






BMJ Open Cancer rehabilitation support by cancer counselling centres (CARES): study protocol of a quasi-experimental feasibility study

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ABSTRACT

Introduction While maintaining or restoring work ability after a cancer diagnosis is an essential aim of the rehabilitation process for working-age patients, problems can arise during the return to work (RTW) or when retaining work. Counselling could provide support for patients with or after cancer with employment-related questions (eg, questions related to RTW and work retention). Outpatient psychosocial cancer counselling centres in Germany offer counselling on work-related questions; however, resources for this are limited. This protocol presents a feasibility study of an intensified needs-based counselling intervention that supports those seeking employment-related advice.

Methods and analysis The CARES (cancer rehabilitation support by cancer counselling centres) project is a feasibility study for a newly developed counselling intervention. The intervention is being developed as part of the project and piloted in about 20 outpatient cancer counselling centres. The CARES study has a quasi-experimental pre-post design with a control cohort. First, patients who undergo regular counselling are recruited. Second, after the counsellors have been trained for the newly developed intervention, participants for the intervention group are recruited from the cancer counselling centres. Quantitative and formative evaluations will be performed in accordance with the existing guidelines. The quantitative evaluation comprises three patient surveys (at the beginning of the counselling process, 3 months into the counselling process and, for the intervention group, at the end of the counselling process) and routine data of the counselling process. The formative evaluation includes interviews with patients, counsellors and other stakeholders, as well as participatory observations of counselling sessions.

Ethics and dissemination Approval has been obtained from the ethics committee of the Medical Faculty of the University Bonn (061/22; 09.04.2022). A data protection concept ensures adherence to data protection regulations for the handled data. The dissemination strategies include discussing the results with the cancer counselling centres.

Trial registration number German Clinical Trials Register (DRKS00028121); Pre-results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Theory-based development of an intervention to support patients with cancer with employment-related questions tailored to the setting of outpatient psychosocial cancer counselling centres and patient needs.
- ⇒ The intervention is being piloted in outpatient psychosocial cancer counselling centres throughout Germany, with heterogeneous characteristics regarding size, sponsorship and region.
- ⇒ This feasibility study is accompanied by an extensive quantitative and qualitative evaluation process.
- ⇒ This is not a randomised controlled pilot study.
- ⇒ Potential of self-selection bias among cancer counselling centres and clients.

INTRODUCTION

Nearly 500 000 people are diagnosed with cancer annually in Germany.¹ For those affected during working age, return to work (RTW) can be a source of not only financial security and independence but also normalcy and identity.² Besides RTW, retention of work is important. In the aftermath of RTW, job changes related to cancer can occur³ and be experienced involuntarily by some.⁴ Moreover, an increased risk of early retirement⁵ and unemployment after a cancer diagnosis⁶ has been observed compared to healthy controls. Barriers to RTW or retention of work change over time, with disease-related and treatment-related aspects being more pronounced shortly after diagnosis, and personal-related and work-related aspects being more pronounced in the long run.⁷ Therefore, restoring and maintaining work ability in those affected during the working age is an important aim of the rehabilitation process. Accordingly, patients with cancer in Germany are entitled to participate in a rehabilitation programme that is usually offered in an in-patient setting, consisting

process. The formative evaluation includes interviews with patients, counsellors and other stakeholders, as well as participatory observations of counselling sessions. The ethics committee of the Medical Faculty of the University Hospital of Bonn approved this study (061/22; 09.04.2022). The CARES project is being conducted between October 2021 and December 2023.

Intervention

In line with the Template for Intervention Description and Replication checklist and guide,¹⁹ the intervention can be characterised as an intensified needs-based counselling support programme for patients with cancer who have employment-related questions. The intervention group receives intensified counselling with intervention components focusing on the occupational situation, networking support and companionship within the healthcare, rehabilitation, social legislation and occupational systems. The intervention is being delivered from October 2022 to the end of June 2023 in the participating outpatient psychosocial cancer counselling centres by specially trained counsellors (mostly social workers and social education workers with work experience in cancer counselling centres) who have participated in a 2-day training course. Counselling sessions for the intervention are carried out in person (usually in the offices of the cancer counselling centres) or via (video) calls. Moreover, as part of the intervention, the specially trained counsellors can accompany the patients to external appointments (eg, job centres or workplaces). The duration of the intervention, number of counselling sessions and contents of the intervention vary depending on the needs and preferences of the patients with cancer. Moreover, the provision of the intervention can be adapted to these needs with the help of facultative components (eg, accompanying patients to external appointments) in addition to the mandatory components (eg, establishing a counsellor–patient relationship). The intervention consists of a minimum of three counselling sessions, including a mandatory final session to conclude the counselling process. In cases with lower support needs, the patients receive a minimum of three counselling sessions (eg, to provide information regarding progressive reintegration into the workplace meaning a plan to progressively increase working hours over an agreed period). In cases with higher support needs, patients can receive more intensive and longer-lasting counselling (eg, to first organise patients' participation in an inpatient rehabilitation measure and to subsequently organise the RTW during the counselling sessions).

Recruitment and sample

Outpatient cancer counselling centres

About 20 outpatient cancer counselling centres are recruited to pilot the support intervention. Applying a purposive sampling approach aiming at a heterogeneous sample, the cancer counselling centres are chosen on the basis of the criteria of the region (federal state and

urbanity), sponsorship and size (number of employees and advice-seeking persons).²⁰ As part of the project team, the Federal Working Group for Outpatient Cancer Counselling Centres (Bundesarbeitsgemeinschaft für Krebsberatungsstellen) informs counselling centres about the CARES study. The participating counselling centres enrol the study participants and offer counselling to them. Employees of participating counselling centres are trained for the enrolment process before the recruitment of the control group begins. They are trained again for the new intervention before the recruitment of the intervention group begins.

Patients with cancer

Patients with cancer are recruited from the participating cancer counselling centres. Advice-seeking patients with cancer contact cancer counselling centres themselves or are assigned by allocators, such as physicians, rehabilitation facilities or local self-help groups. They are informed about the CARES study and screened for eligibility on the basis of the inclusion criteria by the employees of the cancer counselling centres; if the inclusion criteria are met, the employees obtain consent for participation. The inclusion criteria are the following: an oncological disease, problems and/or counselling needs regarding the occupational situation (from training to retirement phase), age of majority, sufficient German language skills, no cognitive limitations that impede participation in surveys or interviews and informed consent. After their inclusion in the study, the participants are handed out the first paper-and-pencil survey. The completion time of the survey is approximately 60 min. The filled-in survey can be returned to cancer counselling centres or sent postally to the German Cancer Society. The participants are surveyed again 3 months after the counselling started, and for those in the intervention group, a third time at the end of the counselling process. To increase the response rate, two reminders will be sent in line with Dillman's Total Design Method for both follow-up surveys.²¹ We aim to reach 250 cases each for the regular and intervention counselling group.

A subsample of participating patients with cancer who express interest is recruited for qualitative semi-structured interviews. Potential interviewees are contacted to inform them about the interview procedure, audio recordings and data usage. Informed consent is obtained from all the interviewees. The sampling is purposive, meaning that interviewees are chosen on the basis of sociodemographic (eg, sex, age and education), disease-related (eg, time since diagnosis), psychosocial (eg, distress) and work-related information obtained from the surveys to increase the heterogeneity of the sample.²⁰ The sampling will continue until further interviews do not generate more knowledge regarding the research topic (expected $n=15-20$).²⁰ Interviews are conducted via telephone calls, video calls or face-to-face. Face-to-face interviews are conducted at the participants' preferred locations. The

interview duration does not exceed 60 min, and the interviewees receive an incentive of €100.

Participatory observations of the counselling sessions by a research team member are intended for case studies (n=2–3). A subsample of participating patients with cancer who express their openness towards observations is selected by applying a purposive sampling approach aimed at creating a heterogeneous sample.²⁰ The patients are contacted to provide them with further information regarding the procedures. Informed consent regarding observation, audio recording and data usage are obtained from the participant and counsellor. In addition to optional audio recordings, the observations are documented using a protocol and field notes.²⁰

Counsellors, representatives of the cancer counselling centres' sponsors and allocators

Semi-structured interviews with stakeholders such as counsellors, representatives of the sponsors of the outpatient cancer counselling centres and allocators of patients with cancer are planned to explore the feasibility of the intervention from different perspectives. Counsellors and representatives of the sponsors are recruited in the cancer counselling centres. Allocators of patients are identified from the allocator networks of the cancer counselling centres. Before obtaining consent, potential interviewees are informed about the procedure, audio recording and data analysis. The interviews are carried out via telephone calls, video calls or face-to-face and are no longer than 60 min. Face-to-face interviews are conducted at the participants' preferred locations. For the counsellors, the criteria for the purposive sampling are their work experience and educational background (eg, psychology or social work).²⁰ Representatives of the sponsors should belong to organisations of different sizes to increase heterogeneity in the purposive sample.²⁰ The sampling will be continued until further interviews do not generate more knowledge about the research topic (expected n=20).²⁰ The interviewees receive an incentive of €100.

Measures

Quantitative evaluation

The quantitative patient surveys consist of validated scales and self-developed measures that have been developed following the standards of survey question development.²² Through the surveys, we aim to investigate the support needs, experiences with RTW, health status, use of healthcare services and experiences with the counsellors of the cancer counselling centres. The survey content of T0–T2 is listed in [table 2](#). The table also informs about the use of each measure for the evaluation, either as a potential outcome sensitive to change as a result of the intervention and/or an effect modifier. The questionnaires used for the regular counselling and intervention group are identical (T0 and T1). Additionally, only the intervention group receives the T2 questionnaire at the end of the counselling process.

Regarding health and psychosocial aspects, the questionnaires include self-developed measures about the

cancer diagnosis, use of rehabilitation, comorbidities and incompatibilities between areas of life due to the cancer diagnosis. Moreover, distress (NCCN Distress Thermometer²³), quality of life (EORTC QLQ-C30²⁴), fatigue (Fatigue Assessment Questionnaire²⁵) and life satisfaction (from European Social Survey (ESS)²⁶) are assessed.

The occupational situation of the patients with cancer is the core topic of the survey. It comprises self-developed measures for the current work situation, occupational status (answer categories adapted from Bundesinstitut für Berufsbildung und Bundesanstalt für Arbeitsschutz und Arbeitsmedizin²⁷), profession, current reception of welfare benefits, the occurrence of job changes since the diagnosis and their voluntariness, working intention (adapted from Sozio-oekonomisches Panel (SOEP)²⁸), pressure to return to work, RTW literacy, experienced burden through RTW and influence of the COVID-19 pandemic on rehabilitation use and RTW. Furthermore, need for occupation-related treatment (including subjective prognosis of employability) (SIBAR²⁹), RTW self-efficacy (RTW-SE³⁰), quality of working life (QWLQ-CS; translated and adapted from de Jong *et al*³¹) and satisfaction with the employment situation (adapted from ESS²⁶) are included.

Trust in the counsellor (adapted from KPF-BK 2.0³²), unmet information needs (adapted from KPF-BK 2.0³²) and the self-developed measures satisfaction with the counselling, counselling relationship, counselling content and assessment and an overall counselling assessment are used to evaluate the counselling experience. Additionally, sociodemographic variables are part of the questionnaires.

To identify suitable outcome variables for this feasibility study, a wider set of endpoints has been chosen. The outcome variables are distress (NCCN Distress Thermometer²³), quality of life (EORTC QLQ-C30²⁴), incompatibilities between areas of life, life satisfaction (from ESS²⁶), current work situation, job changes, the need for occupation-related treatment (SIBAR²⁹), working intention (self-developed; adapted from SOEP²⁸), RTW literacy, RTW self-efficacy (RTW-SE³⁰), experienced burden through RTW, quality of working life (QWLQ-CS; translated and adapted from de Jong *et al*³¹), satisfaction with the employment situation (adapted from ESS²⁶) and measures on the counsellor relationship.

The routine data collected during the counselling process by the counsellors comprise information on the amount, duration, setting and location of counselling meetings as well as the form of contact (ie, personally or via (video) call) and contents. The counsellors also report particularities and adverse events. Moreover, the cancer diagnoses of the participants and information regarding the qualifications of the counsellors are included.

Formative evaluation

The interviews with patients focus on acceptance, attractiveness, feasibility, effectiveness and burden of the counselling, as well as their relationship with the counsellor. Interviews with the counsellors and other stakeholders

Table 2 Measures of the CARES questionnaires

Measure	T0	T1	T2	Use for evaluation
Health situation and psychosocial aspects				
Data cancer diagnosis, recurrence (self-developed)	x	x	x	Modification
Use of rehabilitation (self-developed)	x	x	x	Modification
Distress thermometer (NCCN distress thermometer ²³)	x	x	x	Modification/outcome
Quality of life with physical, role, emotional, social functioning and financial difficulties (EORTC-QLQ C30 ²⁴)	x	x	x	Modification/ outcome
Fatigue (Fatigue assessment questionnaire ²⁵)	x	x	x	Modification
Incompatibilities between areas of life (self-developed)	x	x	x	Modification/outcome
Life satisfaction (from ESS ²⁶)	x	x	x	Modification/outcome
Comorbidities (self-developed)	x			Modification
Occupational situation				
Current work situation (self-developed)	x	x	x	Modification/outcome
Occupational status (self-developed; answer categories adapted from BIBB and BAuA ²⁷)	x			Modification
Profession (self-developed)	x			Modification
Reception of social welfare benefits (self-developed)	x	x	x	Modification
Job changes (including voluntariness) (self-developed)	x	x	x	Modification/outcome
Need for occupation related treatment (including subjective prognosis of employability) (SIBAR ²⁹)	x	x	x	Modification/outcome
Working intention (self-developed; adapted from SOEP ²⁸)	x	x	x	Modification/outcome
Pressure to return to work (self-developed)	x	x	x	Modification
Return to work literacy (self-developed)	x	x	x	Modification/outcome
Return to work self-efficacy (RTW-SE ³⁰)	x	x	x	Modification/outcome
Burden through return to work (self-developed)	x	x	x	Modification/outcome
Quality of working life (QWLQ-CS; translated and adapted from de Jong <i>et al</i> ³²)	x	x	x	Modification/outcome
Satisfaction employment situation (adapted from ESS ²⁶)	x	x	x	Modification/outcome
Influence COVID-19 pandemic on rehabilitation use/return to work (self-developed)	x	x	x	Modification
Relation with counsellor				
Assignment to counselling centre (self-developed)	x			Modification
Overall counselling assessment (self-developed)		x	x	Outcome
Satisfaction counselling (self-developed)		x	x	Outcome
Trust (adapted from KPF-BK 2.0 ³²)		x	x	Outcome
Unmet information needs (adapted from KPF-BK 2.0 ³²)		x	x	Outcome
Counselling relationship (self-developed)		x	x	Outcome
Counselling content and assessment (self-developed)		x	x	Outcome
Sociodemographic: Gender*, birth year*, school leaving certificate*, vocational training*, healthcare insurance*, living situation (from ESS ²⁶), children (in household), marital status, partnership (from SOEP ²⁸), single parent, income (household/own), degree of disability (self-developed)	x	x	x	Modification
T0: beginning of counselling, T1: 3 months after the beginning of counselling, T2: end of counselling *only in T0. BAuA, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin; BIBB, Bundesinstitut für Berufsbildung; ESS, European Social Survey; SOEP, Sozio-oekonomisches Panel.				

address the acceptance, feasibility and effectiveness of the intervention, as well as the resources necessary for the execution of the project and intervention. Owing to their semi-structured characteristics, interview guides with open-ended stimulus questions and further narrative-generating questions have been developed.²⁰ The questions in the interview guide are based on the Consolidated Framework for Implementation Research¹⁶ and the

objectives of a feasibility study.¹⁸ Aspects of the framework and guidelines have been integrated and can be seen in the interview guides (please see the online supplemental files 1 and 2).

To complement the audio recordings of the counselling sessions, the field notes and protocol for the participatory observations focus on visible aspects of the situation and interaction. To allow the observer's attention to perceive

new aspects, the protocol is partly structured to assess basic aspects of the observed situations (eg, present persons, seating arrangement and potential interruptions).²⁰ The protocol can be adapted on the basis of the experiences and contents of the interviews.

To ensure comprehensibility of all measures, cognitive pretests are performed in line with research standards.³³ Relevant contents for the surveys and interview guides are identified using existing literature and through discussions with the multidisciplinary project team and cooperation partners.

Data analysis

Quantitative survey and routine data

Data from the written surveys are digitalised using the TeleForm software, and plausibility checks are performed. The data will be used according to coding manuals after testing their psychometric properties. The possibility of imputing the missing data will be examined. Pseudonymised survey data will be matched with pseudonymised routine data from the counselling process. For potential primary outcomes (see [table 2](#), section Occupational situation), we will follow a stepwise procedure by first describing the change between measurement time points per study group, analysing the effect sizes and, in case of at least medium effect sizes, finally testing for significant differences between the two study groups. The analyses will be carried out using SPSS Statistics, R and Stata. Routine data will be analysed regarding the feasibility of the intervention and fidelity to the intervention manual.

Qualitative interview and observational data

Audio recordings of the interviews and observations are transcribed verbatim. Qualitative content analysis³⁴ will be applied using the MAXQDA software. The analysis starts during data collection so that interview guides and sampling criteria can be altered according to the present state of knowledge.²⁰ Protocols and field notes of participatory observations will be analysed following the Grounded Theory approach.³⁵ The coding process will be both inductive and deductive, with codes derived from the Consolidated Framework for Implementation Research¹⁶ and the objectives of a feasibility study,¹⁸ complemented by codes based on the data.^{20 34} Two researchers will code the data to ensure the reliability of the analysis. Differences in coding will be discussed until consent is reached. The progress of the qualitative content analysis will be discussed by the multidisciplinary research and project team. The results will be interpreted by the team. Data linkage of qualitative and quantitative data is not intended.

Patient and public involvement statement

Representatives of the self-help group Life after cancer! (Leben nach Krebs!) are a part of the CARES project team. Support is received during project completion (eg, during the development of instruments or discussion of results). Moreover, the self-help group representatives are

involved in training the employees of the cancer counselling centres for the new intervention.

ETHICS AND DISSEMINATION

Ethical considerations

A data protection concept has been developed to ensure adherence to data protection regulations for all the handled data. Data are pseudonymised, and the participant identification lists are stored separately. Only the research team can access the final data set. The study documents will be stored for 10 years in the cancer counselling centres. The ethics committee of the Medical Faculty of the University of Bonn has provided approval (061/22; 09.04.2022). Any changes from the study protocol will be documented and, in cases of relevant modifications, reported to the ethics committee. The participants are informed about the study procedure by means of a written study description before obtaining written consent to participate as well as collecting, saving and analysing their pseudonymised data. The participants are informed that they are free to withdraw their consent at any time, demand the deletion of all stored personal data and interrupt or terminate the counselling process at any time without consequences. Particularities or adverse events are reported as part of the process documentation of the counselling sessions.

Dissemination plan

The main goal of the CARES study is to gain an insight into the feasibility of implementing the developed intervention in existing oncological healthcare structures in German outpatient cancer counselling centres. Expected outcomes are explorative and are anticipated to contribute to tailoring and implementing the intervention. Furthermore, the first indications of the effectiveness of the intervention will be examined. We expect that the participants in the intervention group will report better outcomes at T1 than participants in the control group. Thus, the project's potential original contribution will be knowledge on the needs of patients with cancer regarding RTW, work retention and on the manner in which support and counselling need to be designed to fit patients' needs and the structure of the German healthcare system. The study's findings will be disseminated in discussions with the cancer counselling centres for mutual learning, in a workshop with stakeholders and in the research community, in scientific publications and during presentations at conferences. A written report of the results will be prepared for the funder.

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Competing interests CB and CK are employed by the German Cancer Society (Deutsche Krebsgesellschaft). The remaining authors declare no conflicts of interest.

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