionnaire,⁴⁸ which consists of 16 items to be answered on a 4-point Likert scale (1='very easy' to 4='very difficult') and shows an internal consistency of $\alpha=0.51-0.91$. Health literacy-sensitive communication⁴⁹ is assessed via nine items that are rated on a 4-point Likert scale (1='disagree' to 4='fully agree'). The questionnaire shows excellent internal consistency, at $\alpha=0.91$.⁴⁹ Table 1 provides an overview of the questionnaires at all survey time points.

Sample size calculation

Patients' individual data are clustered within 30 ward units in four university hospitals. The patient sample size was calculated using the following criteria: to detect a standardised effect of 0.3 in the independent samples *t* test with a power of 80% at a two-sided significance level

Table 1 Measurements

Measurement	Instrument	Time point		
Physicians and nurses		T0hcp	T1hcp	
Self-efficacy	SEPCQ-27	1	1	
Job content (subscales: psychological and physical demands)	JCQ	0	1	
Social capital	SOCAPO-E	1	1	
Process organisation	MAZE	1	1	
Open communication	MAZE	1	1	
Intervention (including received training, evaluation of training)	Self-developed	0	1	
Burden due to COVID-19	Self-developed	1	1	
Sociodemographics (including sex, age, occupation, work experience)	Self-developed	1	1*	
Patients		T0pat	T1pat	T2pat
Fear of progression	FoP-Q-SF	1	1	1
Anxiety and depression	HADS-D	1	1	1
Health-related quality of life	EORTC QLQ-C30	1†	1	1
Consultation and relational empathy	CARE	0	1	0
Trust in physicians and nurses	KPF	0	1	0
Support by physicians and nurses	KPF	0	1	0
Patient enablement (two items)	PEI	0	1	1
Health literacy	HLS-EU-Q16	0	1	0
Health literacy-sensitivity of communication	HL-COM	0	1	0
Cancer-related information needs (subscales: diagnosis, side effects and medication)	CaPIN	1	1	0
Hospitalisation before study participation	Self-developed	1	0	0
Comorbidities	Self-developed	1	1	1
Cancer diagnoses (including time point of first diagnosis, relapse)	Self-developed	1	0	0
Hospitalisation duration	Self-developed	0	1	0
Use of psychological support during hospitalisation	Self-developed	0	1	0
Use of rehabilitation measures	Self-developed	0	0	1
Current cancer treatment	Self-developed	0	0	1
Previous cancer treatment	Self-developed	0	0	1
Deviation from suggested treatment	Self-developed	0	0	1
Burden due to COVID-19	Self-developed	1	1	1
Sociodemographics (including marital status, children, cohabitation with partner, educational level, occupational status, health insurance status)	Self-developed	1	1*	1*

*T1hcp, T1pat and T2pat contain sociodemographic items likely to change.

†T0pat contains the two global quality of life items.

CaPIN, Cancer Patient Information Needs; CARE, Consultation and Relational Empathy; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer core quality of life Questionnaire; FoP-Q-SF, Fear of Progression Questionnaire—Short Form; HADS-D, Hospital Anxiety and Depression Scale; HL-COM, Health literacy-sensitive communication; HLS-EU-Q16, Health Literacy Questionnaire; JCQ, Job Content Questionnaire; KPF, Cologne Patient Questionnaire; MAZE, Employee Questionnaire for Cancer Centers; PEI, Patient Enablement Instrument; SEPCQ-27, Self-Efficacy in Patient Centeredness Questionnaire; SOCAPO-E, Social Capital Healthcare Organizations - Employee Questionnaire.

of 5%, 175 patients per group are required. The plausible assumption of an intracluster correlation coefficient of 0.04⁵⁰ and an average number of 44 patients per cluster results in a design effect of 2.5. For the primary outcome, N=1320 valid cases are necessary for data evaluation. Further adjustment for heterogeneous cluster size

(+10%), non-evaluable patients (+10%) and three treatment groups results in 1598 patients in 30 clusters. On the basis of the minimum of N=1320 valid cases for data analysis, the total sample size increases to N=2310 after adjusting for the expected patient loss to follow-up (20% per follow-up).

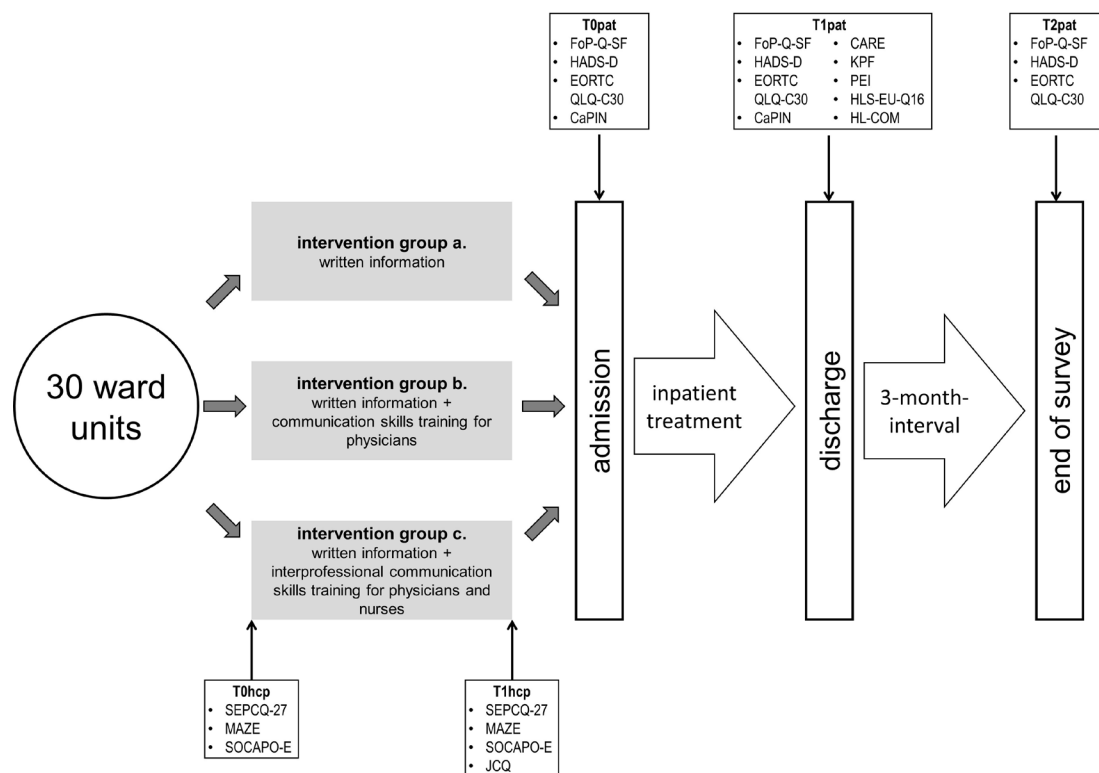


Figure 2 Process chart. CaPIN, Cancer Patient Information Needs; CARE, Consultation and Relational Empathy; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; FoP-Q-SF, Fear of Progression Questionnaire—Short Form; HADS-D, Hospital Anxiety and Depression Scale; HLS-EU-Q16, Health Literacy Questionnaire; HL-COM, Health literacy-sensitive communication; JCQ, Job Content Questionnaire; KPF, Cologne Patient Questionnaire; MAZE, Employee Questionnaire for Cancer Centers; PEI, Patient Enablement Instrument; SEPCQ-27, Self-Efficacy in Patient Centeredness Questionnaire; SOCAPO-E, Social Capital Healthcare Organizations - Employee Questionnaire.

Data collection

Healthcare professionals' data are collected at two time points, that is, before participation in the intervention (T0hcp) and 2 weeks after the intervention (T1hcp). The interval between T0hcp and T1hcp is estimated to be 12 weeks, as recruitment of the healthcare professionals as well as filling out and returning of the questionnaire will take at least 6 weeks for each ward unit, and the subsequent intervention will take no longer than 6 weeks. The study nurses hand out T0hcp on the ward unit, and T1hcp is sent as postal survey to the healthcare professionals.

Patients receive questionnaires at three measurement time points: the first during inpatient stay (T0pat), the second by mail right after discharge (T1pat) and the last by postal service 3 months after discharge (T2pat). T0hcp, T1hcp, T1pat and T2pat data collection is conducted according to the Total Design Method by Dillman (2008) with three postal reminders. The participant timeline is illustrated in figure 2.

Data analysis

The survey data are electronically recorded and processed using the Electric Paper Teleform data capturing software and checked for plausibility by the evaluation team. Scales and indices are calculated according to the coding manuals after testing their psychometric properties. Data are analysed with the IBM SPSS V.27 statistical software.

Data analysis of the primary endpoint is performed blinded and according to the intention-to-treat principle using a mixed model for repeated measurements. Group comparison (global, pairwise) is performed hierarchically for the measurement points T1pat and T2pat; therefore, no alpha adjustment is required. The influence of organisational factors will be analysed by multilevel analysis^{44 51} and structural equation models.

Monitoring

Study monitoring is ensured by monitoring visits at the study centres. All principal investigators allow the monitor to visit the trial sites to review data during the study. Study centres will be excluded if they are permanently unable to recruit patients or repeatedly violate the treatment protocol. If necessary, recruitment in other centres will be increased or additional centres will be recruited. Study documents are archived for at least 10 years in accordance with 13 principles of the Good Clinical Practice guidelines. Participant identification lists are stored separately from the trial documentation at each trial site.

Patient and public involvement

In accordance with our community-based participatory research approach, the development of the intervention was evaluated by cancer patients in a prior qualitative interview study described elsewhere.³⁰ The patient

questionnaires of the KommRhein Interpro trial were pretested in cognitive interviews with patients with cancer. It is planned to present the study results at cancer conferences with public involvement.

ETHICS AND DISSEMINATION

Ethical considerations

A vote of approval has been obtained from the ethics committees of the medical faculties of RWTH Aachen University (EK325/20), University of Bonn (391/20), University of Cologne (20–1332), and Heinrich-Heine University Düsseldorf (2019–796). Any divergences from the study protocol will be documented and relevant modifications of the study protocol will be reported to the ethics committees. Data protection regulations are adhered to for all processed data. Study nurses on the respective wards obtain written informed consent from potential participants after handing out written study information. Participants are informed that they are free to withdraw their consent at any time without giving any reason and without suffering any consequences. In addition, they are informed that they can demand the deletion of all stored personal data at any point. Personal identifiers from participants are pseudonymized. Only the research team can access the final data set. The ethics committees will be informed within 90 days after the end of the study.

Dissemination plan

The final study report, including results, will be submitted to the funding organisation (German Cancer Aid). Dissemination strategies include a transfer workshop with oncology teams and the distribution of the final study report to patients, if requested. The workshops will supply providers with feedback regarding the research results and further serve as a platform for the exchange between providers for mutual organisational learning. To disseminate the findings among the research community, scientific national and international publications in peer-reviewed journals and presentations at conferences are planned.

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Competing interests None declared.

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