Patient involvement and engagement in health services research in the context of psycho-oncological care

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Summary

Optimising healthcare not only needs scientifically generated evidence, but also the experiential knowledge of patients. Health services research (HSR) can involve patients and integrate their expertise by using participatory research approaches which are characterised by patients as research partners and scientists working together as a team to generate knowledge to improve health and healthcare. To emphasise the focus on patients and different intensities of participatory processes, the term 'patient involvement and engagement' (PIE) is used. One of the principles of PIE in HSR is that every type of expertise and every contribution from the research team is considered equal. Furthermore, the principles include transparent communication, patients and professional researchers' co-learning, availability of adequate resources for the participation processes and that the cooperation is characterised by trust, honesty, and respect.

A dissemination of participatory approaches in HSR in German-speaking countries is apparent in requirements of research funders and growing networking. However, the visibility of PIE in HSR in Germany is still low and there are many unanswered questions about its implementation.

Therefore, it was investigated which levels, processes, and results of PIE can be realised in different task areas of HSR, and to what extent participation levels vary in the different project phases and between patient roles (e.g. patients in acute care; patient representatives; former patients as peer supporters). For systematic recording, a special reflection instrument was created based on models of PIE in health (services) research and applied to the four publications of the dissertation projects (DP).

Each DP represents a task area of HSR (investigation of everyday healthcare, development, implementation and optimisation, and evaluation of complex interventions). All DPs have been conducted in the context of psycho-oncological care, as cancer research in Germany has a pioneering role with regard to PIE. The first DP comprises epidemiological analyses of mental disorders in newly diagnosed cancer patients based on health insurance claims data. In the second DP, the development of the new form of care 'integrated, cross-sectoral Psycho-Oncology' (isPO) was evaluated. In DP 3, the participatory development of an instrument for the assessment and optimisation of patient information material was carried out. The fourth DP consists of a multi-perspective mixed-methods evaluation of the isPO onco-guide service.

While there was no PIE in DP 1 but only research *on* newly diagnosed cancer patients, an increased PIE can be observed in the following DPs and thus in the task areas - from preliminary stages of PIE to co-learning. Patient representatives were most intensively involved compared to isPO patients or isPO onco-guides. Data collection and dissemination were characterised by high levels of PIE. If the DPs were not planned with a high level of PIE from the outset, the study design, data analysis, and interpretation of results was conducted without PIE.

PIE proved to be particularly relevant in strengthening the patients' experiential expertise and empowering them for research tasks. The participatory processes led to an increase in the comprehensibility and thus the acceptance of the new form of care isPO. By valuing their perspective and voluntary work, the motivation of the isPO onco-guides was strengthened so that they continue to be active in the peer support service.

Zusammenfassung

Die Verbesserung der Gesundheitsversorgung braucht nicht nur wissenschaftlich generierte Evidenz, sondern auch das Erfahrungswissen von Patient:innen. Die Versorgungsforschung (VF) kann Patienten:innen mit ihrer Erfahrungsexpertise einbinden, indem sie partizipative Forschungsansätze nutzt. Diese sind dadurch charakterisiert, dass Patient:innen als Forschungspartner:innen und Wissenschaftler:innen gemeinsam im Team forschen, um Wissen zur Verbesserung von Gesundheit und Gesundheitsversorgung zu generieren. Eines der Prinzipien von Patienten:innenbeteiligung in der VF ist, dass jede Art von Expertise und jeder Beitrag aus dem Forschungsteam als gleichwertig erachtet werden. Außerdem gehört zu den Prinzipien, dass die Kommunikation transparent ist, Patient:innen und Wissenschaftler:innen voneinander lernen, für die Beteiligungsprozesse angemessene Ressourcen zur Verfügung stehen und die Zusammenarbeit von Vertrauen, Ehrlichkeit und Respekt geprägt ist.

Die Verbreitung partizipativer Ansätze in der VF im deutschsprachigen Raum ist durch die entsprechenden Anforderungen der Forschungsförderer und eine wachsende Vernetzung beobachtbar. Insgesamt ist die Sichtbarkeit von Patient:innenbeteiligung in der VF in Deutschland allerdings noch gering und es bestehen viele offene Fragen zur Umsetzung.

Daher wurde in dieser Dissertation untersucht, welche Patient:innenbeteiligungsgrade, Prozesse und Ergebnisse sich in verschiedenen Aufgabenbereichen der VF realisieren lassen, und inwieweit sich Beteiligungsgrade in den verschiedenen Projektphasen und zwischen Patient:innenrollen (z.B. Patient:innen in der akuten Versorgung; Patient:innenvertretende; ehemalige Patient:innen als Peer Supporter) unterscheiden lassen. Zur systematischen Erfassung wurde basierend auf Modellen zur Patient:innenbeteiligung in der Gesundheits- bzw. Versorgungsforschung ein eigenes Reflexionsinstrument erstellt und auf die vier Publikationen der Dissertationsprojekte (DP) angewendet.

Jedes DP deckt einen Aufgabenbereich der VF ab (Beschreibung und Erklärung der Alltagsversorgung, Entwicklung, Implementierung/Optimierung und Evaluation komplexer Interventionen). Alle DP sind im Kontext psychoonkologischer Versorgung entstanden, da die Krebsforschung in Deutschland eine Pionierrolle bezüglich Patient:innenbeteiligung einnimmt.

Das erste DP umfasst versorgungsepidemiologische Analysen zu psychischen Erkrankungen bei neuerkrankten Krebspatient:innen anhand von GKV-Daten. Im zweiten DP wurde die Entwicklung der neuen Versorgungsform ‚integrierte, sektorenübergreifende Psychoonkologie' (isPO) evaluiert. Für das DP 3 erfolgte die partizipative Entwicklung eines Instruments zur Bewertung und Optimierung von Patient:inneninformationsmaterialien (PIM). Das vierte DP besteht aus der multiperspektivischen Mixed-Methods-Evaluation des isPO-Onkolots:innenangebots.

Während in DP 1 keine Patient:innenbeteiligung erfolgte, sondern *über* neuerkrankte Krebspatient:innen geforscht wurde, ist in den folgenden DP und damit den Aufgabenbereichen eine erhöhte Patient:innenbeteiligung zu beobachten - von Vorstufen der Patient:innenbeteiligung bis hin zu gemeinsamem Lernen. Patient:innenvertretende waren im Vergleich zu Patient:innen in der isPO-Versorgung oder den isPO-Onkolots:innen am intensivsten beteiligt. Die Phasen der Datenerhebung und der Dissemination zeichneten sich durch hohe Beteiligungsgrade aus. Sofern die DP nicht von vornherein mit hoher Beteiligung geplant waren, lagen insbesondere das Studiendesign, die Datenanalyse und Ergebnisinterpretation in der alleinigen Verantwortung der Wissenschaftler:innen.

Die Patient:innenbeteiligung erwies sich insbesondere als relevant, um die Erfahrungsexpertise der Patient:innen zu stärken und sie zu Forschungsaufgaben zu befähigen. Des Weiteren haben die Beteiligungsprozesse zur Steigerung der Verständlichkeit und damit der Akzeptanz der neuen Versorgungsform isPO geführt. Durch die Wertschätzung ihrer Perspektive und ehrenamtlichen Arbeit wurde die Motivation der isPO-Onkolots:innen gestärkt, sodass sie weiterhin in der Selbsthilfe tätig sind.

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Chapter 1

Introduction

Introduction

Involvement and engagement in research are becoming of increasing importance in Germany which is particularly apparent in the initiatives and requirements of government research funding agencies [1, 2]. This also applies to the field of health research [3, 4] and is thus relevant for health services research (HSR), especially regarding involvement of patients and patient representatives [5, 6].

Two participatory approaches that primarily guide patient involvement and engagement in HSR in Germany are Participatory Health Research (PHR) and Patient and Public Involvement (PPI).

PHR is characterised by the cooperation of all stakeholders on an equal footing [7, 8]. This means that professional researchers work together with those affected by the research, e.g. patients and service providers in a research team. The aim is to jointly generate knowledge to improve the health, living or working environment of those affected. Furthermore, PHR entails the continuous reflection on the participatory design of the research process and power relations within the team.

PPI in research is a less defined term and also appears internationally under the terms 'consumer/service-user/lay involvement' [9–18]. Thus, it differs from PHR according to the person group involved (people who use healthcare services or may potentially use them). Another difference is that PPI focuses on complementing the expertise of researchers and service providers with patients' experiential knowledge [10] and decision-making processes in research rather than the joint initiation of change.

There are three main advantages of engaging with participatory approaches in HSR. Previous research experiences indicate that patient involvement increases the relevance of research projects [12, 19], results in patient-friendly information [12, 20], and leads to higher enrolment and lower drop-out rates [21] favouring increased acceptance which in turn is a prerequisite for the implementability of complex interventions and new forms of care.

In Germany, HSR is currently in a phase of orientation and positioning with regard to participatory approaches. The term 'Partizipative Versorgungsforschung' ('participatory health services research') [22, 23], which is becoming established, is not a participative approach of its own. Rather, the involvement of patients and other stakeholders has found its way in for pragmatic reasons, especially in terms of tailored development and implementation of new care concepts and forms [24].

In the context of this thesis, the term 'patient involvement and engagement' (PIE) is used because, on the one hand, the focus is on patients as research partners in HSR and, on the other hand, the two-part term of involvement and engagement covers different approaches and intensities of participation in research.

Despite of the increasing importance of PIE in HSR, the visibility of HSR projects with participatory designs is still scarce [22]. The aim of this cumulative dissertation is therefore to demonstrate for the different task areas of HSR (1. Investigation of everyday healthcare, 2. Development of complex interventions, 3. Implementation and optimisation of complex interventions, and 4. Evaluation of complex interventions) how PIE can be realised in HSR in Germany. Every task area is represented by a publication. As the task areas are not only considered separately, but in an overall course of generating knowledge, this thesis examines the care area of psycho-oncology as an example and is predominantly situated in the project 'integrated, cross-sectoral Psycho-Oncology' [25]. Furthermore, the field of psycho-oncological care is suitable because cancer research in Germany has a pioneering role regarding PIE with a variety of current initiatives [26–30] from patient advisory board to principles of PIE in cancer research.

Chapter 2 provides the theoretical basis for this thesis by explaining the PHR and PPI approaches and focussing on PIE in HSR both internationally and in Germany. In Chapter 3, the research questions of this thesis and the four dissertation projects are derived. Chapter 4 then gives an overview of the methods used in the four dissertation projects. Chapters 5 to 8 contain the four peer-reviewed publications of the dissertation projects. Chapter 9 discusses the PIE in these four projects using a self-compiled instrument based on existing frameworks and models for PIE in HSR. Furthermore, the chapter contains a methodological discussion and implications for research and practice. Chapter 10 completes this thesis with conclusions on PIE in HSR.

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Chapter 2

Background

Background

2.1 Patient involvement and engagement in research

Participation in the context of health is often associated with the involvement of patients in treatment decisions. The underlying concept is that of shared decision-making [1], moving away from paternalistic to patient-centred healthcare with patients and service providers as equal partners. In Germany, the right of patients to participate in decisions regarding healthcare has been legally anchored in the so-called 'Patientenrechtegesetz' ('Patients' Rights Act') since 2013. Furthermore, patient participation incorporates the involvement of patient representatives in committees of the self-administration of the healthcare system at federal and state level (§ 140 f Code of Social Law V). Patient representatives are to be involved in decisions, e.g. on the scope of healthcare services reimbursed by the statutory health insurances (federal level) or the assurance of medical and psychotherapeutic care (state level) by the respective committees [2]. However, the representatives only have the right to have their say and make proposals, not the right to vote.

Regardless of participation on individual or system level, patient participation helps to improve healthcare [3–6] and thus concerns all stakeholders in the health sector as Bethge and Danner underline: *"If innovative forms of care are to achieve an optimal benefit for patients and also for health service providers and service funders, it is necessary to use all available evidence, including knowledge from the patient's and affected person's perspective."* [7] (p. 55). Based on the keywords 'evidence' and 'knowledge', it can be deduced that patient participation plays a role not only for healthcare and health policy, but also for research. Moreover, the reference to 'innovative forms of care' is a referral to health services research (HSR), whose tasks among others include "*evaluating complex interventions to improve care*" [8] (p. 11). In fact, patient participation in HSR is becoming more widespread in Germany. This is characterised by two participatory concepts in particular: Participatory Health Research (PHR) and Patient and Public Involvement (PPI) in research, which are presented subsequently.

2.1.1 Participatory Health Research

PHR considers research as a co-production of different stakeholders, whereby the research process is organised and implemented by all in cooperative partnership and on an equal footing [9, 10]. Those involved are primarily the people whose lives are the subject of the research [9, 10]. The distribution of power between the research partners is continuously reflected [10]. PHR aims to generate scientific knowledge to initiate changes that improve people's health inequalities and promote their health and well-being [9, 10].

In addition to the participation of patients, all groups of people whose living or working environment is the subject of the research can in general be included within the framework of

PHR, depending on the research context, e.g. relatives and service providers. As a research paradigm, PHR is based on the assumption that its application will not only stimulate changes in the setting being researched, but also in all persons involved [9], as it is about valuing everyone's contribution to the co-creation of knowledge [11]. Thus, the PHR approach is not only practice-oriented, but also collaborative and empowering [12]. This means that patients are considered having experienced-based knowledge through living and dealing with a certain disease which is to be valued just as much as professional knowledge from science and healthcare [13], as it is also expressed in the above-mentioned quotation of Bethge and Danner [7].

2.1.1.1 Origins of Participatory Health Research

Participatory approaches were initially widespread in educational science, organisational development, and social work and have their origins in action research, whose best-known and most influential representative is Kurt Lewin [9]. The aim of action research is not only to gain scientific insights into social problems but also to design options for action to solve them [9]. In Germany, this approach had its peak in the late 1960s to the 1970s, while internationally different participatory approaches evolved [9, 11], e.g. Participatory Rural Appraisal (e.g. Chambers [14]), Liberationist Research approaches (e.g. Freire [15]), Lay/Community Epidemiology (e.g. Watterson [16]), Community-Based Participatory Research (e.g. Minkler & Wallerstein [17]), Feminist Research (e.g. Maguire [18]), and Empowerment Evaluation (e.g. Fetterman [19]).

In health research, participatory approaches gained importance from the 1980s onwards, as little evidence was attributed to participatory research compared to quantitative experimental studies which applies to biomedical research and other health research areas such as health services research [9]. PHR has emerged from various participatory approaches [9], so that depending on the research context, methods and concepts from different traditions have been used. However, all approaches have in common a proximity to social movements [9, 11] and share the following two characteristics: 1. the gain of knowledge is directly linked to the development and testing of new options for action (improvement of the involved lives); 2. all participants work together on an equal footing and, as far as possible, carry out all phases of the research process together (i.e., participatory) and are therefore also all referred to as ‘researchers’ [9]. Due to the many different traditions in which PHR is grounded, there is no exhaustive and ultimate description of PHR, and tensions and contradictions can be identified [11]. The decisive advantage of the richness of approaches are the resulting numerous research strategies and methods [11] that can be used depending on the scope of research.

2.1.1.2 Characteristics of Participatory Health Research

Despite the diversity of approaches, the International Collaboration for Participatory Health Research has attempted to identify various characteristics of PHR, but without claiming to be definitive or exhaustive [11]. An overview of the eleven characteristics of PHR, each with a brief explanation, is given in Table 1.

Table 1. Characteristics of Participatory Health Research according to the International Collaboration for Participatory Health Research [11]

Characteristic of Participatory Health Research (PHR)	**Explanation**
1. PHR is participatory	Participation defines PHR and distinguishes it from other health research approaches.
2. PHR is locally situated	The research scope relates to a specific social system that the generated knowledge is available for transformation processes.
3. PHR is a collective research process	Research is not only conducted by professional researchers, but by people from all person groups who are affected by the research issue.
4. PHR projects are collectively owned	All persons who conducted the research hold its ownership.
5. PHR aims for transformation through human agency	In addition to new scientific findings, bringing about change is one of the aimed research results.
6. PHR promotes critical reflexivity	As PHR requires power sharing, research and health professionals need to reflect on their power relations to patients.
7. PHR produces knowledge which is local, collective, co-created, dialogical and diverse	Findings from PHR projects are not, as is typically the case, only addressed to the academic world, but to patients, caregivers, service providers, health policy makers, etc.
8. PHR strives for a broad impact	Research goes hand in hand with learning; all those involved in the research learn from each other.
9. PHR produces local evidence based on a broad understanding of generalisability	Even though PHR is locally situated, the findings should be transferable to similar areas.
10. PHR follows specific validity criteria	PHR needs specific validity criteria, as known methodological standards need to be adapted to the participatory approach.
11. PHR is a dialectical process characterised by messiness	PHR thrives on different perspectives that do not necessarily have to be consensual.

2.1.2 Patient and Public Involvement in research

Unlike PHR, there is no universal, consented definition of PPI in research [20]. Depending on the context, i.e. country or institution, different intensities of involvement are sometimes meant by PPI [20]. Making matters more complicated, various other terms can be found in the literature besides patient and public involvement, such as consumer involvement [21–23], service user involvement [24, 25], lay involvement [26], and patient (stakeholder) engagement [27, 28].

A widely cited definition of the National Institute of Health and Care Research (NIHR) describes public involvement in research "as research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. It is an active partnership between patients, carers and members of the public with researchers that influences and shapes research" [29]. This clearly indicates that PPI in research represents an attitude according to which patients are not research subjects but act as research partners [28]. This goes hand in hand with the challenge of treating all kinds of expertise, be it experiential or professional expertise, equally, so that everyone can contribute to the generation of knowledge [30].

2.1.2.1 Origins of Patient and Public Involvement in research

According to Beresford and Russo [30], two main developmental strands of PPI in research can be identified – a democratic and a pragmatic one.

The earlier origin lies in the emancipatory disability research of the 1970s, motivated by the disabled people's movement [30]. This was due to their dissatisfaction with their care and their experiences of discrimination in society and research. Overall, there was a great distrust of traditional research, whose goals did not consider the needs of disabled people [30]. In this context, emancipatory disability research is linked to other participatory approaches such as feminist research [18] and calls for equal relationships between researchers and researched persons, empowerment of those affected by the research and the initiation of changes that meet the needs of disabled people [30].

The later origin of PPI in research came from researchers and the healthcare system [21, 30]. The interest in PPI was carried and supported by the fundamental political trend in the mid-1990s to empower citizens and let them participate in decision-making processes. At that time, contributions from the social sciences emerged in the medical literature, emphasising that the experiential knowledge of health service users complements the professional knowledge of providers and researchers in identifying relevant research questions and interpreting research findings [21]. In the UK, for example, the conviction of PPI led the Department of Health to set up an Advisory Group in 1996 to support active public involvement in public health and social care research programmes, as well as in the research teams funded by them [21, 31]. Together with a support unit, this project led to the initiative known as INVOLVE whose guideline on PIE

[32] is also referred to by German research funders. Its original title was 'Consumers in NHS Research' and its main aim was to increase the efficiency and effectiveness of research and to use the knowledge of consumers [30]. In this context, consumers are understood on the one hand as members of the public who help to finance the healthcare system with taxes or who may be affected by a certain health condition, and on the other hand as patients who are actual users of healthcare services [21].

2.1.2.2 Characteristics of Patient and Public Involvement in research

Although no longer called INVOLVE, the guideline on PPI is still updated and published by the NIHR [29]. It formulates the six 'Standards for Public Involvement', which were developed, tested, and implemented in a multiannual process. As mentioned above in the definition, the term 'public' also includes patients. The standards provide guidance on what constitutes good involvement. Table 2 lists and explains the standards.

Table 2. UK Standards for Public Involvement according to the National Institute for Health and Care Research (NIHR) [29]

Standard of Public Involvement	Explanation
1. Inclusive opportunities	Offer public involvement opportunities that are accessible and that reach people and groups according to research needs.
2. Working together	Work together in a way that values all contributions, and that builds and sustains mutually respectful and productive relationships.
3. Support and learning	Offer and promote support and learning opportunities that build confidence and skills for public involvement in research.
4. Governance	Involve the public in research management, regulation, leadership and decision making.
5. Communication	Use plain language for well-timed and relevant communications, as part of involvement plans and activities.
6. Impact	Seek improvement by identifying and sharing the difference that public involvement makes to research.

Both PHR and PPI are characterised by the attitude that patients are not only study participants but have valuable experiential knowledge that they bring into the research in cooperation with professional researchers and act as research partners. In PHR, the origins in social movements are much stronger which becomes apparent in the fact that the objective is primarily oriented towards change and empowerment and that there is a continuous reflection on power relations during the process. PPI, in contrast, is primarily pragmatic and consumerist in character and focuses more on the use of knowledge for decision-making and for the benefit of research.

However, as Bereford and Russo [30] correctly state, "*it is a very different matter to be involved in research in an advisory or consultative role than it is in a controlling one*" (p. 148). To keep these different involvement intensities and participatory approaches in mind, the term patient involvement and engagement (PIE) is used within this work.

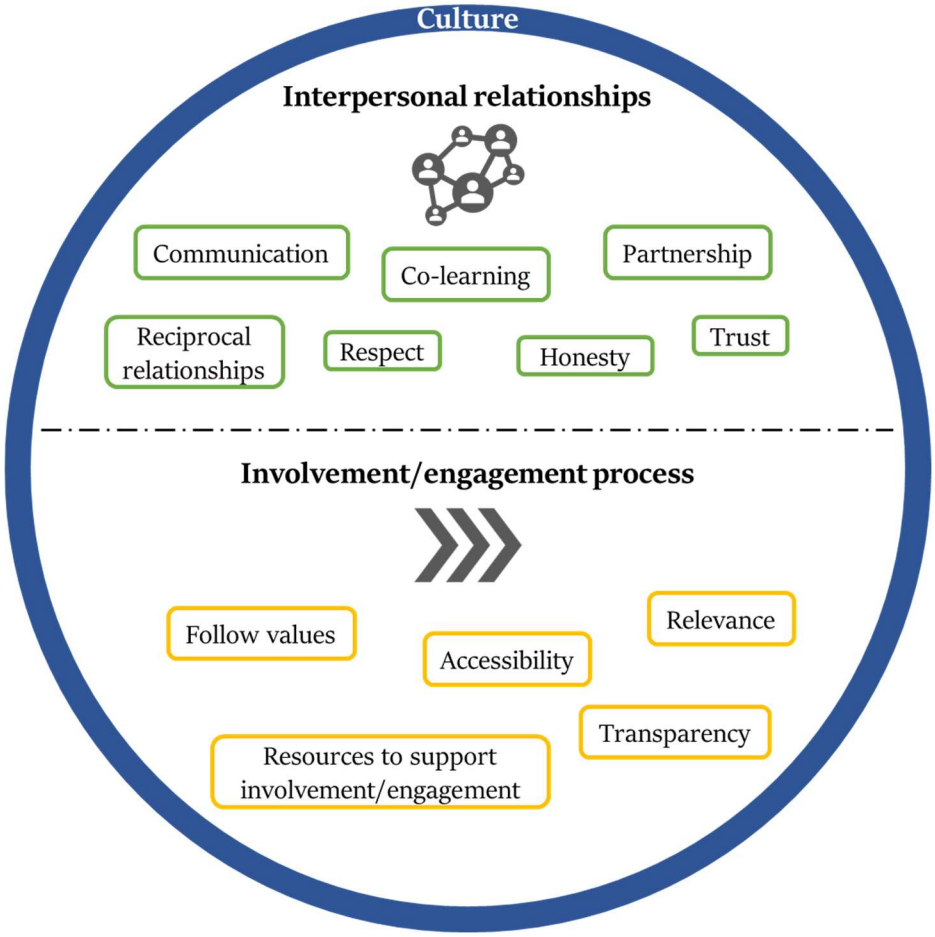
2.2 Patient involvement and engagement in health services research

Looking at the standards of PPI [29] and the definitions of PHR by Wright [9] and HSR by Schrappe and Pfaff [8], one common term captivates: improvement. Furthermore, the origins of the INVOLVE initiative or terms such as consumer or service user involvement also refer directly to HSR [21]. Thus, HSR seems predestined for the application of PIE. Not least because the definition of HSR states that it is "*based on the patient and population perspective*" [8] (p. 691). However, even if HSR takes the patient perspective into account, and deals with topics such as shared decision-making or patient empowerment, this does not automatically mean that PIE is implemented in HSR projects [20]. PHR and PPI differ significantly from research on patient-centred care which focuses on the patient with their preferences, values, and needs as the scope of research [33]. Research on patient-centred care is thus a content-based focus, while participatory approaches are a paradigm guiding the research process [11]. In PIE in HSR, research is conducted together with patients who have experience with, for example, a specific disease, intervention or in the use of the healthcare system [28].

2.2.1 Principles of patient involvement and engagement in health services research

Currently, there is a lack of a common understanding of PIE in HSR, which is reflected in poorly overlapping frameworks [28]. In a systematic review, Chudyk et al. [28, 31] identified models and frameworks for PIE in HSR and compiled their elements. They found thirteen principles that relate to interpersonal relationships, the involvement/engagement process and the environment (Figure 1).

Figure 1. Principles of patient involvement and engagement in health services research [28]



Accordingly, PIE in HSR can only take place if there is a culture as a framework condition (environment) in which every contribution of all involved is treated equally. At the relationship level, PIE in HSR is characterised by mutual communication with continuous feedback, learning from each other and sharing knowledge (co-learning), collaboration in partnership, clarification of roles and tasks and understanding each other's' perspectives (reciprocal relationships) and the values of respect, trust, and honesty. When implementing PIE in HSR, the values and chosen working methods of the patient research partners are followed and barrier-free access to e.g. meeting rooms and information is ensured (accessibility). In addition, PIE needs appropriate resources such as funding for travel expenses and allowances, or intangibles such as training and support in the role of a research partner. The process should also be jointly designed so that it is transparent, comprehensible, and relevant for all involved. This goes hand in hand with a continuous clarification of expectations, interests, and needs.

2.2.2 Impact of patient involvement and engagement in health services research

For all the definition and characterisation of PIE, the question arises as to what advantages it offers. Duffett [13] even cautions against underestimating the hazards. In a review of systematic reviews on the impact of PIE, she identified the following challenges: Involving patients as co-researchers requires more time and financial resources [34–37]; there is a fear that PIE can make the research objectives unfeasible or lead to tokenism [34, 38, 39]. Reflecting on and negotiating power relations and the different perspectives and interests can also lead to conflicts, with researchers feeling uncertain about whether they could resolve them [40]. However, the benefits of PIE outweigh the disadvantages [13]: Patients can play a decisive role in increasing the relevance of research projects [26, 34, 35, 41] which is also reflected in the study design, e.g. with regard to the selection of patient-relevant outcomes [40]. Through PIE, patient information materials and informed consent documents are designed and worded appropriately for the target group [34, 40], and studies with patients as co-researchers also show higher enrolment and lower drop-out rates [38]. PIE also improves the dissemination and implementation of research results [34, 38, 41] and increases public trust in science and research [34, 41].

Results from investigations that were conducted specifically to reflect PIE in specific HSR projects or participation programmes reveal that patients sometimes are referred to as 'consulters' [42] or 'advisors' [37]. According to the aforementioned quotation of Beresford and Russo [30], a consulting role does not resemble a controlling one. However, this participation form seems to be common as evidenced in interviews with patients who were actively involved in data collection and analysis in a HSR project on medication safety and electronic prescribing systems [26, 35]. A patient reported that their experience prior to this project was usually that they were presented with already completed products such as patient information material or project proposals for comment [35]. Professional researchers also perceived PIE in steps such as data analysis as poorly established [26].

Both HSR and PIE are context-specific in themselves [28]. Thus, this is particularly true for PIE in HSR. Now that international experience has been presented, the following section focuses on PIE in HSR in Germany as the dissertation projects are situated in the German healthcare system.

2.3 Patient involvement and engagement in health services research in Germany

The involvement and engagement of patients in HSR in Germany does not have its origins in social movements, but is pragmatically justified, especially through increased implementation research. In order to develop new care concepts and forms in a tailored manner and to implement them successfully in complex contexts, patient and stakeholder involvement is considered a "*holy*

grail" [43] (p. 4). Moreover, the awareness of PIE has been increasing among German health services researchers due to the updated requirements of research funders. For example, the Federal Ministry of Education and Research (BMBF) has anchored patient or patient representative involvement in the so-called ‚Framework Programme for Health Research of the Federal Government' [44], 'Action Plan Health Services Research' [45], and 'Strategy for Participation in Research' [46]. Thus, the BMBF requires in corresponding calls for proposals that a statement has to be made on the involvement of patients and other stakeholders in project applications. Consequently, reviewers are confronted with the evaluation of PIE. For project applications submitted to the Innovation Committee at the Federal Joint Committee, it also has to be considered to what extent patients can be "*actively involved in the development and implementation*" [47] (p. 4). In addition, if PIE is planned, it should be outlined how and with which resources it will be implemented. In the final reports for the Innovation Committee, it has to be stated how the participation in the project was eventually realised. It is not yet common for patients to decide on project applications; patient representatives belong to the Innovation Committee, but they do not have voting rights [48]. Patient representatives are also involved in advising the evaluation of research proposals for HSR calls of the German Pension Insurance [49].

Moreover, influences of the two participatory approaches presented above, PHR and PPI, can be identified in HSR in Germany. For example, the German Network for Participatory Health Research - PartNet was established in 2008, which is a partner network of the International Collaboration for Participatory Health Research and, in its tradition, is not limited to a specific area of health research. Thus, there is a growing number of health services researchers among its members. Therefore, some of the frameworks on PIE and stakeholder involvement and engagement adapted for the German-speaking countries originate from PHR (chapter 2.3.3). In terms of wording, PIE in HSR in Germany is also influenced by PHR which is reflected in the emerging term partizipative Versorgungsforschung (participatory health services research) (chapter 2.3.1). In publications with this term in the title [49, 50], reference is made to the German-language participation matrix by Farin-Glattacker at al. [51] which in turn is based on the types of service user and survivor involvement of Sweeney and Morgan [25] which are attributed to the PPI approach. Furthermore, the definition of partizipative Versorgungsforschung [50] focuses on patients referring to them as consumers which is reminiscent of the concept of consumer involvement as an example for PPI.

2.3.1 Partizipative Versorgungsforschung (participatory health services research)

Even though the term participatory health services research is based on PHR, it should be emphasised that it is not a participatory approach of its own with regard to the origins of PIE in

HSR in Germany. Rather, participatory health services research is to be understood as a type of research within HSR that includes various participatory approaches. This is also reflected in the definition by Farin [50] from 2017: "*Participatory health services research is health services research in which those affected by the research (usually users of the healthcare system) are involved as partners and can influence decisions in various research phases (setting out research needs, project planning and application, review and funding decision, project conduction, publication and dissemination).*" (p. 182). As mentioned above, the definition focuses primarily on patient participation in HSR. Furthermore, it emphasises that PIE is possible in all research phases.

The term participatory health services research is also used in the German Network Health Services Research. In 2018, the equivocal working group was founded. It is currently working on a memorandum (co-written by the author of this thesis) that is intended to help health services researchers conduct participatory research projects. With this memorandum in progress, the definition of participatory health services research is being updated in order to outline the differentiation from PHR and to be adequate to the field of HSR. A further activity towards PIE in the German Network Health Services Research is the establishment of a patient advisory board for the executive board in 2022. At the German Conference for Health Services Research, sessions and pre-conference workshops on the topic of participation have increasingly been organised in recent years, with patients and patient representatives also engaging.

2.3.2 The relevance of cancer research for patient involvement and engagement in health services research in Germany

Cancer research has a pioneering role regarding PIE in Germany. Within the National Decade against Cancer (an initiative of the BMBF to promote cancer research), various measures exist to involve patients. In the Strategy Committee, which defines the goals of the Decade against Cancer and initiates corresponding activities, the members also include patient representatives [52]. The same applies to the working groups established by the Strategy Committee. In a one-year process involving persons from patient representation, research, healthcare, industry, and politics, 'Principles of Successful Patient Involvement in Cancer Research' were compiled and published in 2021 [53]. These cover organisational, relational, capacity-based, methodological, and ethical aspects of patient involvement. In the Alliance for Patient Participation in Cancer Research, various stakeholders concerned by cancer research have committed themselves by signing up to implement the principles in their respective settings [54]. Further institutions can still join the alliance.

Further examples of PIE in cancer research are provided by the German Cancer Research Centre (DKFZ). Its Patient Advisory Board on Cancer Research [55] contributes the patient

perspective by advising on the DKFZ's research strategy and heightening scientists' awareness of the patient perspective so that research projects are conducted in a more target-group-oriented manner. In addition, the Patient Advisory Board supports the public presentation of cancer research and the political efforts of the DKFZ. In practical research terms, the DKFZ supports the integration of the patient perspective with the portal fragdiepatienten.de [56]. Researchers can pass on their survey contents, e.g. on needs and preferences of cancer patients, to fragdiepatienten.de where an online survey is created and published. In this way, low-threshold surveys of the patient's perspective on various oncological issues can be realised.

For the future network of National Centres for Tumour Diseases, a concept for PIE in cancer research was developed, including the Patient Expert Academy for Tumour Diseases which offers an education and training programme for patients and their representatives [57] as well as the Nationale Konferenz – Patienten als Partner in der Krebsforschung (National Conference - Patients as Partners in Cancer Research), which took place for the first time in autumn 2022 [58].

An organisation from cancer patient representation that is involved in the above-mentioned initiatives is the House of the Cancer Patient Support Associations of Germany (HKSH-BV). The umbrella organisation of ten cancer self-help organisations also promotes the topic of PIE itself, for example, by organising a full-day PHR workshop for the voluntary and employed staff of the member associations [59] or its own session on the topic participatory health research at the German Cancer Congress 2022. The HKSH-BV is also involved in numerous health services research projects, such as the Innovation Fund project 'integrated, cross-sectoral psycho-oncology' (isPO) [60], which is the basis for the dissertation projects 2-4 (chapters 6-8).

Despite all the aforementioned initiatives, there is a lack of visibility of PIE in HSR in Germany [49]. Questions arise, for example, about the type of participation, the methods used, and the effects participation had. In the international literature, the need for frameworks and models to critically reflect on participatory research processes is emphasised [28, 61]. Additionally to the matrix by Farin-Glattacker et al. [51], German-language frameworks and instruments for PIE have emerged in recent years which originated from health services researchers or were adapted for the German-speaking region with the participation of health services researchers.

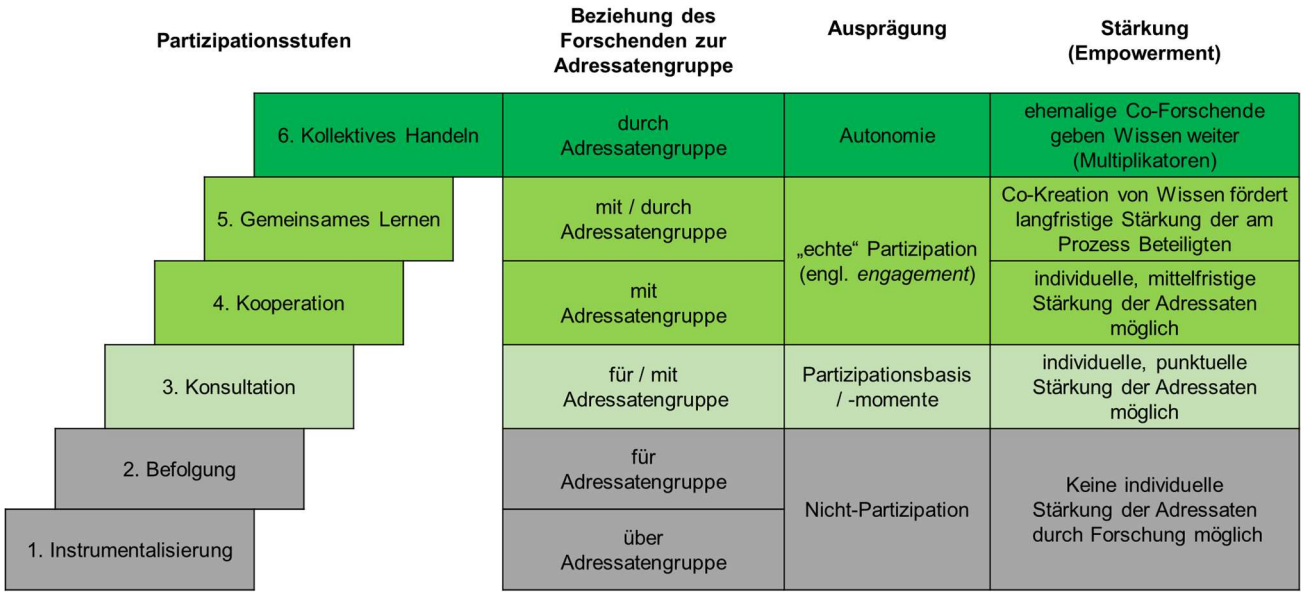
2.3.3 Frameworks for patient involvement and engagement in health services research in Germany

In the following, three German-language PIE frameworks are presented: The Stage Model of Participatory Health Research [62] adapted from Cornwall [63], the Model for Participatory

Health Research [64] as an adaptation of the Conceptual Model [65] for the German-speaking context, and the Participation Web [66]. Due to their different characteristics, the frameworks are all legitimate. Hence, Greenhalgh et al. [61] distinguish various categories of frameworks with specific foci. For example, power-focused frameworks help to surface, explore, and overcome researcher-patient power imbalances. Study-focused frameworks follow the logic of the research process and its phases, and partnership-focused frameworks assure transparency and public accountability in researcher-patient collaborations.

The power-focused Stage Model is based on the six-level participation model by Cornwall [63] which is particularly convincing because it not only describes the different modes of participation, but also clarifies the relationship between the research partners and professional researchers with the help of prepositions. Cornwall's modes of participation can be ranked in terms of participation level, but they are not judgemental. The German adaptation (Figure 2) emerged from the cooperation of a patient representative and two researchers within a HSR project. In addition to the translation of Cornwall's [63] participation levels, the Stage Model describes the degree of participation per level and the extent to which the target group is empowered.

Figure 2. Stufenmodell der Partizipativen Gesundheitsforschung (Stage Model of Participatory Health Research) [62]



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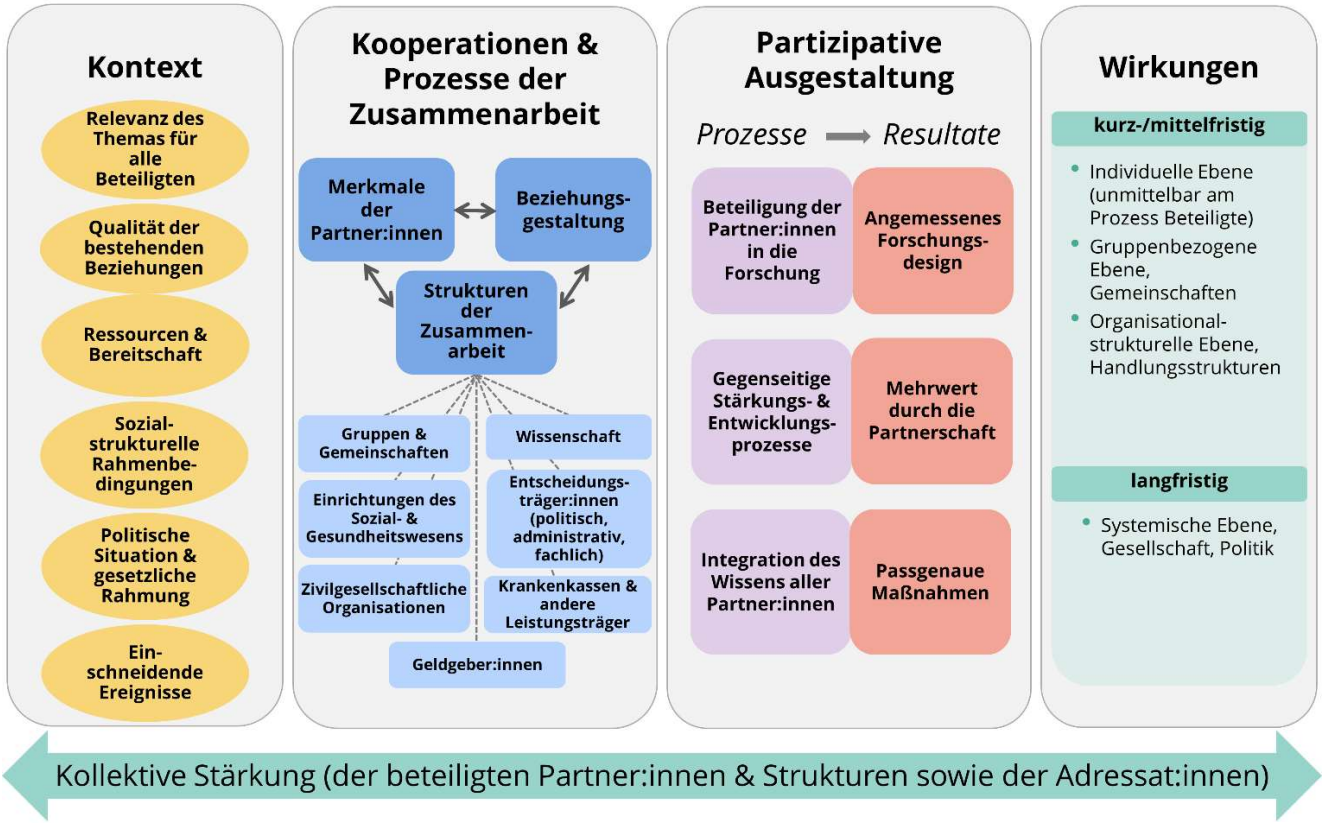
The participation levels are arranged as a stairway so that participation ‘climbs’ from the lowest to the highest stage. According to Houwaart et al. [62], the first two levels ‘Instrumentalisierung’ (Cooption) and ‘Befolgung’ (Compliance) are not participation as there is

no exchange between professional researchers and the target group, e.g. patients. Accordingly, no empowerment of the patients is possible. Level 3, 'Konsultation' (Consultation), represents a pre-stage of participation. For example, participation moments with selective empowerment of patients are created in the research process through single workshops or the pre-test of a questionnaire. Professional researchers and patients come into exchange and the patients' perspective is heard. However, the subsequent decisions remain the responsibility of the professional researchers. Collaboration and research on equal footing take place at level 4 'Kooperation' (Cooperation). This is described by Houwaart et al. [62] as "true participation". This also includes level 5 'Gemeinsames Lernen' (Co-learning). In terms of empowerment, the two levels differ in that cooperation leads to medium-term empowerment and co-learning to long-term empowerment. The sixth level 'Kollektives Handeln' (Collective action) goes beyond participation (autonomy) since patients as former research partners are empowered to the extent that they can initiate research projects themselves.

The Model for Participatory Health Research [64] (Figure 3) was developed in a two-year process of translating and adapting the Conceptual Model [65] from Community-Based Participatory Research. It is based on the conceptual logic model by Wallerstein et al. [67, 68] to understand what influences research collaboration or partnership and how this in turn affects the outcomes of participatory research (partnership-focused framework).

Figure 3. Modell für Partizipative Gesundheitsforschung (Model for Participatory Health Research) [64]



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Health services researchers were involved both in the author team of the German version of the PHR Model and among the participants in the different testing phases. The model covers various components of participatory research and serves as a framework for reflecting on them. It is not required to work through all aspects of the model for a research project but to use the model appropriately to the purpose and context. In project planning and conduction, the model can be used to keep all aspects to be considered in mind. It also helps to design the type and intensity of participation or to evaluate the impact of participation.

The four components of the PHR Model (Kontext; Kooperationen & Prozesse der Zusammenarbeit; Partizipative Ausgestaltung; Wirkungen) do not build on each other linearly but are interrelated so that changes in one component can have an impact on others.

The 'Kontext' (Context) component takes different levels of the conditions for participatory projects into account, from the personal and relationship level, to social, political, and legal settings to incisive events such as global crises, new therapy options, etc. The last aspect was not included in the original version of the model and probably stems from experiences during the COVID-19 pandemic.

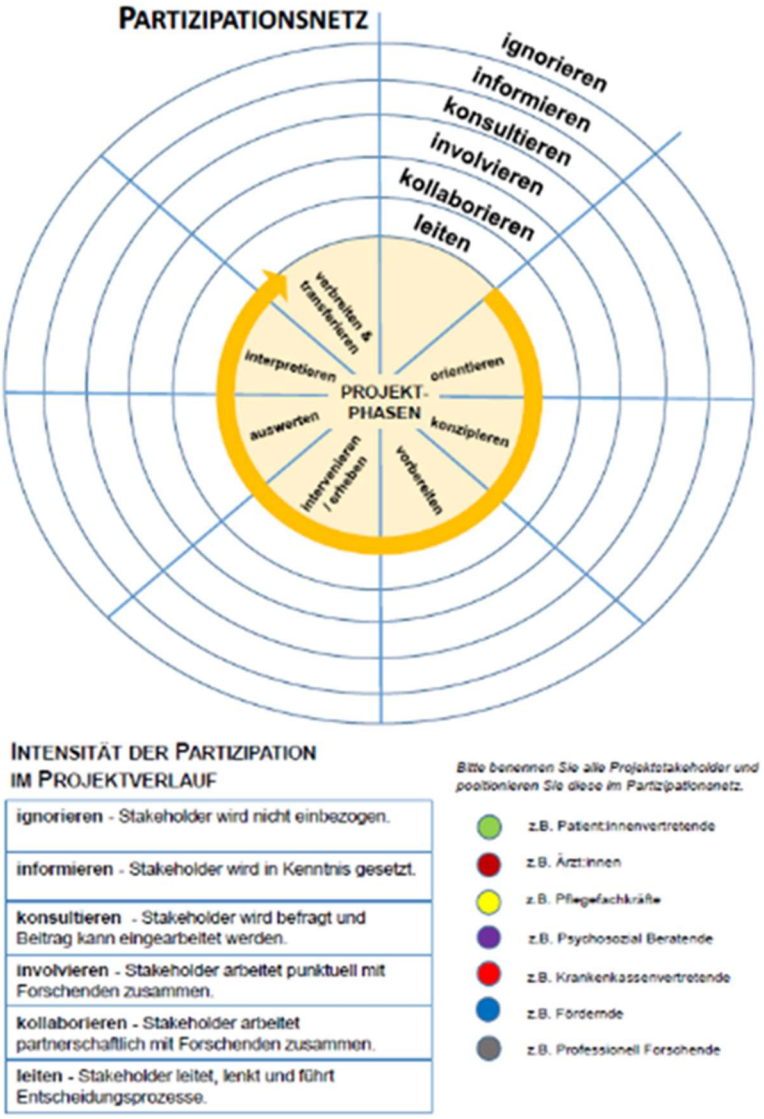
With the component ‘Kooperationen & Prozesse der Zusammenarbeit‘ (Partnership Processes), the motives of different stakeholders can be reflected and the structures of collaboration can be planned. In addition, this component identifies different groups and institutions that may be involved as co-researchers or otherwise have an interest in a project. Patients are not literally named in the PHR Model but can be located as a population group under ‘Gruppen & Gemeinschaften‘ (Groups & Communities). Patient representation organisations are considered as ‘Zivilgesellschaftliche Organisationen’ (Civil society organisations).

In the component ‘Partizipative Ausgestaltung‘ (Intervention & Research), not only the necessary aspects of the conduction of participatory projects are named, but processes and their results are directly contrasted. It is shown that early patient participation leads to relevant research questions and feasible research designs. Learning from and with each other leads to empowerment of all persons in the participatory team, and bringing together the knowledge of all participants (whether experiential or professional) results in measures that are appropriate for the setting being researched.

The fourth component of the PHR Model is 'Wirkungen‘ (Outcomes) and is very comprehensive. As such, it invites consideration at the project planning stage on what desirable but also undesirable effects might occur, for example, for patients, the participatory team as a whole, academia or the healthcare system. Some of the listed objectives and thus desired effects are: empowerment, sustainability of collaborations and projects, equality in research, improvement of political and social conditions, and improved health.

The Participation Web of Krieger and Nellessen-Martens [66] (Figure 4) is not only to be understood as a framework, but above all as a reflection tool for stakeholders in HSR projects. It combines elements of power- and study-focused frameworks.

Figure 4. Partizipationsnetz (Participation Web) [66]



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The instrument contains six intensities of participation but does not represent them as levels but rather as sections of a web so that they can be considered neutral. The rounded arrangement also results from the focus on the different phases of the research cycle from orientation to dissemination and transfer. Participatory research teams can use the Participation Web, for example, to agree at the beginning of a project which stakeholders (represented by different coloured dots) will participate in which phase and with what intensity. This can be recorded on

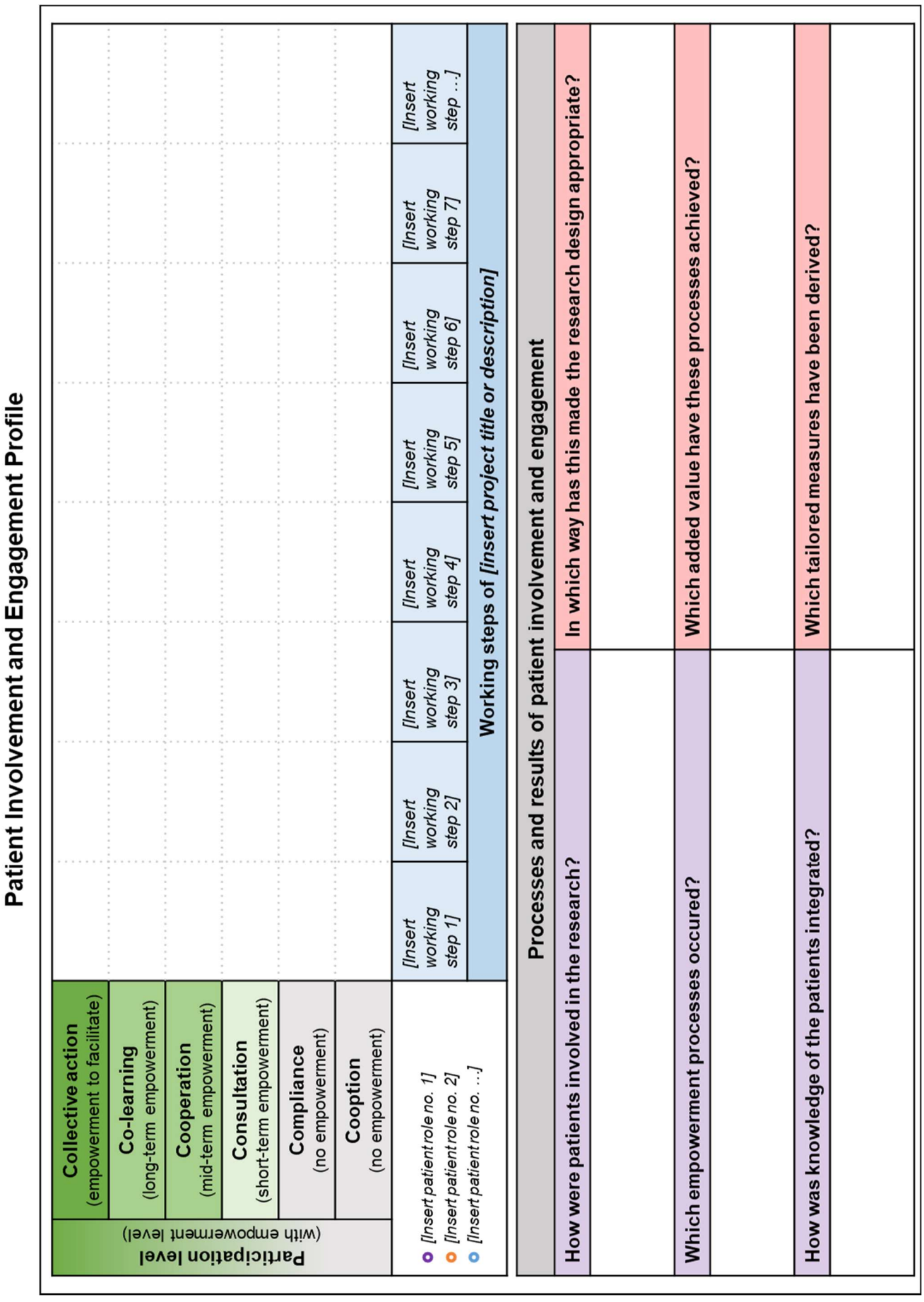
the freely available template of the Participation Web. In the course of the project, the tool can be filled in on a regular basis by each person in the team in order to record the participation actually realised and to reflect on it in the team. If necessary, the original Participation Web is adapted at the beginning of the project. In the example of HSR in the context of cancer, this may be the case if patients can no longer participate to the extent planned due to changes in their health status. The Participation Web thus supports the work of participatory research teams not only in the reflection of power relations but also of the existing capabilities and resources.

2.3.4 The Patient Involvement and Engagement Profile (PIE PRO)

The frameworks presented in chapter 2.3.3 cover numerous aspects of participation in HSR and are generalised to take different stakeholders into account. As Chudyk et al. [28] claim, it is necessary to consider which components of a PIE framework or model are appropriate for the use in a specific context. In order to address the question of the feasibility of PIE in HSR projects in Germany, an instrument was compiled for this thesis based on the existing German-language models that focuses on patients and their participation in HSR. The Patient Involvement and Engagement Profile (PIE PRO) considers levels of participation and empowerment [62], processes and results of participation [64], project phases/working steps [66] as well as different patient roles (Figure 5).

In the retrospective evaluation of PIE in an HSR project, the PIE PRO can be used as follows: For each working step within a project, the realised participation level can be recorded by marking it with a symbol. If there are different patient roles within a project (e.g. patients as users of health services, patient representatives, patients as service providers), each role can be assigned a different colour. This allows an overview of the participation levels across the different roles and enables the assessment over the course of the project. Since the assignment to a participation or empowerment level reveals little about how participation was actually realised, the PIE PRO also consists of open questions that are based on the categories of participatory design of the PHR model [64]. The question format is intended to facilitate reflection on the processes and results regarding patient involvement and engagement, empowerment, and knowledge integration.

Figure 5. Template of the Patient Involvement and Engagement Profile (PIE PRO)



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Chapter 3

Aim and objectives

Aim and objectives

In Germany, there are many initiatives within health services research (HSR) in general and in cancer-related research in particular that aim to strengthen patient involvement and engagement (PIE) in research. These range from review guidelines and patient advisory boards to principles papers and conferences (chapter 2.3.2). Since a number of these efforts are very recent and not yet (fully) established, the question remains as to how PIE can be performed in HSR projects in Germany. Therefore, the aim of this work is to capture the realisation of PIE in HSR projects, using the context of psycho-oncological care. For this purpose, a retrospective evaluation of the PIE in the four dissertation projects (DP) (chapters 5-8) is made applying the 'Patient Involvement and Engagement Profile' introduced in chapter 2.3.4 to every DP.

Each of the four DPs represents a task area of HSR (1. Investigation of everyday healthcare, 2. Development of complex interventions, 3. Implementation and optimisation of complex interventions, and 4. Evaluation of complex interventions). Furthermore, the PIE evaluation is differentiated into the working steps in the respective DP and the roles taken by the patients. The questions of this thesis are therefore:

- At which participation levels and how can PIE be realised in HSR projects in Germany in the field of psycho-oncology?
    - What participation levels, processes, and results occur according to the task areas of HSR?
    - What participation levels occur according to working steps?
    - What participation levels occur according to patient roles?

The objectives of the four DP were as follows:

DP 1 (Investigation of everyday healthcare):

Estimating the prevalence of mental disorders and utilisation rate of mental health services in newly diagnosed cancer patients using health insurance claims data

DP 2 (Development of complex interventions):

Evaluating the development phase of the new form of care 'integrated, cross-sectoral Psycho-Oncology' (isPO)

DP 3 (Implementation and optimisation of complex interventions):

Developing and validating a patient information material assessment following the participatory health research approach

DP 4 (Evaluation of complex interventions):

Evaluating the isPO onco-guide one-to-one peer support from isPO onco-guides', patients' and professional service providers' perspectives

Chapter 4

Methods

Methods

Since the four dissertation projects (DP) cover the different task areas of health services research, a variety of methods was used in line with the objectives (chapter 3). Table 1 provides an overview of the applied approaches.

Table 1. Methods applied in the dissertation projects

DP	Objective	Task area of health services research	Data source/ data collection	Data analysis
1	Prevalence of mental disorders and utilisation rate of mental health services in newly diagnosed cancer patients	Investigation of everyday healthcare	German health insurance claims data	Estimation of 12-month prevalence and utilisation rate Binomial logistic regression analysis
2	Evaluation of the development phase of isPO	Development of complex interventions	Semi-structured focus group and interviews Project documents Questionnaires	Content analysis Document analysis Descriptive analysis
3	Participatory development and psychometric pilot study of the UPIM-Check	Implementation and optimisation of complex interventions	Assessment instrument	Psychometric analysis (Item completion rate, Item-scale correlation, Cronbach's α, Correlation analysis, Comparison analysis)
4	Evaluation of the isPO onco-guide peer support	Evaluation of complex interventions	Semi-structured focus groups and interviews Questionnaires Care data	Content analysis Descriptive analysis Binomial regression analysis Correlation analysis Comparison analysis

Abbreviations: DP dissertation project; isPO integrated, cross-sectoral Psycho-Oncology; UPIM-Check user-friendly patient information material checklist

In the **first DP**, the prevalence of mental disorders and the utilisation rate of mental health services in newly diagnosed cancer patients were examined [1]. For this purpose, health insurance claims data from the 'Statutory Health Insurance (SHI) Sample AOK Hesse/KV Hesse' [2] was analysed. This database was developed and is managed by the PMV forschungsgruppe, University of Cologne and contains a 18.75% random sample of the insurees of the AOK Hesse. The 'SHI Sample AOK Hesse/KV Hesse' is comprised of several data profiles with information on

diagnoses and treatments in the out-patient and in-patient sector, nursing care, and master data like year of birth, sex, and insurance periods. Incident cancer cases were identified to determine the 12-months prevalence of mental disorders in newly diagnosed cancer patients. For the subsample of newly diagnosed cancer patients with mental disorder, the 12-month utilisation rate of out-patient psychotherapy and psychopharmacological prescription was computed. Furthermore, two binomial logistic regression analyses with the criterion variables sex, age group, and tumour entity were conducted. First, prediction of the occurrence of mental disorders in newly diagnosed cancer patients who had no mental disorder prior to cancer diagnosis was examined. Second, regression analysis for the prediction of mental health service utilisation (out-patient psychotherapy and psychopharmacology) in newly diagnosed cancer patients with mental disorder following cancer diagnosis but without mental disorder prior to cancer was performed.

The **second DP** contains the prospective evaluation of the development of the psycho-oncological new form of care 'integrated, cross-sectoral Psycho-Oncology' (isPO) [3] prior to its implementation [4]. A QUAL-quant mixed-methods approach was followed and the perspectives of isPO developers, patients, and service providers were captured. A focus group and single telephone interview with the consortium partners who were in charge of the design and implementation of isPO were conducted. The topics of the interview guideline included (1) anticipated facilitators and barriers of the implementation of isPO, (2) implementation strategies, and (3) cooperation and communication between consortium and project partners. Moreover, project-related documents (quarterly progress reports of designers and statement paper of the patient representative consortium partner) were analysed. An interview with the project leader completed the quarterly progress reports and gave insights into the conceptual framework of isPO. The future isPO professional and peer service providers were asked about their satisfaction with training answering a questionnaire. For the focus group and telephone interview with designers and implementers, deductive-inductive content analysis was performed. The quarterly progress reports were evaluated with a self-developed criteria catalogue, and the project leader interview was thematically analysed. The statement paper was paraphrased. The Likert-scale items of the training questionnaires were descriptively analysed.

The **third DP** dealt with the development and validation of the User-friendly Patient Information Material Checklist (UPIM-Check), an instrument for quality assessment and optimisation of patient information material (PIM) [5]. The multi-step process was guided by the Participatory Health Research approach. As the UPIM-Check was developed within the optimisation of the isPO-PIM, the team consisted of cancer patient representatives, cancer care experts, and health services researchers. After the health services researchers conducted a literature search on PIM quality criteria to develop the preliminary UPIM-Check version, the

patient representatives and cancer care experts pre-tested this version. The UPIM-Check was revised according to the comments. Following the TRAPD approach (Translation, Review, Adjudication, Pre-test, and Documentation) [6, 7], an English version of the UPIM-Check was created. The pre-test was conducted with members of cancer self-help organisations in UK, Ireland, USA, and Canada. Their feedback was used to revise and finalise both language versions of the UPIM-Check. For the German UPIM-Check psychometric pilot study, cancer patients unfamiliar with isPO were asked to assess the initial and optimised isPO leaflet. Completion rate for each item was calculated to evaluate item acceptance. Item discrimination was captured with the corrected item-scale correlations and internal consistency with Cronbach's α. For evaluating the construct validity, (1) Spearman's correlations between the UPIM-Check total score and the four subscale scores were computed, (2) UPIM-Check total scores for the initial and the optimised isPO leaflet were compared with the Wilcoxon test, and (3) Spearman's correlation between the UPIM-Check total score and the completion time was examined.

In the **fourth DP**, the isPO onco-guide one-to-one peer support as one of the isPO care levels was evaluated [8]. A QUAL-QUANT mixed-methods design was conducted taking three perspectives into account: (1) patients, (2) isPO onco-guides (peer service providers), and (3) professional isPO service providers (e.g. isPO case managers, psychosocial professionals, and psycho-oncological psychotherapists). The qualitative data collections comprised telephone interviews with patients, telephone interviews and a focus group with isPO onco-guides, and interviews and focus groups with professional isPO service providers. Content analysis was applied to identify facilitators, barriers, and suggestions for optimisation concerning the isPO onco-guide service. At quantitative level, questionnaire surveys with patients and isPO onco-guides were conducted on their satisfaction. Furthermore, isPO care data from the isPO-specific IT documentation and assistance system were analysed and linked with the patient survey data. Descriptive analyses for key figures like percentage of patients who utilised the isPO onco-guide service, date difference between isPO enrolment and isPO onco-guide consultation, and duration of isPO onco-guide consultation were carried out. Comparison of the isPO care networks in which the isPO programme was implemented was conducted with X^2-test and ANOVA. Binomial logistic regression analyses were performed to identify predictors for the utilisation of the isPO onco-guide service. Paired t-test were used to compare patients' and isPO onco-guides' assessments of the consultation concerning its effect on the patient's coping, confidence, and orientation. The isPO onco-guide survey data was analysed with a focus on their work satisfaction, conducting Spearman's correlation analyses with person-related (age, gender, employment status, and previous experiences in cancer peer support) and work-related variables (workload, number of consultations conducted, satisfaction with training, and work-related sense of coherence).

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Chapter 5

Dissertation Project 1

Published as: [1]

Mental disorders and utilization of mental health services in newly diagnosed cancer patients: An analysis of German health insurance claims data

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Abstract

Objective: People with cancer are often confronted not only with the burdens of medical treatment but also with psychological strain, which can lead to mental disorders (MD). To date, the prevalence of MD in newly diagnosed cancer patients and their utilization of mental health services (MHS) are mainly estimated through data of primary studies than considering healthcare-related claims data.

Methods: Statutory health insurance claims data of the AOK/KV Hesse from 2011 to 2014 was analyzed. The number of incident cancer patients with MD and the utilization of MHS within the period of the quarter of incident cancer diagnosis and three subsequent quarters were determined. For incident cancer patients with an incident MD, the predictive values of sex, age group, and tumor entity on the documentation of MD diagnosis and utilization were investigated.

Results: The 12-month prevalence of MD in incident cancer patients was 31.1% for depression, 11.2% for anxiety disorders, and 9.2% for post-traumatic stress/adjustment disorder (PTSD/AD). Of these, 65.9% received outpatient psychotherapy and 43.0% at least one psychopharmacological drug prescription. Men had a significantly lower chance of receiving an MD diagnosis following cancer.

Conclusions: The prevalence of MD observed was higher for depression and lower for PTSD/AD compared to meta-analyses of clinical trials. Male cancer patients had a lower chance of receiving an MD diagnosis than females, which coincides with existing results.

Background

With a cancer diagnosis, patients are faced with high burdens. Physical stress can be caused by medical treatment and mental health can also be affected. According to diathesis-stress models [1], cancer disease is to be understood as a critical life event that may lead to mental disorder (MD). As a reference, the prevalence of depressive disorders is 7.7% for the general population [2] and 20.7% for cancer patients [3].

Based on numerous diagnostic, clinical and epidemiological studies of the prevalence of MD in cancer patients conducting structured clinical interviews, there are several meta-analyses [3–6] that distinguish between different forms of MD, such as depressive disorders (DD), anxiety disorder (AND), adjustment disorders (AD), and post-traumatic stress disorder (PTSD) which are the most frequent ones.

The first year after tumor diagnosis is an extremely critical time, in which some patients develop an MD. The aim is to identify these patients and enable them to undergo psychotherapeutic or pharmacological therapies. The predictors of MD following cancer can be classified into cancer-related, socio-demographic, and psychosocial factors [7, 8]. It was shown that younger, female [9] as well as breast and head and neck cancer patients [10] have a significantly higher risk for developing an MD.

In surveys and structured interviews of cancer patients with an MD, less than half stated that they have used mental health services (MHS) since their cancer diagnosis [11, 12]. The utilization rates are significantly higher for young [11, 13], female, and socially poorly supported cancer patients [11].

In all of the above-mentioned studies, data were collected either with structured interviews or through patients' self-report. However, to reflect everyday routine care and to avoid distortions such as selection and recall bias, the analysis of healthcare-related administrative claims data is suitable. In the area of estimating the prevalence of MD in cancer patients, data originating from health insurance services have already been used in earlier studies [14–17], whereby only limited data are available covering different tumor entities and newly diagnosed cancer patients.

Therefore, this study aims to (1) estimate the administrative prevalence of the most frequent MD in newly diagnosed cancer patients as well as (2) mental health service utilization rates stratified by MDs, sex, age group and tumor entity, and (3) identify predictors for these outcomes in patients without MD diagnosis prior to a cancer diagnosis.

Methods

Data basis

Data from the "Statutory Health Insurance (SHI) Sample AOK Hesse/KV Hesse" [18] were used for analyses. For further information on the AOK Hesse and the conceptualization of the SHI Sample, see the supporting information. It contains diagnostic and treatment data for outpatient and inpatient care, nursing care data, and master data of insured persons (sex, year of birth, insurance periods) of a regional statutory health insurance. According to the guideline 1 of the "Good Practice of Secondary Data Analysis" [19], permission from an ethics committee to conduct analyses based solely on claims data is not necessary. Nevertheless, analysis of the data for this study was approved by the advisory board "SHI Sample AOK Hesse/KV Hesse" consisting of members of the AOK Hesse, the KV Hesse (association of statutory health insurance physicians and psychotherapists, i.e., responsible for the securing of outpatient care in Hesse), the Hessian Ministry for Social Affairs, and the PMV forschungsgruppe.

Complete data of the insurance periods were available for the years 2006 to 2014, thus the analyses described below refer to this period and a population of 329,300 continually insured persons.

Diagnoses are classified as ICD-10 codes, outpatient services as EBM numbers (EBM refers to the remuneration system for statutory health insurance physicians and psychotherapists in Germany), and drugs as Anatomical Therapeutic Chemical (ATC) Classification System codes.

Identification of relevant cases

Adult insured persons (18 years and older) who received a first documentation of cancer diagnosis (ICD-10 codes C00-C97, excluding C44: nonmelanoma skin cancers as they are very common and have a good prognosis [20]) were identified. With a data basis of 36 quarters, a gold standard disease-free interval of 32 quarters [21] and a defined follow-up of 4 quarters would have included only incident cancer patients in 1/2014. Therefore, the next smaller interval of 20 quarters mentioned in the literature was chosen, so incidences could be determined for quarters 1/2011 to 1/2014.

The cancer diagnoses were validated by using only discharge diagnoses for the inpatient sector, and outpatient diagnoses being classified as 'confirmed' and meeting the M2Q criterion (diagnosis given in at least two of four consecutive quarters) [22].

To observe relevant cases throughout the entire period, only continually insured person who did not die during the observation period were included. According to age, persons ≥18 years were considered and the data cleansing concept of the German Federal Insurance Office was regarded. It describes the handling of incorrect data, for example, exclusion of a dataset, if the date of birth indicates an implausibly high age [23]. This selection procedure resulted in a sample

of 5,289 incident cancer patients as a basis for the following analyses. For insured persons with an unspecified cancer diagnosis (ICD-10 codes C76-C80) in the incidence quarter, the cancer diagnoses of the following three quarters were considered and, if available, an exact cancer diagnosis was assigned for statistical analyses.

Statistical analysis

The 12-month administrative prevalence of DD (ICD-10 codes F32-F34), AND (ICD-10 codes F40-F41), and PTSD/AD (ICD-10 code F43) diagnoses in incident cancer patients was determined. The prevalence was calculated by the following quotient: incident cancer patients with an MD at least once within cancer incidence quarter and three subsequent quarters/incident cancer patients.

This is independent of whether or not they received an MD diagnosis before cancer incidence. Only inpatient discharge and confirmed outpatient MD diagnoses were considered.

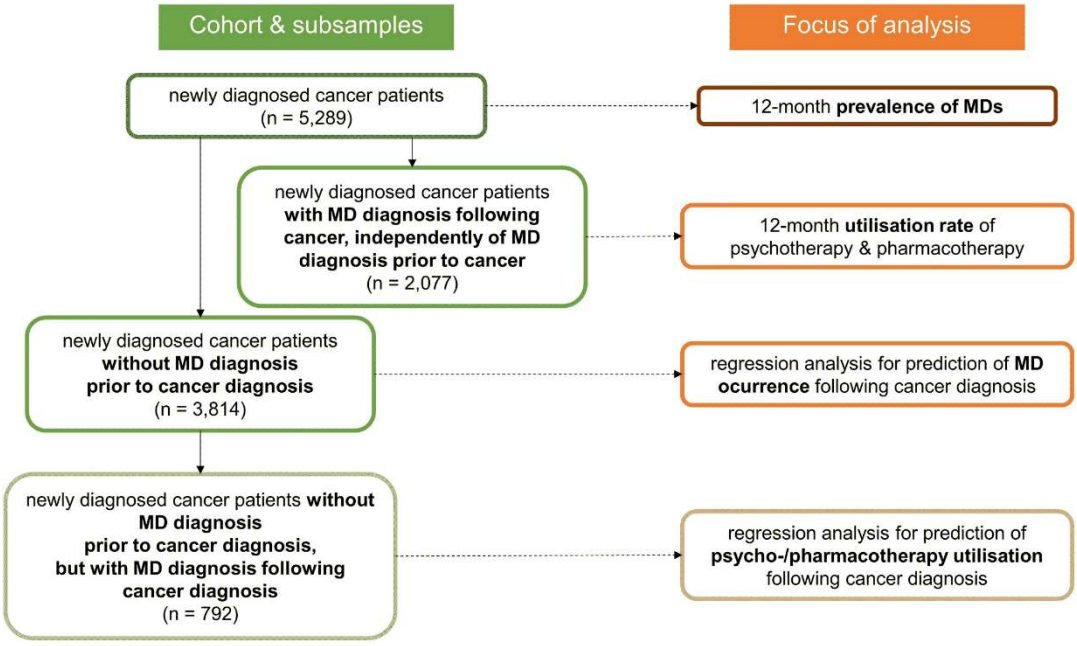
The same period was considered for calculating the proportion of patients with at least one coded treatment. Therefore, only newly diagnosed cancer patients for whom an MD diagnosis could be observed according to the above calculation were included. Outpatient psychotherapeutic services (EBM chapters 14, 21–23, and 35) and prescriptions of antidepressants (ATC code N06A) were used. For patients with AND and PTSD/AD, anxiolytics (ATC code N05B) were also included.

For calculating administrative prevalence and MHS utilization, the proportions were differentiated by the three diagnosis groups of MD and sex, age group, and tumor entity. A comparison was made between the groups of incident cancer patients who had already received one of the above MD diagnoses in the four quarters before cancer incidence and those who did not. The corresponding 95% confidence intervals were calculated using the Agresti–Coull method [24].

For the subsequent regression analyses, only patients who did not receive an MD diagnosis in the four quarters prior to their cancer diagnosis were considered. Patients with MD diagnosis prior to cancer were excluded as their previous MD diagnosis would be a perfect predictor for the occurrence of MD following cancer, thus the predictive value of the other variables would be underestimated.

The binary criterion variables were the presence of an MD diagnosis during the incidence quarter and three subsequent quarters as well as the use of psychotherapy and/or pharmacotherapy during the same period. For the latter criterion, as in calculating proportions, only patients with an MD diagnosis were included in the analysis. The investigated predictors were sex, age group, and tumor entity. Multivariable binomial logistic regression analysis for each criterion variable was conducted. To avoid bias due to the multicollinearity of sex and tumor entity, cases with cancer of the breast, female genital organs, and the prostate were excluded. As sex appeared to be a significant predictor for the presence of an MD diagnosis, further regression analyses including the variables of age group and tumor entity stratified by sex were computed. Data analyses were performed using SQL, Excel, and R. For a graphical overview of the patient samples examined and the analyses performed respectively, see Figure 1.

Figure 1. Investigated cohort as well as subsamples with respectively conducted analyses



Abbreviation: MD, mental disorder

Results

Administrative prevalence of mental disorders

Twelve-month administrative prevalence was 31.12% for DD, 11.19% for AND, and 9.23% for PTSD/AD. Female incident cancer patients received an MD diagnosis more often than male patients (Figure 2A). 50–59-year-olds had the highest prevalence in DD diagnoses. The highest prevalences for AND diagnoses and PTSD/AD diagnoses were found in 30–39-year-olds (Figure 2B). Concerning tumor entities, breast cancer patients had the highest prevalence across all MD diagnoses (Table 1).

12.4% of incident cancer patients who received an MD diagnosis had a comorbidity of DD and AND, 8.8% of DD and PTSD/AD, 2.3% of AND and PTSD/AD, and 3.9% of all three MDs.

The 12-month administrative prevalence of MD was higher in patients with an MD diagnosis four quarters before cancer incidence compared to those without an MD diagnosis prior to cancer (Table S1). For a comparison of the two groups in terms of sex, age group, and tumor entity, see Table S2.

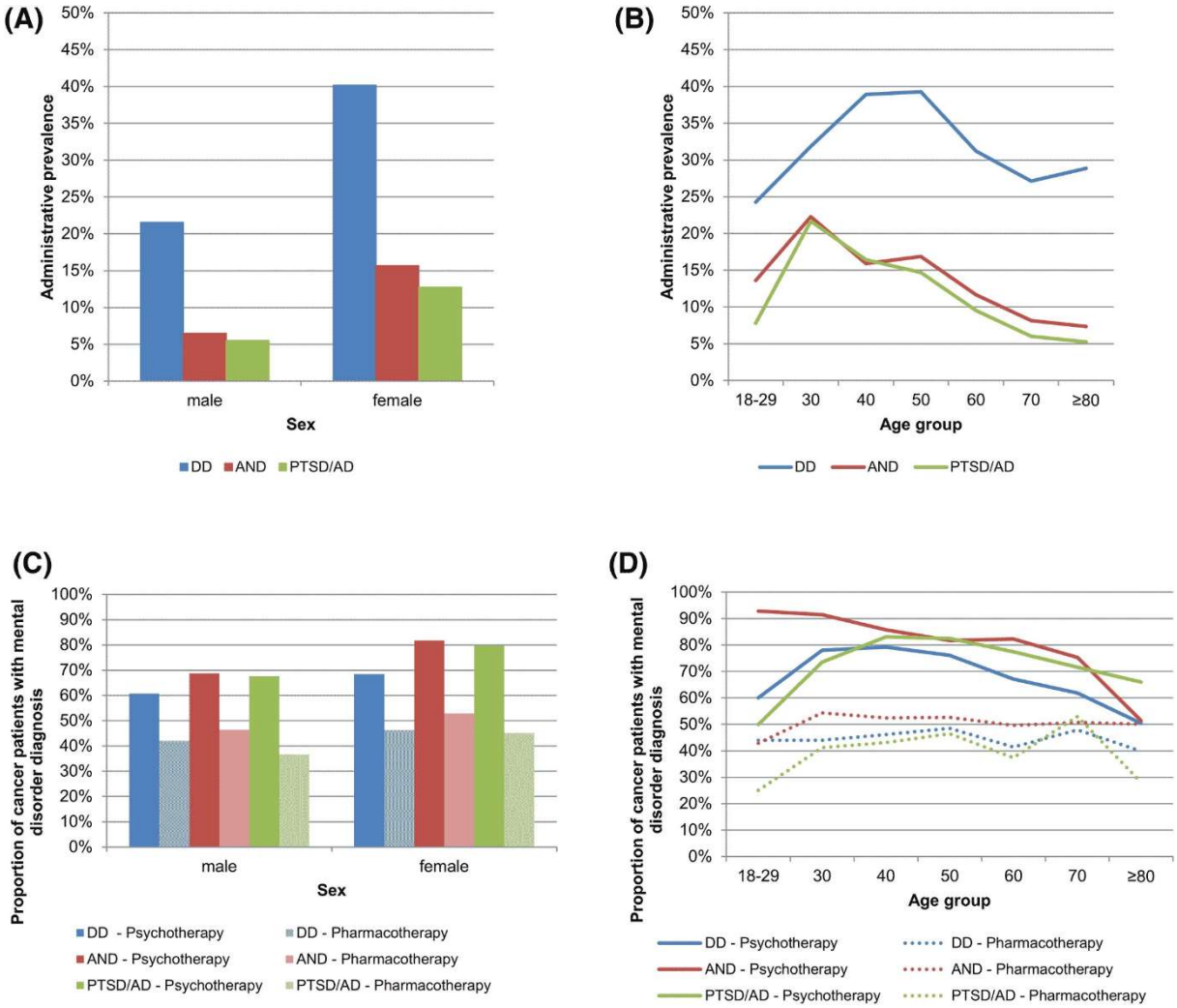
Utilization of mental health services

The utilization rate was 65.86% for psychotherapy and 42.99% for pharmacotherapy. In total, 79.92% received outpatient psychotherapy and/or pharmacotherapy within the period of the quarter of incident cancer diagnosis and three subsequent quarters. Differentiated by diagnosis, the rate was 80.26% for patients diagnosed with DD, 88.18% for those with AND, and 84.22% for those with PTSD/AD.

Female cancer patients were more likely to utilize MHS across all MD diagnoses and therapy forms than male patients (Figure 2C). Looking at the utilization of MHS according to age groups and tumor entities, a largely heterogeneous picture emerges across all forms of therapy and diagnoses considered (Figure 2D and Table 1).

Psychotherapy utilization rates are higher in patients without a previous MD diagnosis compared to patients with a previous MD diagnosis (Table S1).

Figure 2. (A) Administrative prevalence of DD, AND and PTSD/AD in newly diagnosed cancer patients according to sex and (B) age group. (C) Proportion of newly diagnosed cancer patients with DD, AND and PTSD/AD receiving psychotherapy and pharmacotherapy according to sex and (D) age group



Abbreviations: AND, anxiety disorder; DD, depressive disorder; PTSD/AD, post-traumatic stress disorder/adjustment disorder

Table 1. Administrative prevalence and mental health services utilization rates according to different tumor entities

		Administrative prevalence			Psychotherapy			Pharmacotherapy		
		DD	AND	PTSD /AD	DD	AND	PTSD /AD	DD	AND	PTSD /AD
Tumor entity	**n**	**%**	**%**	**%**	**%**	**%**	**%**	**%**	**%**	**%**
Head and neck	278	32.01	9.35	7.91	56.18	73.08	77.27	48.31	61.54	54.55
Esophagus/ stomach	185	23.24	7.03	7.03	65.12	84.62	84.62	39.53	61.54	23.08
Colon/rectum	660	25.76	9.09	7.42	55.29	70.00	73.47	43.53	60.00	44.90
Liver	43	23.26	4.65	6.98	80.00	50.00	100.0 0	50.00	50.00	66.67
Pancreas	80	20.00	7.50	5.00	81.25	83.33	75.00	68.75	50.00	25.00
Lung	307	26.71	7.49	7.49	56.10	82.61	65.22	45.12	56.52	47.83
Malignant melanoma	501	38.92	12.57	9.98	64.10	74.60	60.00	49.23	50.79	42.00
Breast	775	39.74	18.45	16.90	77.92	86.71	89.31	40.26	44.06	40.46
Female genital organs	423	37.59	17.49	14.89	77.99	89.19	77.78	42.77	45.95	38.10
Prostate	706	19.97	5.52	4.39	58.87	66.67	80.65	40.43	41.03	35.48
Kidney/ urinary tract	217	35.48	9.68	10.14	59.74	66.67	77.27	44.16	52.38	36.36
Bladder	341	22.87	7.92	5.87	66.67	77.78	60.00	43.59	44.44	50.00
Hematologic malignancies	441	29.02	10.43	7.48	68.75	78.26	63.64	49.22	60.87	42.42
Other	933	33.23	11.68	8.57	60.97	70.64	72.50	46.13	55.96	48.75
All entities		31.12	11.19	9.23	65.86	78.04	76.23	44.84	51.01	42.62

Abbreviations: DD, Depressive disorder; AND, Anxiety Disorder; PTSD/AD, Post-traumatic stress disorder/Adjustment disorder.

Regression analyses

The logistic regression analyses were intended to identify predictors for the incident diagnosis of MD and the use of corresponding health services. The multivariable regression analysis of the variables sex, age group, and tumor entity (sex-specific entities excluded) as predictors for the occurrence of an incident diagnosis following cancer showed that male cancer patients were less likely to receive an MD diagnosis than female patients (OR 0.53, 95% CI 0.44–0.65). In the analysis stratified by sex, neither age group nor tumor entity was found to be a significant predictor in the male subsample. In female cancer patients, the chance of receiving an MD diagnosis was significantly higher in patients with breast cancer (OR 2.32, 95% CI 1.59–3.46) and with cancer of the kidney/urinary tract (OR 2.20; 95% CI 1.17–4.09) compared to female patients with colorectal cancer (Table 2). These sex- and tumor-specific results could no longer be found in terms of utilization (Table 2).

Table 2. Results of binomial logistic regression analyses

Model	Incident diagnosis of MD			Utilization
	Model without sex-specific tumor entities (n = 2,546)	Model for male subsample (n = 2,065)	Model for female subsample (n = 1,747)	Model without sex-specific tumor entities (n = 456)
Predictors	**OR (95%-CI)**	**OR (95%-CI)**	**OR (95%-CI)**	**OR (95%-CI)**
Sex		[a]	[a]	
male	0.53 (0.44-0.65)***	-	-	0.89 (0.58-1.38)
female[b]	-	-	-	-
Age group (years)				
18-29[b]	-	-	-	-
30-39	1.29 (0.53-3.24)	0.33 (0.04-1.86)	1.75 (0.84-3.75)	1.69 (0.25-11.70)
40-49	1.74 (0.84-3.91)	1.71 (0.59-6.28)	1.44 (0.77-2.80)	3.24 (0.57-16.04)
50-59	2.06 (1.03-4.49)	1.58 (0.57-5.63)	1.52 (0.83-2.89)	1.19 (0.24-4.69)
60-69	1.25 (0.63-2.71)	0.85 (0.31-3.01)	1.14 (0.63-2.14)	1.69 (0.34-6.73)
70-79	0.93 (0.47-2.01)	0.71 (0.26-2.49)	0.74 (0.41-1.39)	1.74 (0.35-6.86)
≥ 80	1.00 (0.50-2.18)	0.71 (0.25-2.55)	0.72 (0.39-1.37)	2.11 (0.41-8.81)
Tumor entity				
Head and neck	1.04 (0.66-1.62)	0.87 (0.46-1.60)	1.24 (0.63-2.37)	1.34 (0.49-4.09)
Esophagus/stomach	0.99 (0.58-1.62)	0.83 (0.40-1.62)	1.21 (0.54-2.53)	0.72 (0.25-2.26)
Colon/rectum[b]	-	-	-	-
Liver	1.33 (0.47-3.22)	1.75 (0.48-5.53)	0.85 (0.12-3.60)	1.29 (0.19-25.80)
Pancreas	0.43 (0.15-1.02)	0.40 (0.06-1.40)	0.46 (0.11-1.41)	0.99 (0.13-20.22)
Lung	1.26 (0.83-1.89)	1.47 (0.87-2.49)	0.91 (0.46-1.76)	0.96 (0.40-2.42)
Malignant melanoma	1.30 (0.90-1.88)	1.37 (0.80-2.34)	1.21 (0.73-2.00)	1.33 (0.57-3.21)
Breast	[c]	[c]	2.32 (1.59-3.46)***	[c]
Female genital organs	[c]	[c]	1.50 (0.98-2.32)	[c]
Prostate	[c]	1.01 (0.67-1.55)	[c]	[c]
Kidney/urinary tract	1.54 (0.98-2.40)	1.06 (0.52-2.05)	2.20 (1.17-4.09)*	1.05 (0.40-3.00)
Bladder	1.07 (0.70-1.62)	0.84 (0.47-1.46)	1.69 (0.88-3.19)	0.96 (0.39-2.49)
Hematologic malignancies	0.83 (0.55-1.23)	0.70 (0.38-1.24)	0.92 (0.52-1.59)	0.94 (0.39-2.36)
Other	1.24 (0.91-1.71)	1.41 (0.91-2.19)	1.04 (0.67-1.64)	0.90 (0.44-1.77)

[a]Variable not included in the model as it was used for stratification.

[b]Reference category.

[c]Tumor entity was not considered in the model as it is sex-specific.

*p > .05; **p > .01; ***p > .001

Discussion

Clinical implications

Until now, results for MD prevalence and the utilization of MHS in cancer patients have mainly been available from clinical and survey studies. The purpose of this study was to analyze these outcomes for newly diagnosed cancer patients using health insurance claims data considering routine care.

Comparing the administrative 12-month prevalences with the 12-month prevalences estimated through meta-analysis by Mitchell et al. [3], a higher prevalence was observed for DD (31.1% vs. 20.7%), a similarly high prevalence for AND (11.2% vs. 10.3%), and a lower prevalence for PTSD/AD (9.2% vs. 19.4%). Regarding the data from a German multicenter epidemiological study [9], the difference in prevalences of DD is even higher (31.1% vs. 12.5%). The comparability concerning AND and PTSD/AD is limited as Kuhnt et al. [9] included PTSD in AND. Thus, there is a difference between the documentation in routine care and the recording of MD in clinical interview studies where the diagnosticians are specially trained for standardization. However, the question arises as to why the prevalence of DD and PTSD/AD differs between studies. The differential diagnosis of AD is seen quite critically [25, 26] and depends on the diagnostic competence of the service provider (see limitations section). For example, while AD is a common diagnosis in psycho-oncological care, it is less frequent in general practice [27]. Mehnert et al. [10] addressed this diagnostic challenge by adding DSM-IV-based questions to the structured clinical interview for AD. Such adaptations are beyond the scope of claims data.

Both the analysis of the 12-month prevalence across the factors sex, age group and tumor entity and the regression analysis for the subgroup of newly diagnosed cancer patients with incident MD have shown that MD is documented more frequently for female cancer patients. This is consistent with the results of previous studies [8, 9] indicating that female cancer patients have a significantly higher risk for MD. Sex-stratified regression analysis supports the results by revealing tumor entity as a significant predictor for a documented MD diagnosis only in the female subsample. That the chance was notably higher in female patients with cancer of the breast and kidney/urinary tract could be an indication for the mutual reinforcement of the two conditions (1) that physicians who deal with sex-specific diseases, respectively sex-differences in diseases tend to pay more attention to the mental health of female cancer patients and (2) that women are more willing to talk about their mental state compared to men [28].

Despite documented MD, not all newly diagnosed cancer patients with an MD diagnosis have utilized MHS. Comparing the observed value of almost 80.0% with the results of patient surveys [11, 12], cancer patients with a diagnosed mental comorbidity rarely report having received MHS (43.6% and 44.8%, respectively). In the MD diagnoses considered, there was hardly any

difference in the utilization rates which suggests a similar level of care provision. Regarding the utilization rates according to the factors sex, age group and tumor entity, the results did not show a consistent picture. The literature also shows contradictory results on the predictors of the use of MHS by cancer patients [11, 12], especially between different health care systems [13]. When considering the two treatment forms, a higher utilization rate for psychotherapy than pharmacotherapy was found across all MD diagnoses, sexes, age groups, and tumor entities. Freytag et al. [29] reported similar results on nationwide AOK data for persons with an incidence of depression. The fact that newly diagnosed cancer patients with incident MD diagnosis use psychotherapy more frequently than pharmacotherapy compared to those who had already been diagnosed with MD prior to a cancer diagnosis can be reconciled with the German guideline on psycho-oncological care, in which pharmacotherapy is seen as a complementary procedure to psychotherapeutic and psychosocial interventions in psycho-oncology [30].

Study limitations

The analysis was based on data from a single German region and one statutory health insurance and no private insurance, which limits the generalizability of our results. It relied on ICD-10 codes for billing purposes in the health insurance system, which could not be externally validated. The correctness of the diagnoses depends on how accurate they are documented wherefore internal validation strategies have been applied. Prevalence and incidence are dependent on utilization and documentation and therefore are characterized as “administrative” in contrast to other methods of assessment. The validity of the diagnoses also depends on the diagnostic competence of the service providers, but can only be analyzed for outpatient services using claims data. Primarily general practitioners documented MD (Table S3). However, it remains unclear whether this actually indicates less valid diagnoses, as a diagnosis has to be given to bill a service, or noncomprehensive care from specialists.

This analysis only included newly diagnosed cancer patients who were fully observable within the quarter of incident cancer diagnosis and three subsequent quarters, that is, who did not die during this period. Thus, no statements can be made about the psycho-oncological care of cancer patients who died within the first year after diagnosis. As the data were only available on a quarterly basis, it cannot be said for MD diagnoses in the quarter of cancer incidence whether they were actually given after the cancer diagnosis. By defining that an MD diagnosis has to be documented at least once within the incidence quarter of cancer diagnosis or in the three subsequent quarters, could lead to overestimation of prevalence rates and does not follow the M2Q criterion (see methods section). However, acute stress reactions would have been excluded by the M2Q criterion. A potential bias could also be present by limiting the analysis to the three most frequent MD. This may underestimate the occurrence of MD in cancer patients.

Furthermore, the analyses were restricted to outpatient psychotherapeutic and psychopharmacological drug prescription. Inpatient psychosocial and psychosomatic services are only indirectly reflected in the payment system. In addition, MHS services of psychiatric institutional outpatient units, outpatient cancer counselling centers and rehabilitation hospitals are beyond the scope of the data source used. Claims data give insight into only a very limited aspect of psycho-oncological care, thus not capturing all cancer patients' psychosocial needs [31].

Concurrently, claims data studies have the advantage that the data originate from routine care and thus enables an approach to the care process. Comparing the survey results of Faller et al. [11], the self-reported utilization rates are considerably lower than the administrative rates, which could be due to the risk of recall bias and can be avoided by the use of claims data. Though the data from a regional statutory health insurance were used, a sex, age, and entity distribution similar to that of representative, standardized analyses [32] was found for the observed sample. Thus, the applicability of the results to the population of newly diagnosed cancer patients can be assumed.

Conclusion

While the results of the regression analyses on possible predictors of MD diagnosis and the use of MHS confirm previous studies, there are clear differences between the 12-month administrative prevalence of DD and PTSD/AD and the utilization rates of psycho- and pharmacotherapy compared to primary studies. This can, to some extent, be explained by selection bias in surveys [33]. Not all patients with a documented MD diagnosis utilize mental health service, thus, a comprehensive psycho-oncological care provision does not appear to be ensured.

It should be avoided, as demanded by Casey and Bailey [25], to psychopathologize distress following cancer even if the care system requires a diagnosis for billing services. At this point, the importance of understanding psychological distress as a continuum [34] and integrated, need-driven psycho-oncological care becomes apparent, which requires the patient's perspective.

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Conflict of interest

The authors have no competing interest to declare.

Author contributions

Sandra Salm designed and performed the analyses and drafted the manuscript. Nadine Scholten supported the conceptualization of the study and the definition of the concrete analyses' contents. The process was accompanied by Peter Ihle, Ingrid Schubert, Antje Dresen, and Holger Pfaff. Peter Ihle and Katja Blaschke provided technic and scientific support for the analyses. The final manuscript has been critically revised and approved by all authors.

Data availability statement

Research data are not shared.

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Supporting information

Supplementary material 1

Methods (Supplement)

The AOK Hesse

The AOK Hesse is German regional statutory health insurance in the Federal State of Hesse. Altogether, there are 11 AOK in Germany. In 2014, the AOK Hesse had approximately 1,520,000 insurees [1] which is a quarter of the Hessian population in 2014 [2]. (There were 132 different health insurances in Germany in 2014 [3].)

Comparing the sociodemographic characteristics of all AOK members in Germany with the total population, less women are insured in an AOK and the ratio of unemployed to employed persons is higher [4].

The Statutory Health Insurance (SHI) Sample AOK Hesse/KV Hesse

Within the scope of a methodical research project, the PMV forschungsgruppe developed a concept for a person-related longitudinal database from health insurance claims data considering technical and organizational aspects. At the same time, it was agreed with the KV Hesse, the AOK Hesse, and the Hessian Ministry for Social Affairs to build up a sample of insured persons on the basis of the concept in order to answer research questions, e.g. from health care research and epidemiology. The database was developed in compliance with the legislation on data protection and the social laws on statutory health insurance in Germany.

In order to address data economy a sample of the members of the AOK Hessen was drawn. The necessary sample size was derived from a concrete research project (epidemiology and health care in diabetes mellitus), so that the database is a random sample of 18.75%, called 'Statutory Health Insurance (SHI) Sample AOK Hesse/KV Hesse' [5].

To assess whether the SHI Sample is suitable for research questions on cancer care, incident cancer cases of the years 2011, 2012 and 2013 were estimated (0.66%, 0.62%, and 0.60%) and compared with data of German nationwide cancer registries (0.63%, 0.62%, 0.61%) [6] which are similar.

Availability of health insurance claims data

Without a database such as the SHI Sample, the use of claims data for research purposes requires a high organizational and technical effort. For example, the transfer of data from the health insurance company to the research institution must be approved by the responsible supervising authority. Since claims data are originally collected for administrative and not for research purposes, they have to be plausibility-checked and prepared for the analyses.

There are also time disadvantages when obtaining new claims data. The health insurance companies themselves have complete data of a year until the end of the following year.

Hence, when conceptualizing and establishing a health insurance claims database it is not unusual that there is a time span of three years between data delivery and the latest data provided. Due to the high effort of data linkages and plausibility checks, newer data is added at intervals of several years. For the SHI sample, this will probably be done next time in early 2021. So, for the analyses reported in this work, data from 2014 were the latest available.

These must therefore be evaluated as historical, subsequent analyses in the context of cross-sectoral psycho-oncological care with recently ordered claims data are planned.

Besides, at the time of the start of this study, with the SHI Sample a longitudinal, plausibility checked and prepared for analysis database was right off readily available.

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Supplementary material 2

Table S1. Administrative prevalence and mental health services utilization rates within 12 months after cancer incidence according to occurrence of a previous mental disorder (MD) and different MD

No previous MD (n = 3,814)						Previous MD (n = 1,475)					
DD		AND		PTSD/AD		DD		AND		PTSD/AD	
%	95%-CI	%	95%-CI	%	95%-CI	%	95%-CI	%	95%-CI	%	95%-CI
12-month administrative prevalence after cancer incidence											
13.95	12.88-15.09	5.69	5.00-6.47	5.58	4.90-6.36	75.53	73.27-77.65	25.42	23.27-27.71	18.64	16.74-20.71
Proportion with psychotherapeutic care											
73.12	69.19-76.72	86.18	80.91-90.18	79.81	73.89-84.68	62.39	59.50-65.19	73.33	68.63-77.56	73.45	67.93-78.33
Proportion with pharmacotherapeutic care											
36.09	32.12-40.26	40.55	34.24-47.20	31.46	25.59-37.98	49.01	46.09-51.95	57.07	52.01-61.98	51.27	45.39-57.12

Note: DD, Depressive disorder; AND, Anxiety Disorder; PTSD/AD, Post-traumatic stress disorder/Adjustment disorder.

Supplementary material 3

Table S2. Characteristics of total sample, of cancer patients without a previous mental disorder (MD) and with a previous MD

	Total		No previous MD		Previous MD	
Characteristic	***n***	**%**	***n***	**%**	***n***	**%**
Sex						
male	2,571	48.61	2,067	54.20	504	34.17
female	2,718	51.39	1,747	45.80	971	65.83
Age group (years)						
18-29	103	1.95	84	2.20	19	1.29
30-39	157	2.97	97	2.54	60	4.07
40-49	396	7.49	272	7.13	124	8.41
50-59	777	14.69	520	13.63	257	17.42
60-69	1,208	22.84	871	22.84	337	22.85
70-79	1,692	31.99	1,278	33.51	414	28.07
≥ 80	956	18.08	692	18.14	264	17.90
Tumour entity[a]						
Head and neck	278	5.26	193	5.06	85	5.76
Esophagus/stomach	185	3.50	148	3.88	37	2.51
Colon/rectum	660	12.48	503	13.19	157	10.64
Liver	43	0.81	30	0.79	13	0.88
Pancreas	80	1.51	60	1.57	20	1.35
Lung	307	5.80	230	6.03	77	5.22
Malignant melanoma	501	9.47	318	8.34	183	12.41
Breast	775	14.65	544	14.26	231	15.66
Female genital organs	423	8.00	292	7.66	131	8.88
Prostate	706	13.35	591	15.50	115	7.80
Kidney/urinary tract	217	4.10	156	4.09	61	4.14
Bladder	341	6.45	271	7.11	70	4.75
Hematologic malignancies	441	8.34	313	8.21	128	8.68
Other	933	17.64	634	16.62	299	20.27

Note: [a]Sum of percentages higher than 100 due to multiple incident tumour entities.

Supplementary material 4

Table S3. Outpatient mental health service utilization rates according to professional groups stratified by mental disorders

	DD (n = 1,084)	AND (n = 462)	PTSD/AD (n = 372)
Professional group[a]	%	%	%
General practitioner (family doctor)	48.89	34.85	40.32
Medical practitioner (family doctor)	2.77	3.25	2.96
Internist (family doctor)	8.49	5.41	6.18
Anesthesiology	0.55	0.43	0.00
Ophthalmology	0.37	0.00	0.00
Orthopedics	0.74	0.00	0.00
Surgery/rheumatology	0.37	0.00	0.27
Gynecology	12.92	24.68	26.88
Special obstetrics and perinatal medicine	0.00	0.00	0.54
Otorhinolaryngology	0.18	0.43	0.27
Venereal diseases and dermatology	0.28	0.22	0.81
Internist (specialist)	0.46	0.22	0.54
Hematology and oncology	0.09	0.22	1.08
Cardiology	0.09	0.22	0.00
Nephrology	0.09	0.00	0.00
Internal medicine/rheumatology	0.00	0.00	0.27
Neurology and psychiatry	10.70	6.49	6.45
Neurology	1.01	1.08	0.27
Psychiatry and psychotherapy	11.07	12.34	10.48
Psychosomatic medicine and psychotherapy	0.65	0.43	1.08
Psychotherapeutic physician	1.38	1.08	2.69
Urology	1.01	3.46	1.88
Psychological psychotherapist	3.69	2.38	8.87

Note: DD, Depressive disorder; AND, Anxiety Disorder; PTSD/AD, Post-traumatic stress disorder/Adjustment disorder.

[a]Sum of percentages higher than 100 due to service utilization of multiple professional groups.

Chapter 6

Dissertation Project 2

Published as:

Conducting a prospective evaluation of the development of a complex psycho-oncological care programme (isPO) in Germany

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Abstract

Background: Evaluating the development phase of a complex intervention programme can be challenging. A prospective evaluation approach is presented based on the example of the new complex psycho-oncological care programme isPO (integrated, cross-sectoral Psycho-Oncology). Prior to programme implementation, we examined (1) if isPO was developed as intended, and (2) if it was relevant and transferable into the newly developed psycho-oncological care networks in North-Rhine Westphalia, Germany. Further, we investigated which implementation facilitators and barriers were anticipated and which implementation strategies were planned by the programme designers (multidisciplinary professionals and cancer supporting organizations who developed the isPO programme components and the networks).

Methods: A mixed-methods approach was applied. Qualitative data were collected by quarterly progress reports, interviews and a focus group with the programme designers. Evaluation criteria for document analyses of the quarterly progress reports were developed and applied. Content analysis was applied for analysing interviews and focus group. Quantitative data were gained from evaluating the programme training for the isPO service providers by short written questionnaires that were analysed descriptively.

Results: An implementable prototype of the isPO programme has been developed within 15 months, however no piloting was conducted. The programme's complexity proved to be challenging with regard to coordination and communication of the numerous programme designers. This was intensified by existing interdependencies between the designers. Further, there was little communication and participation between the programme designers and the prospective users (patients and service providers). Due to these challenges, only context-unspecific implementation strategies were planned.

Conclusion: The required resources for developing a new complex care programme and the need of a mature implementation strategy should be sufficiently addressed. Programmes may benefit from prospective evaluation by gaining insightful knowledge concerning the programme's maturity and anticipating implementation facilitators and barriers. A mixed-methods evaluation design was crucial for achieving profound insight into the development process.

Trial registration: The study has been registered in the German Clinical Trials Register (No. DRKS0 00153 26) on 30.10.2018.

Background

Introduction

Cancer is a global health challenge. For the year 2020, 19.2 million new cases and 9.9 million cancer deaths have been reported [1]. A high level of psychological distress was found in over 50% of cancer patients across different tumour entities and at different stages in their trajectory [2]. Over one third of cancer patients show psychological distress considering self-reports within their visit of an oncology centre [3]. Further, psychological and social stress has a negative impact on the general wellbeing and recovery of cancer patients [4–6].

In addition, service providers such as psycho-oncologists, physicians and nurses emphasise the relevance of psycho-oncological care as an integral part of cancer care [7]. Cancer patients who experience less mental health problems are considered to be more compliant to medical cancer therapy [8], indicating that psycho-oncological care can indirectly positively impact the success of biomedical cancer therapy [9]. The management of psychosocial effects of cancer is regarded as a crucial part of comprehensive cancer care [10]. The German National Cancer Plan calls for "need-driven psycho-oncological support for all cancer patients" [11]. In 2014, a German guideline for psycho-oncological diagnosis, counselling, and treatment was published that provides recommendations and instructions for the care of adult cancer patients [12]. However, a nationwide comprehensive psycho-oncological care provision is still missing.

The psycho-oncological care provision gap in Germany should be diminished by developing, implementing, and evaluating a structured and need-driven psycho-oncological care programme.

We aim to outline the benefits of a prospective evaluation and to provide a useful methodological approach. We demonstrate this with the prospective evaluation of the development of the complex care programme isPO (integrated, cross-sectoral psycho-oncology), in order to stimulate the practical application.

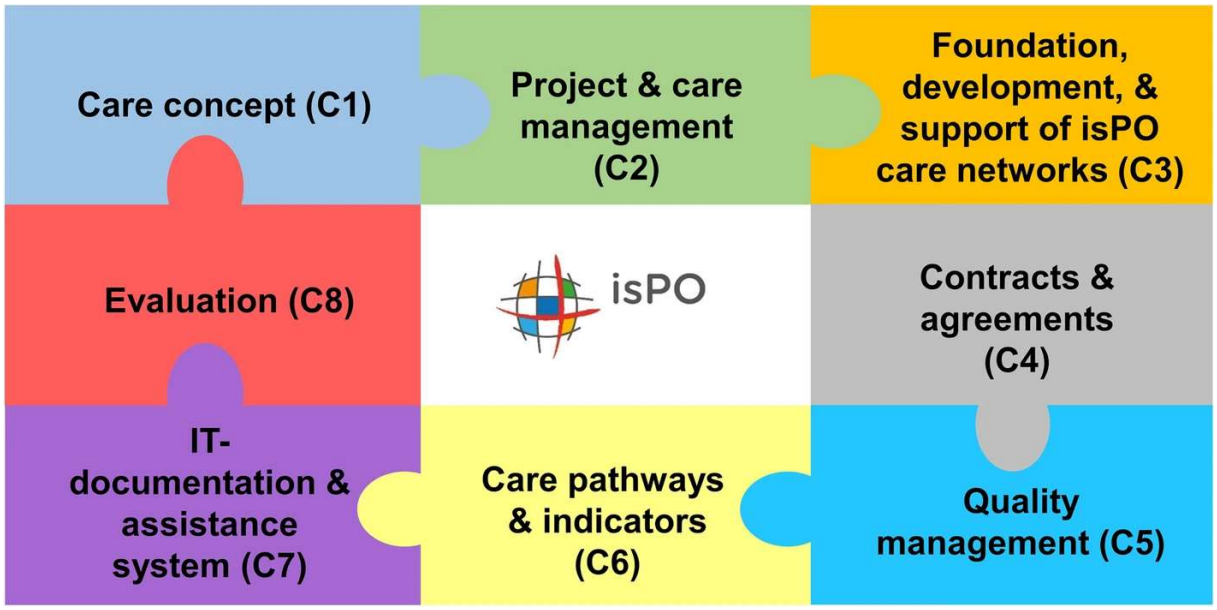
The integrated, cross-sectoral psycho-oncology (isPO) project

The German *integrated, cross-sectoral psycho-oncology (isPO) project* addresses the beforementioned international and national requirements, guidelines and goals [6, 11, 12] towards closing the care provision gap and integrating psycho-oncology into cancer routine care [13]. The aim of isPO is twofold: (1) reducing depression and anxiety in newly diagnosed cancer patients within 12 months after diagnosis, and (2) offering a psycho-oncological care programme for comprehensive implementation into nationwide cancer care. It consists of two parts: care programme and study. The Innovation Fund (IF) of the German Federal Joint Committee is financing isPO between 10/2017–03/2022.

Within the *isPO care programme*, newly diagnosed cancer patients can seek psycho-oncological care from the time of diagnosis until up to 12 months afterwards. On the basis of the patients' distress and individual needs, as assessed by different instruments (e.g. Hospital Anxiety and Depression Scale), personalized support is offered according to the stepped-care approach [14]. Psycho-oncological care is delivered parallel to the oncological treatment. The patients are supported by a multidisciplinary team, consisting of isPO case managers, isPO onco-guides (cancer survivors working as volunteers providing basic psychosocial information), psychosocial professionals (social workers responsible for psychosocial care), and psychotherapists. The specific care services and roles are described in detail elsewhere [15].

The isPO programme is a complex intervention [16]. It comprises of eight components (Figure 1) that needed to be developed, implemented and tested by different consortium partners during the project (see Additional file 1).

Figure 1. The eight components of the isPO care programme



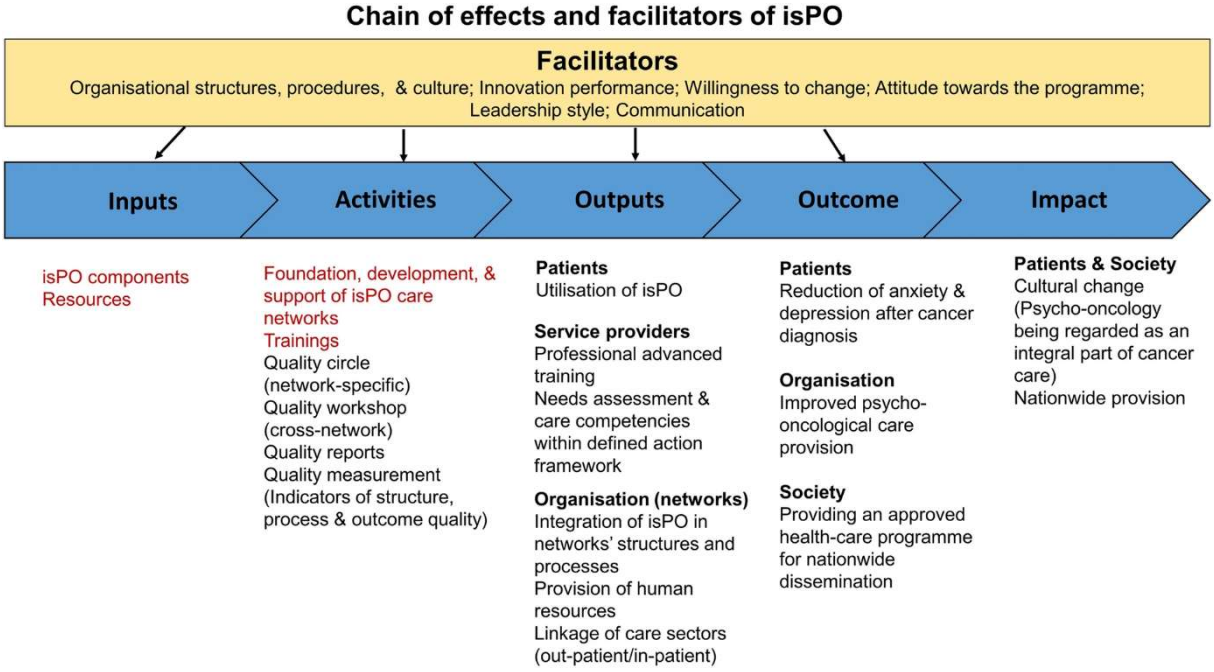
The programme was implemented in 2019 in four especially established cross-sectoral care networks in North Rhine-Westphalia, Germany. They respectively consist of at least one certified cancer centre hospital that cooperates with local oncological out-patient practices.

isPO is intended to be implemented into routine cancer care, if positively evaluated in the summative evaluation. Therefore, the isPO programme is accompanied by a *study*, enabling an internal and external evaluation of the programme as required by the funding organisation IF [17]. The external evaluation is conducted by the independent Institute of Medical Sociology, Health Services Research, and Rehabilitation Science, University of Cologne (IMVR). The IMVR team accompanies the entire project, but is not actively involved in the development, implementation or care provision of the programme. In order to optimise the programme,

evaluation results are continuously fed back to the project management team, who then decides if action needs to be initiated, and in some cases directly to the respective programme designers.

The content-related basis of the evaluation concept follows a logic model (Figure 2).

Figure 2. Chain of effects and facilitators of the isPO care programme. Adapted from [18] Anderson et al. (2011); [19] Damschroder et al. (2009)



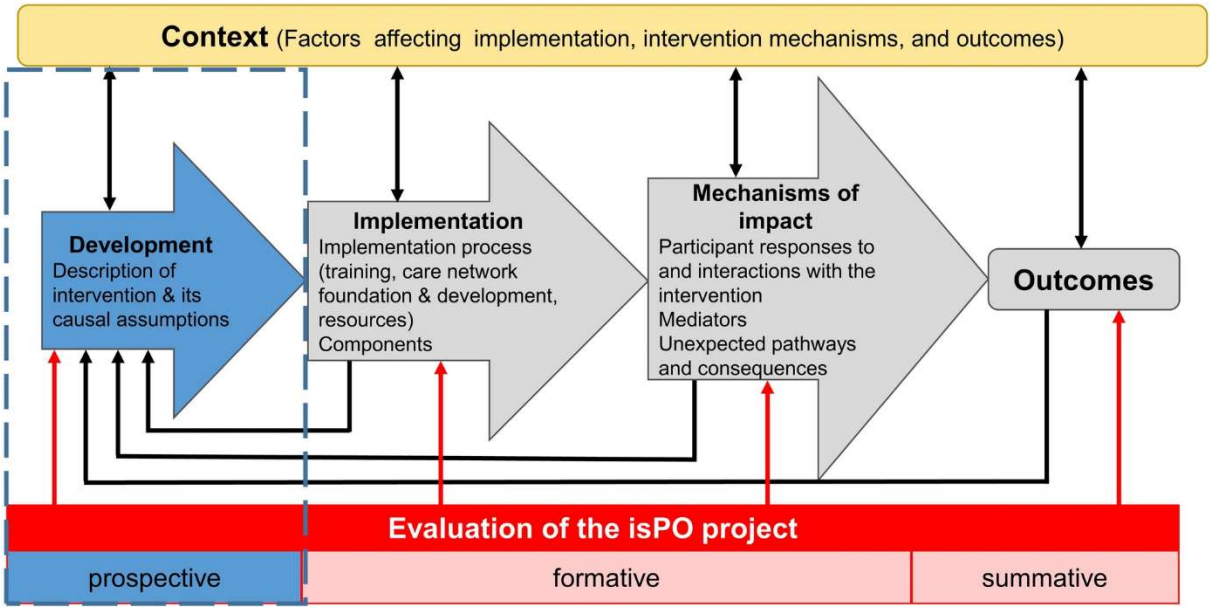
Aspects that were examined within the prospective evaluation are highlighted in red

The evaluation team conducts a tripartite process evaluation (Figure 3), based on the Medical Research Council (MRC) Framework for analysis and evaluation of complex interventions [20]. The constructs of the Consolidated Framework for Implementation Research (CFIR) [19] defines several facilitators (Figure 2, overarching part) for a successful implementation.

For the isPO-programme, the specific chain of effects is examined, especially its inputs (components), activities concerning programme implementation (e.g. care network foundation), and outputs at patient, service provider, and organisational level.

This article focuses on the prospective evaluation and its methodological approach. The entire study design for the evaluation of the isPO programme is described in detail elsewhere [13].

Figure 3. Tripartite process-oriented evaluation design of the isPO programme. Adapted from [20] Moore et al. (2015)



Objectives of the prospective evaluation

This article demonstrates the prospective evaluation of the isPO programme, also referred as developmental formative evaluation [21]. The aim of the prospective evaluation was to assess the relevance and transferability of the isPO programme prior to its implementation. With regard to the inputs and activities in Figure 2, the prospective evaluation is guided by the following research questions (RQ):

RQ1: Were all isPO programme components developed as intended according to the project proposal?

RQ2: How were the isPO care networks recruited and developed?

RQ3: How did the isPO programme designers experience their communication and cooperation within the project?

RQ4: Which implementation facilitators and barriers did the designers anticipate and what was their implementation strategy?

RQ5: Does the concept of the isPO programme appear to be consistent and useable?

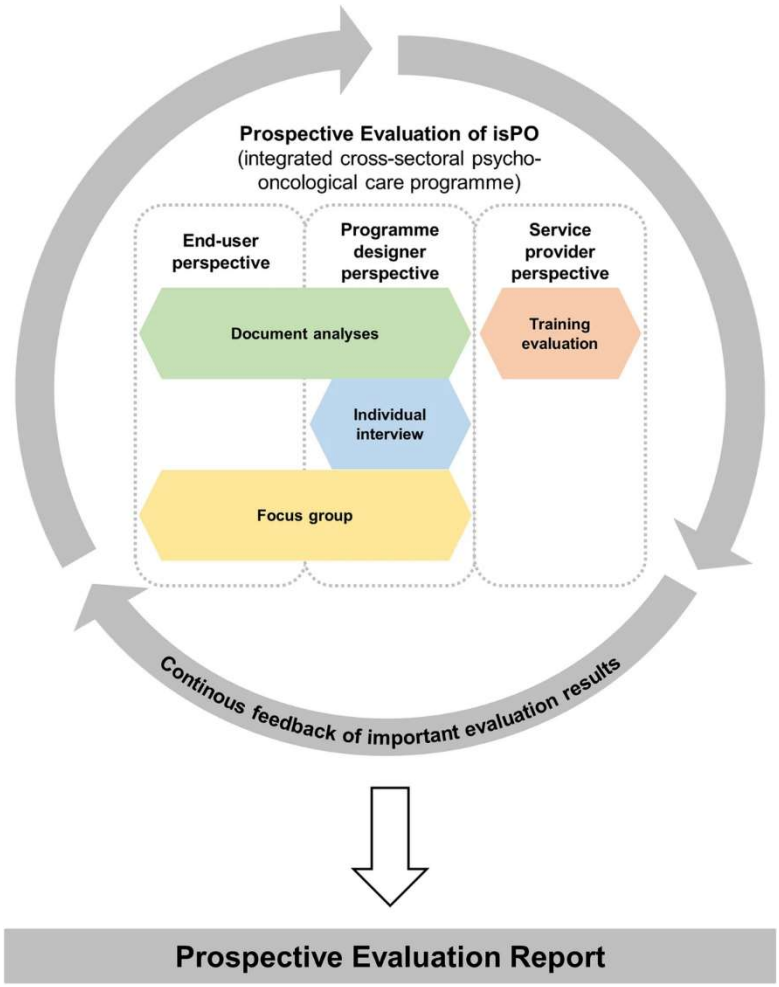
Methods

This prospective evaluation was conducted by a multidisciplinary evaluation team with expertise in Health Services Research, Public Health, Psychology, and Sociology.

To assess the relevance and transferability of the isPO programme before its implementation, all developed isPO components were examined.

A QUAL-quant mixed-methods design [22, 23] was chosen (Figure 4) in order to gain rich insight into the stakeholders' experiences as well as the development and working process itself.

Figure 4. The mixed-methods design of the isPO programme's prospective evaluation

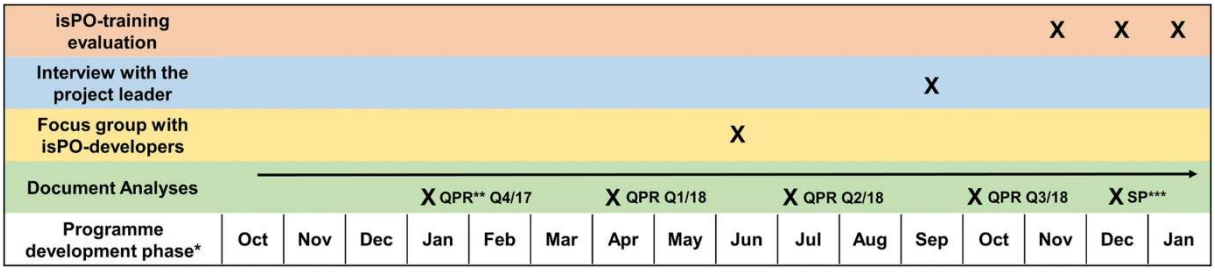


In order to assess the programme's development and its readiness for implementation, knowledge was gathered from three perspectives: (1) end-user (cancer patient), (2) service provider and (3) programme designer (Figure 4). The House of Cancer Patient Support Associations of Germany (HKSH-BV) represented an overarching patient perspective on the programme's development, as it is the German umbrella organisation for ten cancer self-help organisations with approx. 1,500 self-help groups and is familiar with consulting and supporting research projects in cancer care. Persons within the HKSH-BV and its ten affiliated organisations are typically cancer patients, survivors or caregivers who provide peer support or engage politically as patient representatives. Employees of the HKSH-BV with long-term experience in representing cancer patients consulted the isPO project. The representation was necessary as patients could not have any experiences with the programme at that phase of the project. This also applies to the service providers, which is why they were asked about their experience with the isPO-trainings that were conducted at the end of the development phase, just before implementation started. The majority of data on the programme's development process therefore originates from the programme designer's perspective.

Four different data collection methods were applied: (1) document analyses, (2) individual interviews, (3) focus group interview, and (4) training evaluations (Figure 4).

The focus on qualitative data collection allowed a more elaborate insight into the programme's development process and therefore it was helpful to gain comprehensive knowledge. However, quantitative data collection was used to evaluate the service providers experience in the pre-implementation isPO-training. The resulting mixed-methods design allows a multi-perspective and detailed data collection to answer the posed research questions [24]. Figure 5 shows the applied data collection methods in the programme development timeline.

Figure 5. Timeline of the used data collection methods in the prospective evaluation of isPO



Legend: *Programme development phase started in October 2017. Implementation and patient recruitment started in January 2019 in one isPO care network. The following months the other three care networks also started recruitment. **QPR Quarterly Progress Reports that are written by all programme developers. ***Statement paper of the House of Cancer Patient Support Associations of Germany

Document analyses

The document analyses' aim was to gain deeper insight into the programme designers' work and perspective within the project. We evaluated if: a) the isPO programme components (Figure 1) were developed as intended (RQ1), b) the programme is consistent and usable (RQ5), and c) how the isPO care-networks were recruited and developed (RQ2). For this purpose, it was necessary to analyse three different document types: 1) contracts (e.g. regulating the provision of the isPO care services in the care networks), 2) project-associated documents that help to understand the programme's development (e.g. SOPs for patient recruitment), and 3) quarterly progress reports of all programme designers.

To enable the intended realization of psycho-oncological care in the isPO care networks, it was necessary to establish a contractual framework. These contracts were evaluated by the evaluation team by: 1) comparing them with the project proposal, in which the legal parameters for the contractual framework of isPO were already strategically planned and set out, and 2) by assessing if the contracts allow a comprehensive dissemination of the isPO programme into the networks, but also potentially into nationwide routine care.

The evaluation team also assessed certain project-related documents that are relevant for a successful implementation or evaluation of the isPO programme, e.g. training documents or protocols of project meetings.

The consortium partners responsible for the development of the respective programme components were requested to report about their work progress on a regular basis, in so-called quarterly progress reports (QPR). A semi-structured QPR frame was set up by the evaluation team, allowing for consortium partners' adaptions to individual requirements.

Fifteen QPRs from six consortium partners were evaluated with a specially developed criteria catalogue (Table 1). The QPRs and their systematic evaluation helped to gather information on the isPO programme's development, progress and scientific foundation, as well as information concerning the designers' expectations and identification with their role in the development and implementation of the care programme.

Table 1. The isPO QPRs Evaluation Criteria Catalogue

Evaluation structure	Evaluation criteria	Explanations and in-depth evaluation criteria
General Information	Author	
	Structure	
	Orientation on deadlines	
	Orientation on the template	
	Annexes	
Theme-specific evaluation	Role in the project	Description of the task area
		Comparison with the project proposal
		Role in the project becomes apparent (consortium partner knows own role and can differentiate it from other roles)
		Application orientation / "view for practice" (definition and description of target groups; if known, it is described)
		Classification of the subtasks within the area of tasks
		Is the subtask visible as part of the task area (embedded vs. subtasks)
	Scientific / specialist background	Presentation and justification of the basic principles (if applicable: guidelines, standards, laws, theories, experience, etc.)
		Context of the tasks comprehensible
		Comparison with project proposal
	Goals	Project reference, embedding in the task area (if necessary, use table)
		Milestone vs. additional goals
		Definition of the goals: specific, measurable, achievable, realistic, terminated ('SMART' principle)
	Ways to achieve aims / measures	Explanation of content and transparent justification, comprehensible
		achievement of goals (can this measure achieve this goal?)
		Representations are intersubjectively comprehensible
		Type of measure (sub-measure)
	Results	Transparent presentation of the results (partial results)
		Were the (quarterly) goals achieved?
		How many goals are there with no result? Are there goals without a result?

Evaluation structure	Evaluation criteria	Explanations and in-depth evaluation criteria
		Existence of deviations
		Description of deviations
		Evaluation and handling of deviations for the achievement of individual goals and milestones
		Measures and solutions for the deviations
		Planned changes
		Description of the changes
		Evaluation and handling for the achievement of goals and milestones
		Measures and approaches regarding the changes
	Further procedure / future orientation	Description of the planned milestones and goals (and planned measures, if any)
		Comparison with project proposal
		Comprehensible justification for additional goals
	Focusing and prioritising of topics (qualitative)	Which topics are in focus (occur how often in the sense of unconscious prioritization)
	Cooperation with the consortium partners (dependencies etc.)	Scheduling / project meetings
	Implicit, conscious or unconscious communication content	Institutional traces (author / non-writer) / institutional exhibition (Goffman, 1972), Personal and institutional intentions in the presentation—documentary method
		If applicable, which topics are not mentioned (or not addressed actively)
	Contradictions	Text vs. traffic light (milestones vs. task description)
	Orientation towards guideline *S3 Psycho-oncology* (overarching embedding)	
Document comparison ("conversation between documents"; intra and inter)	Contradictions	
	Cooperation (mutual naming of the consortium partners)	
	Timeline: Course of a consortium partner (internal)	Comparison of the subtasks
		Do the tasks build on each other?
		Are the tasks embedded?
Conclusion	Concise assessment as a consequence of previous analyses	

The evaluation team compared the respective work results with the initial project proposal and prevailing healthcare guidelines and laws. Specific requirements were defined for each programme component by the project proposal. These should be met by the programme designers by the end of the development phase.

Additionally, a statement of the HKSH-BV was included in the prospective evaluation as an overarching patient perspective on the programme's development.

Interview with project leader

In order to gain the project management's perspective, an interview with the project leader was conducted by an evaluation team member at month 12 of the development phase (Figure 5). It aimed to supplement the respective QPRs, but also to gain more profound explanations on the isPO programme's conceptual framework.

Additionally, fundamental topics, such as the conceptual framework of the programme and its implementability, were addressed. The interview lasted two hours, was audio recorded, transcribed and thematically analysed [25]. The results were included in the evaluation of the QPRs.

Focus group and telephone interview

To gather the programme designers' and prospective end-users' perspectives, one focus group and telephone interview were conducted. The aim was to identify: a) possible implementation facilitators and barriers (RQ4), b) if the programme designers anticipated these factors (RQ4), c) if the programme designers established implementation strategies (RQ4) and d) how the programme designers experienced communication and cooperation within the isPO project (RQ3). Purposeful sampling was applied by inviting at least one person of each programme designer group involved in the programme design (sub-project leaders) [26]. In all, seven representatives participated in the focus group. The cancer patient perspective was represented by the participation of the HKSH-BV. Six programme designers, who were respectively responsible for developing a specific programme component, attended the focus group (one to two representatives per programme component, Figure 1). The representative of the IT-documentation and assistance system CAPSYS^{2020} was not able to attend, but was willing to participate in a telephone interview, post focus group.

The focus group interview was conducted nine months into the programme's development phase (Figure 5). The individual telephone interview followed shortly after.

The focus group was conducted in the premises of the IMVR by two evaluation team members (one main moderator and one co-moderator). Both, the focus group and the telephone interview were conducted in a semi-structured form by using interview guidelines. After

conducting the focus group, the interview guideline was augmented with topics that arose during the group interview, which also allowed the interviewee of the phone interview to comment on it (Table 2). The focus group lasted 115 min and the telephone interview 16 min.

The focus group and the interview were audio recorded and transcribed. Content analysis was performed [27, 28], assisted by the MAXQDA software (version 12.0). The coding and analysing process was conducted by the same evaluation team members that collected the data. First, coding was conducted independently. Next, codes were discussed, the transcript recoded, discussed again until a consensus was reached and the final coding system was decided upon (see Additional file 2). Coding was at first based on the guideline leading questions (deductive), however, during viewing the transcript, codes were also derived inductively [27].

Table 2. Topics included in the interview guideline for the focus group and telephone interview

Topics in the focus group guideline
Cooperation between programme designers
Cooperation with and perception of the care networks
Implementability of the programme
Implementation strategies
Facilitating and hindering factors for programme implementation
Activities to achieve project goals
Programme's potential to be disseminated into national care structures
Topics additionally included in the telephone interview
Information flow within the project
Perception of service providers' acceptance towards the care programme during CAPSYS^{2020} training sessions

Quantitative evaluation of the isPO-training

To gain the perspective of the service providers before the programme's implementation, the isPO-training was evaluated using short written questionnaires (Figure 4). The service providers' training courses were conducted mostly as frontal lectures at the end of the development phase by the respective programme developers (Figure 5). First, all service providers received an overall introduction into the project that lasted approx. three hours, followed by three hours training regarding their specific role in the isPO service provision. Additionally, special training for the newly developed IT documentation and assistance system CAPSYS^{2020} were realized in face-to-face training and with the help of videos, which were uploaded on an e-learning platform. Lastly, as basis for their certification, special 5-h-training was conducted for the isPO onco-

guides, who are cancer survivors, and not professional service providers. Their training was conducted as lectures as well as role-playing exercises for conversation conduction.

The service providers attending the basic isPO-training (7 training sessions with 6 to 13 participants each), filled out an anonymous evaluation questionnaire with 13 to 15 items that was developed by the evaluation team. It was used for each training session and included questions about the comprehensible communication of the following summarized content: project structure, care concept, development and function of the care networks, respective care pathways within the care programme, quality management, patient recruitment, isPO onco-guide concept, and tasks within the personal role in the isPO programme. Furthermore, participants were asked to evaluate, if 1) all questions were clarified during the training, 2) the time frame was appropriate, 3) the trainee was competent and motivated, 4) the training was well organised and 5) they were satisfied with the training. Lastly, participants were asked to suggest improvements.

The evaluation questionnaire for the programme's IT system training also included system specific questions (see results). For all items, participants were able to rate their (dis-) agreement on a four-point Likert scale from 1 'not at all' to 4 'totally', with an additional 'don't know'-option. Descriptive analysis was conducted with SPSS 25 and respectively summarised. The results where then send to the respective training instructors to provide direct feedback.

Bundling of results in the evaluation report

By the end of the development phase, a prospective evaluation report was written up, including all results in detail (Figure 4). It aimed to illustrate and interlink the evaluation results from the three relevant perspectives (end-users, programme designers, and service providers) and to draw conclusions and lessons learned from the programme's development for the following implementation phase.

The report is similarly structured to a standard scientific manuscript, and differentiates between conclusion, lessons learned and recommendations. By this differentiation, we aimed especially for a content condensation and interpretation of the results that was relevant for further programme development and implementation, as well as the evaluation processes themselves. The report was forwarded to project leadership.

Results

The prospective evaluation results are presented at an end-user, programme designer and service provider level (Figure 4).

Document analyses and interview with the project leader (end-users' and programme designers' perspectives)

Patient perspective (end-user) on the isPO project, represented by the consortium partner HKSH-BV

The HKSH-BV emphasised the importance of psycho-oncology for the care of cancer patients resulting from cooperation between different professions. Three conditions in the isPO programme were very welcome: (1) former cancer patients are trained and included as volunteer isPO onco-guides and complement the professional isPO support team with the peer support, (2) the cancer self-help is represented contractually for the first time in Germany, and (3) the management of the isPO onco-guides' care provision is financially covered. In addition, there was a quality assurance for the care provision by isPO onco-guides through defined requirements for the certification as an isPO onco-guide. This includes a special training, a conflict of interest statement, and a commitment statement.

The overcoming of sector boundaries (in- and outpatient) is perceived as a fundamental, patient-relevant feature of the isPO programme. This ensures continuous psycho-oncological care, even in the case of a transferal from one sector to the other within medical cancer care (e.g. from in-patient to out-patient care). The clear definition of care pathways, with the deposit of necessary documents, is seen as an important measure for a high quality of care, which in turn is decisive for patient safety. Due to the development of a comprehensive care programme, the isPO programme is considered by the end-users (HKSH-BV) as sustainable.

The HKSH-BV reports that, in addition to the advisory function, other tasks were taken on during the project year. The consortium partner engaged in developing the isPO onco-guide concept, recruiting former cancer patients and training them as isPO onco-guides.

The cooperation with the other consortium partners is perceived as "close, fruitful and appreciative". The high level of commitment of all project members is valued.

Programme designer perspective on the isPO project

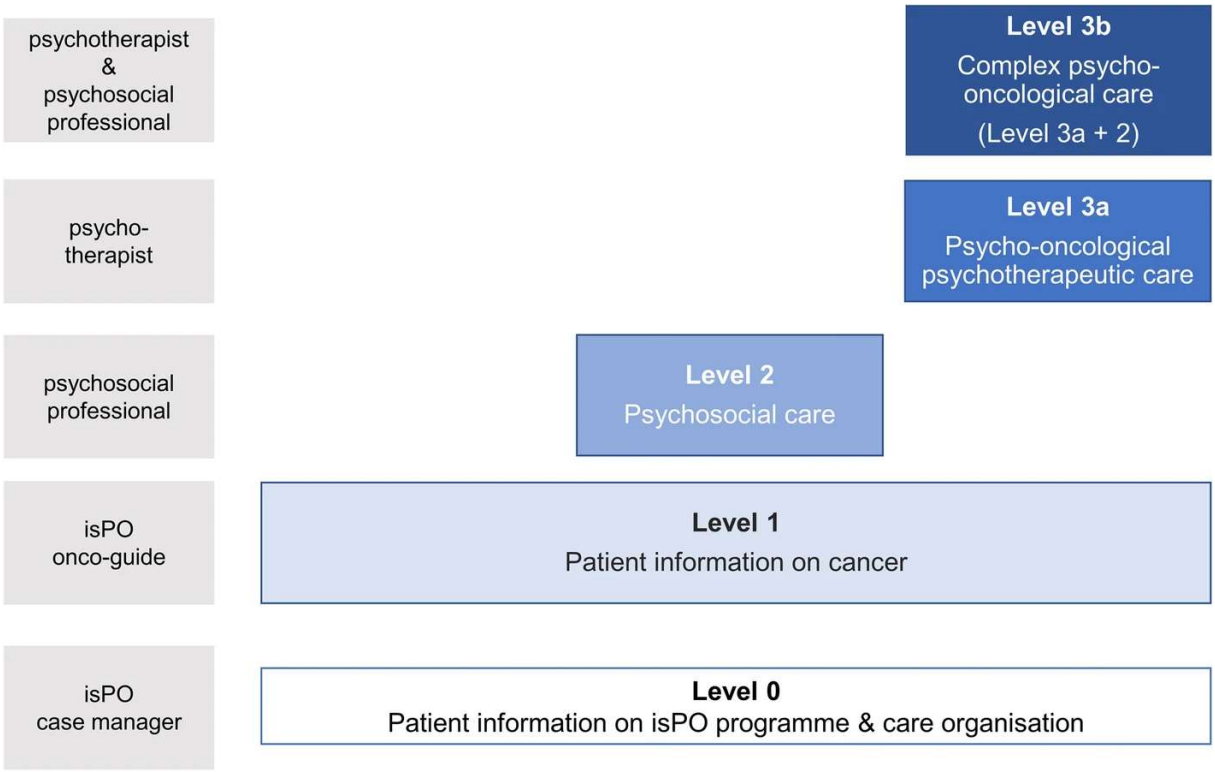
In order to summarise the programme's development process for each programme component, the actual working achievements are illustrated in comparison with the aims according to the project plan in additional file 3. Each objective is assigned to the corresponding working result and further activities beyond the project plan are displayed. Due to the programme's complexity and delays in the development process, creating the isPO prototype took 15 months (10/2017–01/2019).

Care concept (C1)

The scientific basis of the care concept was developed. Consequently, the isPO care provision can be offered according to patient's needs at different care levels (Figure 6; see detailed description of the care concept elsewhere [15]), to which different measures and service providers are assigned.

Due to the short timeframe for the programme development, interdependencies among the consortium partners, and partially insufficient communication, the complete care concept has not been written down comprehensively at the end of the development phase. This was postponed to the start of the implementation phase.

Figure 6. Care levels of the isPO programme and the service providers working at each level



Project & care management (C2)

A document control system was created and elucidated, as along with the necessary organisational structure for managing care in the care networks. Regular meetings with consortium partners and the steering committee were established.

Foundation and development of isPO care networks (C3)

In addition to the University Hospital Cologne, three more networks were recruited to cover a broad spectrum of different population and care structures. However, these various prerequisites lead to different states of network establishment at the end of the development phase. Based on the hospitals' scope of care and personnel resources, it was assumed that the planned

recruitment goals could be achieved whilst providing other patients with the hospitals' regular psycho-oncological care in parallel, albeit, with significantly increased effort. Altogether, the four care networks were developed within 16 months.

Contracts & agreements (C4)

All necessary contracts and agreements for care provision have been signed. The "isPO care contract" has achieved an innovation in the German healthcare system, especially with regard to the integration and financing of psychosocial care and organisation of self-help services (isPO onco-guide).

Quality management (C5)

A beta version of the project-related quality management manual was produced. Quarterly internal care network quality circles and cross-network quality workshops were planned, aiming to involve the care networks in the optimisation process (participatory quality development approach).

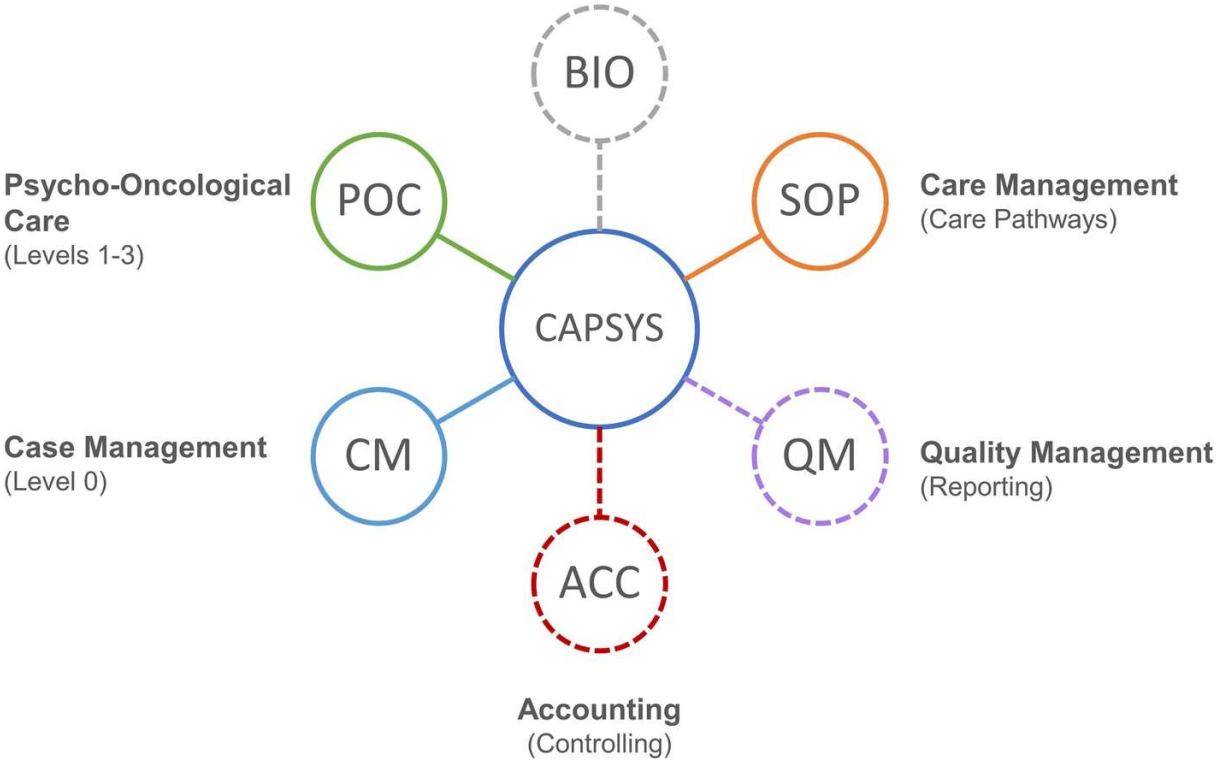
Care pathways & indicators (C6)

Basic SOPs for care levels 0 to 3a (Figure 6) and care pathways for care level 0 to 2 were modulated. The SOPs will be further elaborated, adjusted, if necessary, and finalised as part of a continuous improvement process during implementation in practice.

IT-documentation and assistance system (C7)

Due to interdependencies between consortium partners, some important goals were not achievable. The development of the three areas "accounting", "quality management" and "cancer registry data" (the latter being used for evaluation purposes) remained immature (Figure 7). Therefore, a paper-based documentation will be utilised during the initial transitional period in the implementation phase, and later transferred into the IT system.

Figure 7. Documentation and care management elements of the 'Computer-based Assistance System Psycho-Oncology' (CAPSYS[2020])



Functions that have not been finalised at the end of the development phase are presented in dashed

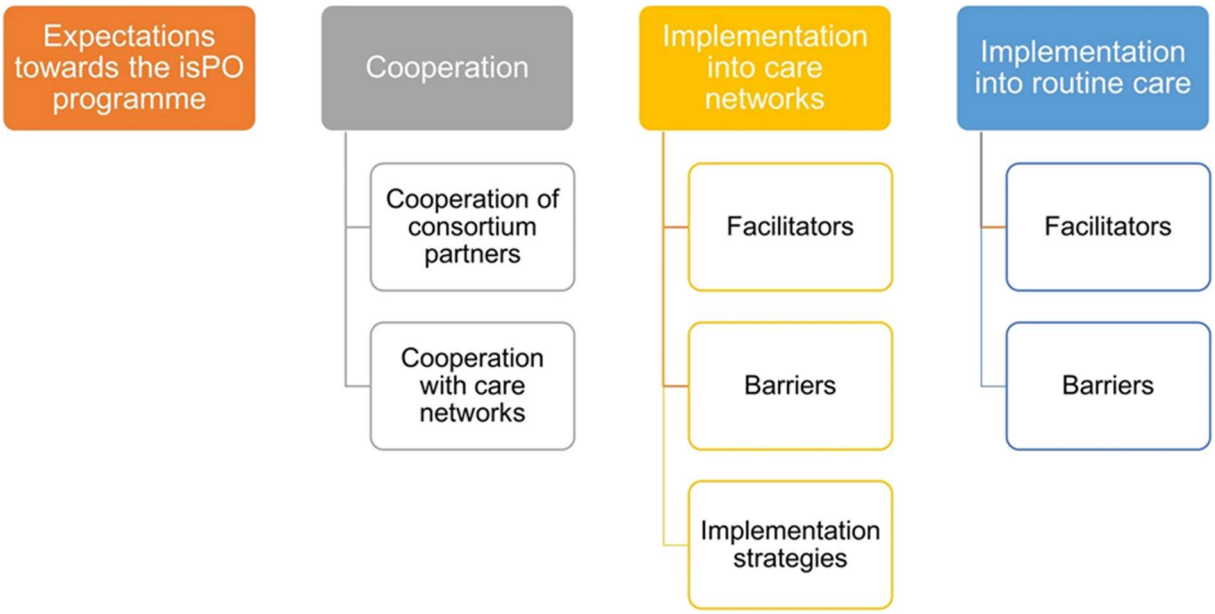
Evaluation (C8)

In order to enable a comprehensive study as well as external evaluation of the care programme an isPO data warehouse was set-up, and a comprehensive data protection concept was developed. Due to delay in the development of quality indicators (C6), the programming of the care statistics was not carried out in the development phase. To partially compensate this milestone deviation, extracts from the cooperation agreements were used to derive test quality indicators and thus build up the processes of statistical calculation and data preparation.

Focus group and telephone interview (end-users' and programme designers' perspectives)

The results are presented in accordance with the four core categories: expectations, cooperation, implementation into care networks, and implementation into routine care (Figure 8).

Figure 8. Overview of the developed core categories for coding the focus group and the telephone interview



Expectations towards the isPO programme

Both, the patients' representatives and the programme designers expect that isPO implementation will lead to evidence-based, structured, improved and effective psycho-oncological care. In addition, they expect that it will contribute to: (1) optimising the current psycho-oncological care structures, and (2) including psycho-oncology in the billing system and in the catalogue of services of the statutory health insurance. This goes hand in hand with the expectation that psycho-oncology will be strengthened in its position as an integral part of cancer therapy.

Cooperation of consortium partners

All participants described the cooperation amongst themselves as constructive, and communication at a personal level as good. The working groups involved in the isPO programme's conceptual design, in particular, were in close contact with each other.

All partners mutually appreciated the very high level of commitment of each partner. They described this fact as motivating for their own work. It reflects that everyone was aware of the importance and scope of this project. Despite the high level of commitment, concerns were expressed as to whether the project tasks could be completed within the timeframe. The workload was perceived as emerging and very high.

> *"... we are now facing the challenge, especially in the first year, of bringing up a complex programme in a very short time on many different levels and dimensions. And this with many instances or with many different partners."*

The timeframe was perceived as an obstacle, since several interdependencies between the consortium partners exist. For their own progress, they were reliant on information from and the results of the work of others.

The internal communication within the project was viewed critically by most partners. A lack of a "*superordinate unit*", distributing relevant information to all participants, was perceived. This was stressed especially by those partners who were not directly involved in the programme conception. They would like to see "*a denser flow of information*" and reported that they would receive completed project steps "*at best by chance*".

Cooperation with care networks

So far, the cooperation with the care networks was almost exclusively with the consortium partner responsible for the care networks' development. The other partners were not engaged with the care networks during the programme's development.

The care network developers described the cooperation as intensive. Regular monthly working meetings took place. In addition to providing information about the project and its implementation, there was a need to increase the intrinsic motivation of the care networks to get involved in the isPO programme. It was experienced that reservations and concerns (see subsection 'barriers to implementation into care networks') had to be dealt with. Therefore, information was passed on carefully and "*diplomatically*" in order to convey a realistic picture of the requirements, but not to trigger a feeling of being overwhelmed that might lead to resistance. All programme designers found it important to be open to criticism and the experiences of the care networks, as this will support the implementation in practice.

Facilitators of implementation into care networks

The programme designers perceived the acceptance and motivation of the care networks' service providers as crucial for the isPO programme's implementation. During the care networks' development process, a pronounced interest in the project and an increased level of motivation were noticeable. Nevertheless, it was found to be important to continuously promote the service provider's acceptance, as this might facilitate the implementation. This can be done by emphasising both the importance of the project, as well as the role and contribution of each individual in the care networks. Also, the importance of structuring and formalising the psycho-oncological documentation should be continuously communicated, especially to increase the acceptance of the new computer-based documentation and assistance system CAPSYS[2020].

> *"...if you provide regular and modern care today, then first of all you have to document this care properly and secondly, [...] including the healthcare system, that we also have to strengthen the process orientation in care ..."*

IsPO is perceived as a patient-oriented programme. Despite the fact that it is assigned to a specific care level, each screening should be used to check whether patients are receiving adequate care.

Considering the different structural situations before the implementation, for example personnel capacities, might be central for the implementation process. Existing care network structures with regard to diagnostics and documentation may facilitate its implementation.

The focus group participants hoped that the monetary incentives, given for care within the isPO programme, would offer a reimbursement for the additional efforts. IsPO enables the refinancing of psycho-oncological care services for the care networks for comprehensive psycho-oncological care.

Due to the participatory quality development approach, participants also perceived a high potential for the implementation phase. It was pointed out that both, the structures and the tasks of the different roles in the care network were clearly defined, which favours implementation.

Barriers to implementation into care networks

Low acceptance and motivation of the care networks have also been seen as a barrier to the implementation process, provoking a negative attitude towards isPO. Thus, resistance of service providers was perceived as possible, due to associated change processes in their respective work place. The project specifications could lead to restrictive feelings among the service providers with regard to previously established working processes (vs. new isPO processes) as well as therapeutic freedom in the form of a "*forced corset*".

The participants assumed that care networks might perceive isPO as a “threat” to their internal care structures, should the implementation of isPO replace these. However, such fears could be refuted at the level of therapeutic freedom, since isPO care is only intended to provide a "*framework*", within which the service providers can "*continue to choose the intervention themselves*".

It is important to consider the needs and experiences of the service providers so that they do not feel "*overwhelmed*". Another reason for resistance might be attributed to the study part of the project. Since certain procedures are linked to the fact that isPO is not only a new care form, but is accompanied by a study, service providers may feel restricted in their scope of action.

> *"...that you simply say that in this project it has to be constructed in a certain way, which we know does not correspond to real life in all places. So, to remove the fear, that this is how it should be done in the future."*

Service providers may see the fact that isPO requires new processes as an obstacle to patient-oriented work.

Moreover, it was stated that certain scenarios had not yet been conclusively clarified and that the care networks had, up until now, little detailed programme knowledge. This may lead to uncertainties in the care networks during implementation.

Reservations from the management (e.g. higher personnel costs) could influence the implementation process, acting as a barrier.

Implementation strategies

The training for all service providers and the availability of target group-specific manuals as a written form of the programme's concept were outlined as essential implementation strategies. It was important to create a balance between detailed description of the programme's content in the manuals and its scope, as not all care scenarios could be covered. Above all, the isPO manual and quality management manual are intended to provide guidance for work in isPO beyond the training. In addition, CAPSYS[2020] is supposed to guide the service providers through the process. During the discussion about implementation strategies, the participants focused on possible communication strategies and how to deal with care networks' resistance. They stated that a communication interface between programme designers and care networks was needed:

> *"...whatever that is, we need a feedback system."*

Collecting similar questions and distributing information to all networks might be solved by this platform. The designation of a contact person was considered useful to support and accompany the care networks in the "*first orientation phase*" of the implementation.

Implementation into routine care

Since the isPO project addresses a field of care that is currently insufficiently provided in Germany, its potential to be implemented in routine care was estimated as high. Furthermore, its unique design, which according to the stepped-care approach addresses patient needs, enforces this notion. The structured nature of the isPO programme was seen as a facilitating aspect for the implementation into routine care, as it

> *"...will generate significantly greater acceptance, also on the part of the medical professions, but also on the part of politics, and thus integration into the health insurance remuneration system, ..."*

It was considered to be of central importance to already become politically involved during the project period in order to promote nationwide adoption after project completion.

Moreover, it was perceived as necessary not only to prove the interventions' effectiveness (end-user level), but also to identify and consider as many implementation factors as possible (e.g. attitude of the service providers, acceptance of the patients towards the programme). A

high-quality evaluation could shorten the time required for assessment by key institutions and thus accelerate adoption, so that the care provision gap after project completion is kept short.

However, a potential conflict was perceived at the professional political level since psychotherapists' position will be strengthened by isPO, but relevant decision-making committees are more occupied by physicians. At the level of national psycho-oncological care structures, fears were expressed that bureaucratic processes would impede rapid adoption into routine care.

Regarding the programme's implementation into routine care, uncertainties were expressed, that there were currently no plans of the funding organisation (IF) on how to practically organise a comprehensive implementation of funded new care forms like isPO. This raised the question:

> *"... will the conditions be created to ensure that a new care form ... in Germany in the field of psycho- oncology ... will continue to be possible in the future..."*

Methodological aspects might also impede the nationwide adoption. If the isPO project had methodological weaknesses, for example due to the fact that the care programme was not carried out in accordance with the concept or lack of data and inadequate analyses, there is a risk of a negative evaluation outcome.

Evaluation of the isPO-training (service providers' perspective)

Introduction to isPO and role-specific training

Two types of training were offered to the service providers: (1) introduction to isPO and care levels 0 and 1, and (2) training courses on care levels 2 and 3.

The two training sessions on the "introduction to isPO" and the care levels 0 and 1 were evaluated by 21 participants (response rate: 87.5%). The evaluations of the items on the comprehensibility of the contents were predominantly positive (mean values between 2.89 and 3.59 of 4) (see Additional file 4). In particular, the basic structure of the project was conveyed in an understandable way. However, the case managers' area of responsibility with regard to onco-guide care was the least comprehensible. The items concerning the trainers and the training organisation were also rated highly positively, with the time taken and the clarification of open questions rated on average at 2.57 and 3.00 points, respectively.

The high complexity of the project was emphasised in the free text field of the questionnaire, and a resulting confusion and incomprehensibility of the training was described. It was noted that too much information was passed on to the participants in a too short time. Furthermore, the suggestion was made to focus the training more on practical information. Many questions had remained open.

The training courses on care levels 2 and 3 (n = 7; response rate: 53.8%) were predominantly rated "totally agreed" in the organisational aspects (see Additional file 5). The mean values for the training contents also range between 3.17 and 3.67 points. In particular, the contents regarding level 3 (psychotherapeutic psycho-oncological care) were assessed as being comprehensibly conveyed.

isPO onco-guide training

Nineteen participants (former cancer patients) of two different onco-guide training sessions contributed to the evaluation (response rate: 100%). All items on the training content had average values ≥ 3.5 (highest value on the scale: 4) (see Additional file 6). Participants of the first of the two sessions agreed strongly that the training on theoretical contents (onco-guide concept, isPO programme) was sufficient.

In the open question, it was suggested that role playing that was performed to train the conducting of conversation should be carried out with an observer or in front of the whole group. At the second training session conducted two weeks later, the participants gave a particularly positive assessment of the content relevant to practical work as an onco-guide. It was suggested that the training should include content on the tasks of the case manager, social services and the psychosocial specialist (as a differentiation from the onco-guide) as well as general information on "types of cancer". The organisation of the training was similarly positively evaluated. The corresponding items achieved a mean value of > 3.3.

CAPSYS²⁰²⁰ training

For the analysis of the CAPSYS²⁰²⁰ training evaluation the data of only one training session were available (n = 5, response rate: 83.3%), as the evaluation team was not informed about all planed and conducted course dates.

For all items, average values of > 3.0 (with a highest possible value of 4) were found (see Additional file 7). Six of the nine items were rated by all participants as "totally agree". These relate to the training contents according to the application of CAPSYS²⁰²⁰ as well as to the assessment of the trainers and the training organisation. In comparison, the item "All my questions were clarified in the training" has the lowest value of 3.40. In the open text field, it was noted that the training could have taken place at a slightly earlier point in time before implementation. A more precise time window was not specified.

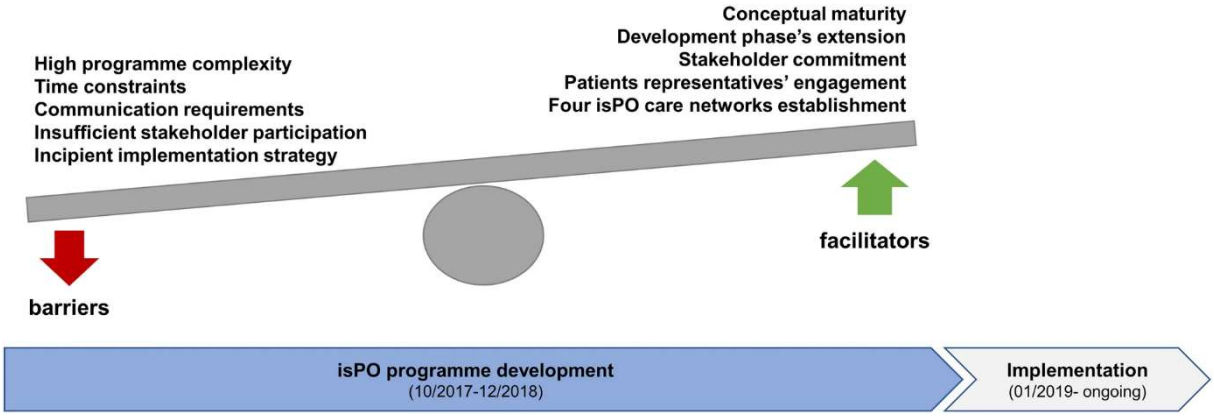
The results and findings of the prospective evaluation were fed back to the project leader and/or consortium partners, so that the isPO programme is continuously being optimised. Furthermore, a written report on the outcome of the prospective evaluation was submitted to

the project leader, so all results were available for programme and implementation optimisation (Figure 4).

Discussion

During the isPO programme's development phase, the evaluation team conducted a prospective evaluation with a QUAL-quant mixed-methods design. It assisted in gaining deep insight into the programme designers' developing and working processes (for a condensed presentation of the results see Figure 9) and the maturity of the programme.

Figure 9. Condensed mixed-methods results of isPO's prospective evaluation, representing end-users', programme designers' and service providers' perspectives



In this respect, the prospective evaluation research questions (see introduction) are answered in the following and implications for other projects are given.

Contextual challenges

Programme development

At the end of the first project year, the components of the isPO programme have reached a level of maturity that allows its implementation. However, its complete development could not be finished without three additional months (see results, chapter 'document analyses and interview with the project leader'). At this moment we were certain that the optimisation and finalisation of the components could take place in parallel to the implementation without impairment at the end-user or service provider level. Thus, the service providers' experiences with the new programme can directly support its further development and optimisation processes. The particularly innovative components include, for example, the comprehensive quality management that enables a quality-based implementation and optimisation as well as the IT system, which serves not only for documentation but also for care management.

Recruitment and development of the isPO care networks

The four care networks were recruited and developed as anticipated in the project plan. The selection of the cancer centres was guided by criteria instead of randomised cluster sampling [29]. The participating hospitals are structurally diverse in, for example, bed capacity and number of organ centres within the cancer centres. Due to the different structures, processes, and organisational cultures, the developmental states vary between the care networks.

The development of the care networks has been carried out through time-consuming meetings. However, it benefited from the participation of different stakeholders from psycho-oncological and medical care, quality management and IT, as well as out-patient oncological care providers [30].

In some care networks concerns were repeatedly expressed about insufficient voluntary participation of physicians in this process. That might be due to the fact that psycho-oncological care has low priority in their daily routine, and to frequent medical staff turnovers. The isPO project management and the network developers were informed of this and meetings with the responsible hospital managers and medical directors were scheduled again.

Communication and cooperation of the programme designers

All consortium partners mutually appreciate the high level of commitment with which the isPO project is being developed. However, the interdependencies of the individual and emerging task areas and strong time constraints were perceived as challenging.

The lack of cooperation between designers and service providers was regretted. The programme's contextual maturity would benefit from including expertise of real-world care practice, as it has also been experienced by other researchers [31–33].

The communication flow was found to be insufficient. However, in complex interventions, communication is central for the implementation's success and therefore must be also integrated in the implementation strategies [34]. In our case, the programme designers' suggestion to set up a superordinate communication body within the project management team is welcomed by the evaluation team, as an elaborated communication structure between project partners is crucial in a complex intervention project [35]. Even though tensions were not directly described, the limited time and human resources, the interdependencies and unclear lines of communication can be seen as risk factors. In addition, working with multidisciplinary partners requires mutual understanding [36]. In addition, all isPO consortium partners bring in their individual experience from previous projects and have partly already worked together, so that perhaps old conflicts are carried forward. This means that project management also needs to create mutual trust and offer opportunities for joint and co-creative learning and finding a collective language [37, 38]. The inclusion of the patient representatives' perspective on the

programme development (e.g. onco-guide conceptualisation) was beneficial, as therefore patients' voice (e.g. opinion and expectations) was integrated. Patient involvement in the development process has also been suggested by other researchers, e.g. O'Cathain et al. [32].

Implementation facilitators and barriers, and implementation strategy

A positive attitude of the service providers and the clear concept of the isPO programme were considered as the two most important implementation facilitators, which is in line with the framework of actions for intervention development [32].

The programme designers regarded the lack of valuing the attitude and motivation of the stakeholders as obstacles in the implementation of isPO. It is therefore remarkable that the programme designers did not enter into an exchange with the service providers during the development phase (see RQ 3). In order to increase programme comprehensibility, and therefore acceptance, it would have been beneficial to involve all stakeholders in designing and refining the programme [32].

It was not anticipated that the design of the isPO programme itself could contain barriers. This may explain why few concrete suggestions were discussed for implementation outside of the project plan, such as the establishment of a helpdesk.

It has become apparent that during development of the programme components it was not considered in detail how they should be implemented, and thus no elaborate and context-specific implementation strategy was available. However, implementation strategies, including communication and providing feedback, are important for complex intervention programmes [34].

Consistency and usability of the isPO care programme

The complexity of the isPO programme was repeatedly challenging due to the limited amount of time, unexpected additional work required, and the coordination of the programme designers' task areas and communication. The delayed completion of the programme's development had a negative impact on the service providers in that the training sessions took place later than intended. As a further consequence, the service providers criticised that the training content was presented in a very compressed form. A lack of in-depth knowledge of processes and the resulting difficult working conditions could reduce service providers' acceptance towards the new programme and make the implementation more difficult. Better articulation of the programme idea [32] may reduce resistance.

Even if the interdependencies were experienced as a challenge, it demonstrates that the isPO components were developed in the sense of a coherent complex programme [16].

The patients' representatives (HKSH-BV) also evaluated the isPO programme as sustainable, especially because of the stepped care approach [14], which pursues needs-based care and thus considers health economic requirements by preventing overprovision.

With regard to the characteristic 'integrated', isPO is particularly innovative, as it contains the integration of self-help and psychosocial care as fixed, contractually anchored, and financed care components, which currently are not part of the German Code of Social Law. In addition, the isPO programme, with its cross-sectoral approach, overcomes sector boundaries and hence facilitates the reduction of care interruptions and safeguards care quality [39].

Altogether, the prototype of a scientifically based care programme for the psycho-oncological care of newly diagnosed cancer patients was developed, which for the most part fulfils the requirements for successful implementation.

Implications for other projects

Conducting a prospective evaluation, i.e. identifying facilitators and barriers and assessing the suitability and the maturity of health programmes prior to their implementation, helps to avoid research waste [40] and harm through research and interventions [41]. This is possible by (1) increasing the maturity and comprehensibility of the programme, (2) ensuring its implementability in the health care system, and (3) gaining a sound understanding of each stakeholder's needs [42, 43]. Thus, a prospective evaluation offers the benefit of supporting a smooth implementation [42] so that patient recruitment is easier and that the intervention is delivered by the service providers as intended [44]. In this way, subsequent follow-up costs for optimisation measures can be saved and the effectiveness and quality of the health programme can be enhanced [45]. Thus, a prospective evaluation reduces uncertainty about a programme's degree of success for all stakeholders: implementers, evaluators, but also funders and patients.

Following the reported findings, a prospective evaluation can be recommended especially for complex interventions [20].

Methodological discussion

Conducting a process-oriented prospective evaluation

Prospectively evaluating a complex intervention programme was perceived as challenging. Because the respective care programme is a prototype that is not implemented, end-users or service providers cannot be asked about their experience with the new programme. Therefore, the prospective evaluation needs to be process-oriented, which is also emphasized in research regarding the development phase of complex interventions [46]. However, there are currently no exemplifying publications for comprehensive prospective evaluation concepts (before implementation).

Beside the fact that the funder required an external evaluation of the isPO-programme, investing in a comprehensive prospective evaluation was experienced as highly relevant by both the evaluation team itself and the programme designers. Before the implementation of the programme into practice possible facilitators and barriers were identified and a sound understanding of the programme's development from an external perspective was gained. Findings were actively fed back to the project leadership which might positively influence the implementation. Moreover, the prospective evaluation may support the entire evaluation process (e.g. exploring the outcome) of a complex intervention, as its structured, systematic approach offers an in-depth programme understanding (e.g. components, stakeholders, context) [21, 47]. However, due to the role of the external evaluator, and how it was set in the project plan, dissemination concerning the evaluation results by the evaluation team were mostly provided to the project leader who then decided if it should be forwarded to the other consortium partners. This top-down approach hinders or impedes communication and constructive feedback transmission (selection bias). Direct and independent feedback to those who are involved in the process may be even more effective for the programme development, as suggested by Moore et al. [20].

Limitation and strengths of applying a mixed-methods evaluation design

The evaluation team's findings show that applying a mixed-methods design seems to be crucial when aiming to evaluate a programme's development, as recommended by other researchers [21, 48]. In particular, by collecting different kinds of qualitative data it was possible to obtain rich records on different aspects of the development phase [49]. Hereby, qualitative data (focus group and telephone interview and document analyses of the QPRs) were the most valuable data sources for conducting the prospective evaluation.

The focus group assisted in identifying "blind spots", e.g. insufficient implementation strategies. Moreover, it allowed the evaluation team to interact with the programme developers, and therefore to gain a better impression of the cooperation and interpersonal aspects which are important factors in successfully developing and implementing a programme. Nevertheless, the focus group and telephone interview took place only once, so there is limited data on the course of the development. Therefore, a total of 15 QPRs were analysed.

This helped to systematically explore how the designers dealt with project and work plan deviations. However, the development of a QPR evaluation system turned out to be important (Table 1) in order to recognize critical aspects and to track the course of development. The criteria catalogue presented in this article may provide a good basis for other programme process-oriented evaluations, as it includes many criteria on work progress itself, and allows isPO-programme-specific criteria to be altered for respective usage. Additionally, the regular receipt

of the QPRs allows evaluators to be more "in the loop" and give systematic and timely feedback to the project leaders. However, the QPRs did not fully reflect the cooperation and communication between the project partners, which could be captured by the beforementioned interviews.

Gathering the patients' perspective in the prospective evaluation

The patient perspective was included in our prospective evaluation as proposed by different researchers [32, 47] by including participants of the HKSH-BV in the focus group. This was crucial for the prospective evaluation, as little attention was given to the patients' perspective during the isPO programme's development. Development was carried out top-down with a low degree of patient participation, as the HKSH-BV was limited to its advisory role.

Lessons learned

Resources

The estimate of a one-year timescale for the development of such a complex care programme as isPO proved to be too tight. Enabling and managing the communication between the numerous project stakeholders appeared to be challenging, thus, the development of a project communication strategy would have been vital [34, 35]. Moreover, the establishment of the legal and ethical framework within the development phase was challenging in terms of time and effort. This is because the structures of the isPO programme go beyond the current legal situation, and the EU General Data Protection Regulation came into force. It is important to consider a realistic timeframe for setting up a contractual and ethical framework, because the start of a programme's implementation is highly dependent on this.

Implementation strategy

A mature implementation strategy was not developed but would be highly beneficial [34]. Moreover, to develop a programme suitable for everyday care with regard to its feasibility and to tailor its implementation by considering the characteristics of the care organisations, two measures would have been helpful: (1) stakeholder analysis and (2) use of a participatory approach at selected points in the development phase [31, 50]. Simply transferring knowledge, as is the case with the conducted training sessions, appeared to be insufficient and needs to be augmented by on-the-job training in the care organisations [32]. Furthermore, if sufficient resources are available, the conduction of single or focus group interviews with (former) patients is recommendable to obtain information on key aspects that need to be considered in the development of a new intervention programme.

A process-oriented evaluation design

Complex interventions benefit from a process-oriented evaluation design that starts in the development phase. For a mature prospective evaluation concept with specifically defined outcomes, we found it helpful to orientate towards national requirements and make use of mixed-methods to obtain rich data and gain deep insight into the programme's development process. In addition to the QPRs, a focus group with representatives of all involved programme designers is especially recommendable in order to gain rich insight into attitudes, communication processes, and to identify blind spots, e.g. with regard to implementation strategies. Furthermore, the project leader has an extensive overarching understanding of the complex programme. Therefore, an interview with project leadership, which usually equals project management, allows deep insight into the programme concept beyond the project proposal.

Dissemination of evaluation results

In a complex intervention programme with a narrow time-frame it could be more manageable, helpful, and practice-oriented to give regular feedback to project leadership about important or urgent evaluation results. This helped project management in coordinating the programme's development and gave programme designers the opportunity to find solutions for their blind spots. Still, the prospective evaluation report (at the end of the programme's development phase) includes more detailed results and a thoroughly written up conclusion, lessons learned and recommendations which allow them to be put into context and enable further action, if necessary.

Conclusions

By the end of the development phase, the fundaments for the programme's implementation in practice for four German psycho-oncological isPO care networks had been laid.

As the development of a complex care programme is considered as crucial for a programme's implementation success, the programme development should not be underestimated in terms of resources, e.g. finances, and availability of sufficient and skilled personnel. Furthermore, a realistic timeframe is essential, as the coordination of and communication between the various consortium partners needs to be addressed. A complex programme invests in developing comprehensive project management and context-specific implementation strategies as well as participatory involvement of the service providers and patients to facilitate practice-oriented programme optimisations.

A systematic mixed-methods approach turned out to be fruitful in evaluating a complex care programme prospectively. During the development phase, besides producing a final prospective

evaluation report, proactively providing regular and critical feedback from the evaluation team is supporting the development process with regard to its implementation in practice.

The prospective evaluation should be given more importance in the research of healthcare programmes to prepare tailored implementations. In addition to the evaluation design, the prospective evaluation should also be considered in the publication plan, as this allows all evaluation phases to be retraced.

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Authors' contribution

SS and NC contributed towards the conceptualisation, the study design, data analysis and interpretation and writing the original draft. IJ was a project manager during the study and contributed to the conceptualisation, the study design, data analysis and interpretation. HP and NS were supervisors during the study and acquired the funding. AD contributed to the process of conceptualisation and study design and was a supervisor. TK contributed towards the conceptualisation, data visualisation and was a project manager. IJ, HP, NS, AD and TK reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to ethical and legal restrictions but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The ethics committee of the Medical Faculty of the University of Cologne has approved the isPO project and its study design (No. 18–092). Written informed consent was obtained from the participants. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

Prof. Dr. Holger Pfaff is an Editorial Board Member of BMC Health Services Research. The remaining authors declare no conflicts of interest.

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Supplementary information

Additional file 1

Table A.1. List of consortium partners conducting the isPO project

Abbreviation	isPO consortium partner
MED I	Department of Internal Medicine, Section: Clinical Psycho-Oncology, Working Group Psycho-Oncological Health Services Research, University Hospital of Cologne
KPP	Clinical Psychology and Psychotherapy, University of Cologne
IMSB	Institute of Medical Statistics and Computational Biology, University of Cologne
IGKE	Institute of Health Economics and Clinical Epidemiology, University of Cologne
MIFH	Department of Computer Science (Medical Informatics), University of Applied Sciences and Arts Dortmund
IMVR	Institute of Medical Sociology, Health Services Research and Rehabilitation Science, University of Cologne
KGNRW	Cancer Society North Rhine-Westphalia
HKSH	House of Cancer Patient Support Associations of Germany
TK	Techniker Krankenkasse (statutory health insurance fund)
BARMER	BARMER (statutory health insurance fund)
AOK	AOK Rheinland/Hamburg (statutory health insurance fund)

Additional file 2

Table A.2. Coding system for the analyses of the focus group and telephone interview

Core categories	Subcategories
Expectations of the isPO programme	
Cooperation of project partners	Communication
	Distribution of tasks
	Overarching cooperation of the project partners
	Workload
	Intensity
	Engagement of the project partners
	Dependencies
Cooperation with care networks	Communication
	Intensity
	Contents of the cooperation

Core categories	Subcategories
Facilitators of implementation into care networks	Acceptance and motivation of the service providers
	Structure and quality assurance of the isPO programme
	Monetary incentive
	Patient orientation
	Care networks' structure
	Preservation of therapeutic freedom
Barriers of implementation into care networks	Care networks' negative attitude
	Increased expenditure
	Determination of included professions
	Structure of the care networks
	Study part of the isPO project
	Financial interests of the care networks
	Low patient orientation
	Ambiguities and uncertainties in the care networks
Implementation strategies	Dealing with resistance / non-execution of the isPO guidelines
	Contact person
	Communication paths
	Trainings
	CAPSYS
	Preparation of the concept contents
	Handouts
Facilitators for implementation into conventional care	Patient interest
	Useful evaluation
	Political commitment
	Uniform care structure
Barriers for implementation into conventional care	Professional policy factors
	Bureaucratic hurdles
	Methodological weaknesses
	Unclear implementation framework

Additional file 3

Table A.3. Aims of the development phase concerning each programme component and their actual achievements. If aims have been met in full, they are indicated with a check mark (✓) in the achievement column

Components	Aims within development phase	Actual achievements at the end of development phase
C1: Care concept	• **development of a care concept** based on/compliant with - programme theory [1] - "best practice" model [2] - S3 guideline for psycho-oncology [3] → requirements: - developing effect theory for each care level - evidence summary on genesis of psychological and psychosocial distress in cancer patients, associated consequences and suitable interventions - description on how care should be provided according to patients' needs at different care levels • **providing a treatment manual** as translation of isPO care concept into practical psycho-oncological care	• **development of scientific basis of the care concept** - effect theory developed - screening instruments for assigning patients to care levels developed • **first version of treatment manual available**
C2: Project & care management	• **development of document control system**: contains clear descriptions for all contract-related processes (C4), defining activities, responsible persons, times, etc. (C1, C5, C6)	• **creation of database and document control system** based on an Excel file that was made available to all care networks (C3) • **further activities:** - provision of a milestone plan with overview on the provision and delivery of results and products in all task areas to all consortium partners - continuous and regular meetings between project leader and consortium partners - establishment of semi-annual steering committee meetings with all consortium partners and representatives of care networks (C3)

Components	Aims within development phase	Actual achievements at the end of development phase
C3: Foundation, development, & support of isPO care networks	• **foundation and development of four care networks** → requirements: - recruiting three non-university care networks in addition to the University Hospital Cologne on the basis of criteria of (economic-)geographic, population structural and cross-sectoral psycho-oncological care structural characteristics - training of service providers on the structure and functions of the care networks, on the stepped care concept (C1), on quality management (C5) and on the different care level processes depending on their role in the programme - recruiting, training and certification of isPO onco-guides	• **four care networks have been founded and basic care structures have been developed** ✓ - training documents were produced and basic training with service providers was conducted → in-depth courses still to come - isPO onco-guide teams for every care network have been recruited, trained and certified, but acquisition process is ongoing • **further activities:** - gathering a written overview of the current psycho-oncological care structures in each care network for designing the implementation process - planning the set-up of a helpdesk to ensure that acute problems in isPO-related care provision are promptly and efficiently dealt with
C4: Contracts & agreements	• **signed consortium partner agreement**: regulating areas of responsibility of the consortium partners and their cooperation (C2) • **four signed cooperation agreements**: specifying the tasks of the participating care networks in the context of care and the study (C3)	✓ ✓ **cooperation agreements have been signed by all parties involved**

Components	Aims within development phase	Actual achievements at the end of development phase
	• **signed care contracts between the care networks and the participating health insurance companies:** regulating the obligations, requirements and services of the contractual partners, and the financing of psycho-oncological services (C3)	✓ → care contract meets the requirements of German social law
C5: Quality management	• **development of quality management concept** as it is required by German social laws and according to DIN EN ISO standards for quality management especially for health care organisations	• **a beta version of the isPO QM manual has been produced**
	• **conceptual design of intra- and inter-institutional quality assurance measures** (C3 & C4) (participatory quality development approach)	✓
C6: Care pathways & indicators	• **development of SOPs** operationalising care concept (C1) and care management (C2): - specification who, why, which service should be performed in patient care ("doing the right thing") - definition of how and when, and the goal of the activity ("doing the right thing right") → SOPs also basis of the programming of CAPSYS^{2020} (C7)	• **development of basic SOPs for care levels 0 to 3a**
	• **modulation of SOPs as treatment paths** for integration into quality management (C5) during the course of the project	• **modulation of care pathways for care levels 0 to 2**
	• **development of quality indicators** (see also C8)	• **quality indicators have not been developed so far**, as the methodological approach planned appeared to be inappropriate and was adapted

Components	Aims within development phase	Actual achievements at the end of development phase
C7: IT-documentation & assistance system	• **development of the computer-based documentation and assistance system CAPSYS^{2020}** with the following functions: - structured care management (C2, C6) - automatic reporting for QM (C5) - accounting functions for controlling (C4) - patient-related and cross-patient planning, documentation, monitoring, and evaluation of care provision (C1, C8) - supporting functions according to different service provider roles (C1, C3) - processing of cancer registry data (C8)	• **development of CAPSYS^{2020} completed for the following functions**: ✓ - - ✓ ✓ -
C8: Evaluation	• **programming of care statistics** based on quality indicators (C6) for automatic quality reports (C5) as a function of CAPSYS^{2020} (C7) • **setting up a data warehouse** for controlled and secure transfer of isPO care data (C7) to evaluating institutes (KPP, IGKE, IMVR) • **developing a data protection concept**	• **derivation of test quality indicators** from the cooperation agreements (due to delay in C6) ✓ ✓ • **further activities**: - the health insurance companies involved in the project requested a health economic evaluation after project beginning that had to be implemented additionally

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Additional file 4

Table A.4. Descriptive statistics for each item of the basic training evaluation 'introduction to isPO and care levels 0 and 1'

Item	Valid cases	Missings	M	SD	Min	Max
The training provided a comprehensible introduction to...						
... the fundamental structure of the project.	21	0	3.57	0.51	3	4
...the concept of the isPO care form.	21	0	3.24	0.77	2	4
...the structure and function of the care networks.	21	0	3.05	0.74	2	4
...the care procedures in the care levels.	21	0	3.10	0.70	2	4
...the quality management system.	20	1	3.05	0.60	2	4
...the procedures for patient information and enrolment.	20	1	3.10	0.72	2	4
... the onco-guide concept.	20	1	3.35	0.59	2	4
...my task area in the onco-guide's care.	17	4	2.88	0.86	1	4
All my questions were answered during the training.	18	3	2.78	0.73	2	4
The time frame of the training was appropriate.	20	1	2.70	0.80	1	4
The trainers were competent.	21	0	3.76	0.44	3	4
The trainers were motivated.	19	2	3.74	0.45	3	4
The training was well organised.	21	0	3.43	0.60	2	4
Overall, I am satisfied with the training.	21	0	3.24	0.70	2	4

Additional file 5

Table A.5. Descriptive statistics for each item of the basic training evaluation 'care levels 2 and 3'

Item	Valid cases	Missings	M	SD	Min	Max
The training provided a comprehensible introduction to...						
...the concept of the psychosocial care.	7	0	3.43	0.53	3	4
...the procedures of the psychosocial care.	7	0	3.29	0.49	3	4
...the evaluation of psychosocial support needs.	7	0	3.43	0.53	3	4
...the concept of the psycho-oncological-psychotherapeutic care.	7	0	3.43	0.79	2	4
...the procedures of the psycho-oncological-psychotherapeutic care.	6	1	3.67	0.52	3	4
...the structure of the intervention modules of the isPO manual.	6	1	3.17	0.41	3	4
...the concept of the complex psycho-oncological care (level 3b).	6	1	3.33	0.82	2	4
...the procedures of the complex psycho-oncological care (level 3b).	6	1	3.50	0.55	3	4
All my questions were answered during the training.	6	1	3.50	0.55	3	4
The time frame of the training was appropriate.	7	0	3.71	0.49	3	4
The trainers were competent.	7	0	3.86	0.38	3	4
The trainers were motivated.	7	0	4.00	0.00	4	4
The training was well organised.	7	0	3.86	0.38	3	4
Overall, I am satisfied with the training.	7	0	3.86	0.38	3	4

Additional file 6

Table A.6. Descriptive statistics for each item of the isPO onco-guide training evaluation

	Session 1						Session 2					
Item	**Valid cases**	**Missings**	**M**	**SD**	**Min**	**Max**	**Valid cases**	**Missings**	**M**	**SD**	**Min**	**Max**
There has been sufficient training on…												
…the isPO care programme.	8	1	4.00	0.00	4	4	10	0	3.60	0.52	3	4
…the onco-guide concept.	9	0	3.78	0.44	3	4	10	0	3.60	0.52	3	4
…the contents and use of the onco-guide information package.	9	0	3.56	0.53	3	4	10	0	3.60	0.52	3	4
…the task area of the onco-guide	9	0	3.78	0.44	3	4	10	0	3.70	0.48	3	4
…the conversational technique of an onco-guide.	8	1	3.38	0.52	3	4	10	0	3.80	0.42	3	4
…the documentation of the onco-guide meeting.	9	0	3.56	0.53	3	4	9	1	3.89	0.33	3	4
… data protection and confidentiality.	9	0	3.78	0.44	3	4	10	0	3.90	0.32	3	4
…the transition from certification to deployment in the care networks.	8	1	3.63	0.52	3	4	10	0	3.40	0.70	2	4
All my questions were answered during the training.	9	0	3.56	0.73	2	4	9	1	3.33	0.50	3	4
The time frame of the training was appropriate.	9	0	3.56	0.53	3	4	10	0	3.70	0.48	3	4
The trainers were competent.	9	0	3.78	0.44	3	4	10	0	3.90	0.32	3	4
The trainers were motivated.	9	0	3.78	0.44	3	4	10	0	3.90	0.32	3	4
The training was well organised.	9	0	3.89	0.33	3	4	10	0	3.90	0.32	3	4
Overall, I am satisfied with the training.	9	0	3.78	0.44	3	4	10	0	3.80	0.42	3	4

Additional file 7

Table A.7. Descriptive statistics for each item of the CAPSYS[2020] training evaluation

Item	Valid cases	Missings	M	SD	Min	Max
The general usage of CAPSYS was explained comprehensibly.	5	0	4.00	0.00	4	4
The use of the functions that are relevant for me was explained comprehensibly.	5	0	4.00	0.00	4	4
The care management by CAPSYS was explained comprehensibly.	5	0	4.00	0.00	4	4
All my questions were answered during the training.	5	0	3.40	0.55	3	4
The time frame of the training was appropriate.	5	0	3.60	0.55	3	4
The trainers were competent.	5	0	4.00	0.00	4	4
The trainers were motivated.	5	0	4.00	0.00	4	4
The training was well organised.	5	0	4.00	0.00	4	4
Overall, I am satisfied with the training.	5	0	3.80	0.45	3	4

Chapter 7

Dissertation Project 3

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Participatory development and preliminary psychometric properties of the User-Friendly Patient Information Material Checklist (UPIM-Check)

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Abstract

The aims of this study were (1) to design a user-friendly instrument to assess and optimize patient information material (PIM), (2) to develop an English version, and (3) to test its psychometric properties. The instrument was needed to optimize the top-down developed PIM of the psycho-oncological care programme isPO. First, a literature-based PIM checklist was developed by a team of patient representatives, cancer care experts and professional researchers. Next, the checklist's reliability and validity were analysed by having cancer survivors assess the initial and optimized version of the isPO-leaflet. The *User-friendly Patient Information Material Checklist (UPIM-Check)*, developed participatorily, was found to be effective for evaluating PIM. It uses a traffic light scale, and suggestions for improvement can be given for each criterion. Its reliability appeared to be excellent ($\alpha = 0.927$). The optimized leaflet was rated significantly better than the initial one. The UPIM-Check is a reliable and valid instrument, which enables end-users (e.g. patients) to assess and optimize the quality of PIM according to scientific criteria and the needs of end-users. A bottom-up approach was essential for developing and validating the UPIM-Check. End-users constantly contributed with their specific knowledge. Thus, their position as co-researchers was significantly strengthened.

Introduction

Patient information material (PIM)

Patient information material (PIM) is written and audio-visual media developed to provide general information on a disease, its early detection, diagnosis and treatment or coping, without presupposing prior medical knowledge [1]. Such information is provided so patients can make health-related decisions [1] and are empowered to communicate with service providers [2]. Therefore, PIM is also of particular importance in intervention studies. Convincing PIM contributes to the acceptance and effective use of interventions [2]. Existing sets of criteria for PIM can guide the development of new PIM. They are similar in terms of structural, content-related and graphic requirements [1, 3, 4]. Furthermore, it is recommended to involve end-users in the development of PIM to ensure they contain easily readable, understandable and valid information for the end-users [1, 3]. Thus, it may be useful to also determine criteria for PIM together with end-users.

With this article, we would like to present how a user-friendly instrument to assess and optimize PIM was designed with end-user engagement. This is exemplified by the participatory optimization process of PIM in the German project isPO (integrated, cross-sectoral Psycho-Oncology).

The psycho-oncological care programme isPO and its project-specific PIM

The isPO project is developing, implementing, and evaluating a new, needs-driven psycho-oncological care programme [5, 6]. The design process of this complex psycho-oncological intervention proved to follow a top-down approach [7]. Similarly, the project-specific PIM for patient recruitment and study information also was developed with minor end-user participation. Both patients and service providers reported that the PIM for isPO (isPO-PIM) was too extensive, partly redundant and not linguistically appropriate for end-users (newly diagnosed cancer patients). This led to low programme acceptance by patients and especially made patient recruitment challenging. Therefore, the PIM was optimized by a team of cancer patient representatives from the House of the Cancer Patient Support Associations of Germany (HKSH-BV), experts from the Cancer Society North Rhine-Westphalia (KG-NRW) and health researchers of the University of Cologne. The entire optimization process [8] was guided by the participatory health research (PHR) approach according to Cornwall [9], with its six participation levels (Figure 1). Conducting PHR is a process of power-sharing, so participation levels can vary during the course of a project. The aim was to attain the 5th level of co-learning.

Figure 1. Participation levels, relationship of researchers to end-users, and characteristics of participation adapted from Cornwall (1996, p. 96)

		Relationship of researchers to end-users	Characteristics of participation
Participation level 6	Collective action	by end-users	end-users set their own agenda and mobilize to carry it out, in the absence of outside researchers and facilitators
	Co-learning	with/by end-users	end-users and researchers share their knowledge, to create new understanding, and work together to form action plans, with researcher facilitation
	Cooperation	with end-users	end-users work together with researchers to determine priorities, responsibility remains with researchers for directing the process
	Consultation	for/with end-users	end-users' opinions are asked, researchers analyse and decide on a course of action
	Compliance	for end-users	tasks are assigned, with incentives; researchers decide agenda and direct the process
1	Cooption	on end-users	token; representatives are chosen, but no real input or power

The isPO-PIM optimization process gave rise to the need for a PIM assessment instrument following existing quality criteria. For the systematic evaluation of the isPO-PIM and the systematic collection of improvement suggestions at the same time, a PIM assessment and optimization instrument was needed. It was important to develop it with patient engagement, so that it corresponds to the PHR approach. Furthermore, existing PIM quality criteria had to be followed.

PIM assessment instruments

Besides the various sets of criteria for the quality of PIM, there are several validated instruments to assess PIM quality [2, 10–13]. According to Clayton [12], PIM assessment instruments can be divided into three types – (1) attribute checklists, (2) readability tests, and (3) rating scales. Several literature reviews on PIM assessment instruments revealed the DISCERN as a commonly used rating instrument [2, 4, 12] (see below). Due to its specification to PIM on treatment choices and considering certain PIM quality criteria, new instruments have been developed in recent years [2, 12, 13]. Most of these rating instruments already have been applied in the context of cancer care [14–20].

In German-speaking countries, DISCERN [11] and the Patient Education Materials Assessment Tool (PEMAT) [13] have been used to assess cancer-related PIM [21, 22].

Of these two instruments, only DISCERN was designed to be applied by professionals in health care, health research, and health policy as well as patients. Patients took part in the development and pilot testing of DISCERN, but not in the evaluation of its reliability. Both

DISCERN and PEMAT are solely quantitative instruments assessing the quality of PIM with rating scales. Text fields for documenting improvement suggestions are not provided. Regarding the content, DISCERN focuses on the reliability and completeness of information, whereas PEMAT addresses structural and graphical requirements of PIM and assesses their actionability.

Objective of this study

There was no PIM quality instrument available which could be intuitively applied, especially by PIM end-users. Moreover, existing instruments cannot be directly used for assessment as well as optimization of PIM, e.g. with open text fields for improvement suggestions. More particularly, the usually applied German-speaking PIM instruments do not cover all PIM quality areas. Hence, within the process of optimizing the isPO-PIM, a criteria-based **U**ser-friendly **P**atient **I**nformation **M**aterial **Check**list (UPIM-Check) was developed with perpetual engagement of end-users. It was designed to enable quantitative assessment as well as the optimization of PIM.

In this paper, we report on: (1) the participatory development of the UPIM-Check, (2) the translation process into English, and (3) the psychometric pilot study of the German version.

Materials and methods

Ethical approval

The study was performed according to the Declaration of Helsinki. The ethics committee of the Medical Faculty of the University of Cologne has approved the isPO project and its study design (No. 18-092; date of approval: 15 October 2018). The relevant national and European data protection regulations were considered for data collection. The isPO project study is registered in the German Clinical Trials Register (No. DRKS00015326).

Development of the UPIM-Check (German version)

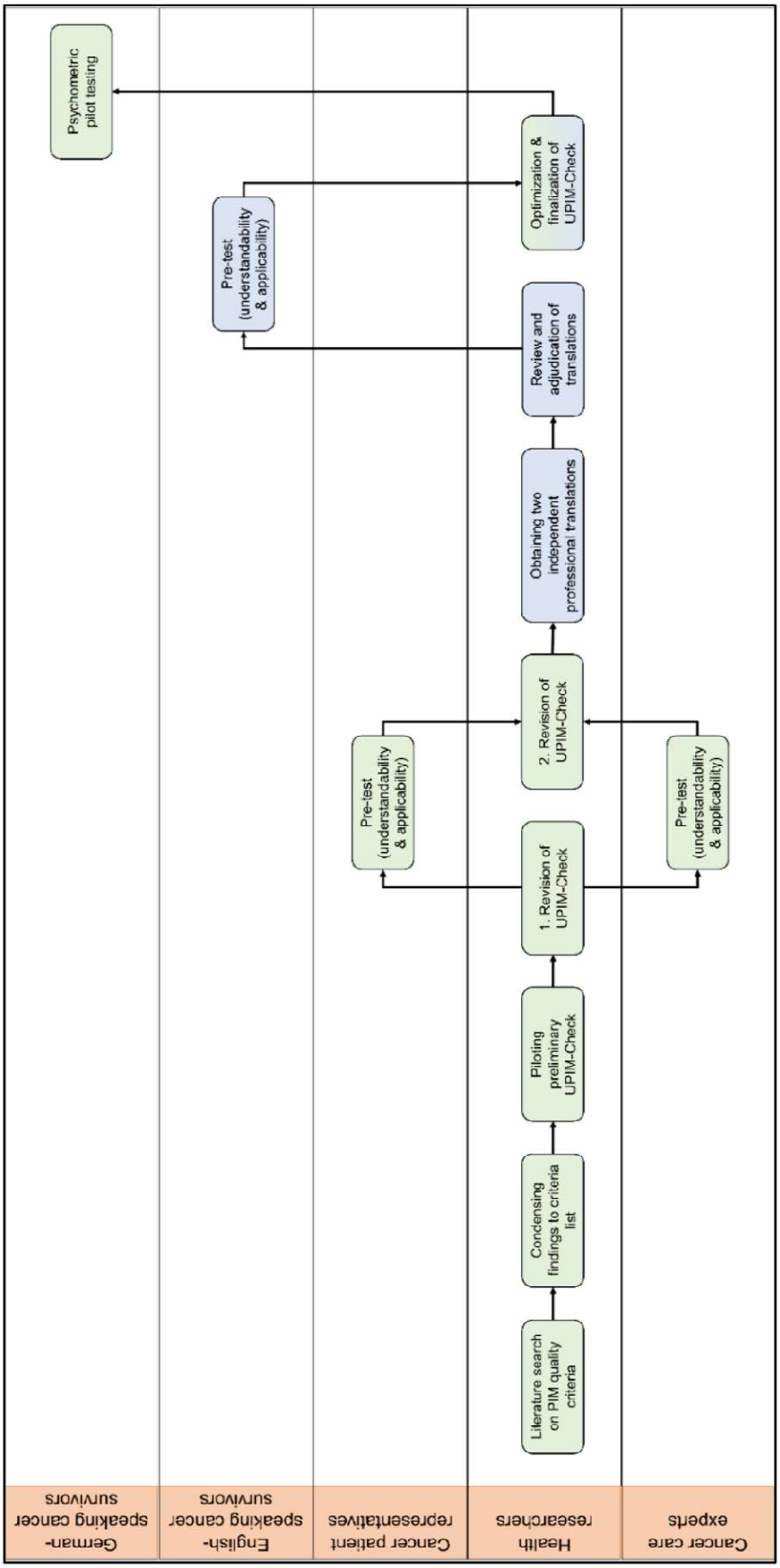
The development of the UPIM-Check took place in a multi-step process, which is shown in Figure 2. It was part of the preparation phase within the isPO-PIM optimization process [8], so the team composition of patient representatives, cancer care experts and researchers was identical.

The design of the new PIM quality instrument was based on the literature on quality criteria and creation manuals for written PIM [1–3]. In addition to the written isPO-PIM (leaflets and information folders) there is also an isPO website for patients who are interested in taking advantage of the isPO care programme. So, literature on web-based PIM was also included [4]. The quality criteria that were found were first condensed to a set of 27 criteria by one person from the group of researchers and then grouped into four areas based on the quality indicators of Herm and Linden [3]. This preliminary version of the UPIM-Check was structured into the two sections *Correctness and validity of content* (Does the information appear to be correct and

valid?) and *Readability* with the three sub-sections *Readability of content* (Is the content easy to read and the used language appropriate for the end-users?), *Structural readability* (Is the word and sentence complexity appropriate for the end-users?), and *Graphical readability* (Is the graphical design appropriate for the end-users?). For an intuitive assessment of the criteria, a three-point traffic light scale was chosen. The new instrument had to be designed to both assess and optimize PIM, so evaluation and improvement suggestions come from one source to make the instrument efficient. Therefore, an open text field for suggestions for improvement was assigned to each criterion. Three further researchers from the isPO-PIM team piloted the preliminary version of the UPIM-Check and added four items based on the literature mentioned above.

To pre-test the UPIM-Check, it was presented to the other isPO-PIM team members (n = 5; two patient representatives and three cancer care experts) to test it on the isPO-PIM. They were asked to critically review it in terms of comprehensibility and applicability. Improvement ideas were inserted on the UPIM-Check form and the UPIM-Check was adapted. In particular, patient representatives suggested linguistic changes to improve clarity and to use language that would empower patients (i.e., motivating them and guiding their actions).

Figure 2. Process of the UPIM-Check development, translation, and psychometric pilot study



The steps are assigned to the group who facilitated and/or conducted this action. Steps in green represent the UPIM-Check German version, steps in blue represent the UPIM-Check English version

English translation of the UPIM-Check

To make the UPIM-Check internationally available, an English-language version was generated according to the TRAPD approach (**T**ranslation, **R**eview, **A**djudication, **P**retest, and **D**ocumentation) [23, 24]. The basis was the pre-tested and adapted UPIM-Check German version.

Two professional translators independently translated the UPIM-Check into English (T). A team of four researchers who were active in (psycho-)oncological health services research was formed. Three of them were involved in the development and/or piloting of the preliminary UPIM-Check German version. The fourth person was a native English speaker with eight years of German language experience. Together, they reviewed the two English translations in relation to the German version (R). As the two translations were very similar, linguistic subtleties had to be discussed (e.g. “appropriate” vs. “adequate”). To consent the final English version (A), linguistic consistency within the instrument and an easy language were guiding this step.

The pre-test (P) of the English version had to take place in written form instead of face-to-face interviews, so a special UPIM-Check pre-test form was created. It had an open text field below each criterion so respondents could enter comments on the comprehensibility and relevance of the criterion. In addition, a final text field was available for general comments on the UPIM-Check. To make the UPIM-Check applicable and the comments comparable, the same PIM was made available to all English version pre-test participants. Freely available leaflets on psycho-oncological care in English-speaking countries were researched using an internet search engine. The isPO-PIM team then selected a leaflet published by the national health system of an English-speaking country based on seriousness and independence. The pre-test documents included an invitation letter explaining the aim of the UPIM-Check and how the pre-test would be conducted.

Several methods were used to recruit participants for the pre-test of the English version: The contacts of the HKSH-BV to English-speaking sister organizations were used, and further cancer self-help associations in the UK and USA were identified. In each case, the chairpersons were contacted by email and asked to distribute the pre-test documents to their members. Nine organizations were contacted in up to two contact attempts.

One person each from four organizations provided written feedback on the UPIM-Check. That feedback was incorporated into the final English version of the UPIM-Check. In the pre-test of the English version, it was suggested for some items to formulate them as questions. To be consistent throughout the instrument, the criteria were still formulated as key terms, but questions were added to every item, guiding its assessment (e.g. *“Neutral language – Is the PIM presented in an open-minded, not manipulation way?”; “Illustrations – Are the pictures and*

graphics used concise and understandable?"). Consequently, these questions were also added to the German version to align the both language versions.

Pilot study on the psychometric properties of the UPIM-Check German version

Pilot study design and participant recruitment

Since the UPIM-Check was originally developed in German, this version was tested for its psychometric properties first. It was presented to cancer survivors who had no connection to the isPO project or the development of the UPIM-Check. Two versions of the isPO leaflets were assessed – the initial one and the optimized one. To avoid bias because of preconceptions, the study invitation stated only that two leaflets on psycho-oncological care were presented, but not that they were based on an optimization process. Two study groups were defined: (1) participants who evaluated the initial leaflet first and the optimized one second, and (2) participants who evaluated the optimized leaflet first and the initial one second.

Participants for the pilot study were recruited from: (1) the ten associations in the patient organization HKSH-BV, (2) the eight associations in the self-help section of the cancer care expert organization KG-NRW, and (3) Facebook groups organized by and for cancer patients. Up to two contact attempts for each organization were made.

To guarantee their anonymity, interested persons were asked to provide their postal address to the isPO-Trust Centre, which was separate from the research staff in terms of personnel and space.

The recruits were randomly assigned to one of two study groups and given numbers to be used as pseudonyms. Two copies of the UPIM-Check were given to each person, one for each version of the isPO-leaflet.

At the end of the pilot study, all participants received a written report on the results and the UPIM-Check German version for free use.

Materials

The following materials were sent to the pilot study participants by the isPO-Trust Centre to carry out the two assessments: an application guide and two envelopes, each containing a copy of the UPIM-Check and one of the two leaflets. The application guide was a one-page document explaining step-by-step how to conduct the UPIM-Check pilot testing. In this way, the pilot study participants were instructed to open the envelopes and apply the UPIM-Checks in the specified order. The envelopes were numbered according to the study group. For participants in group 1, envelope no. 1 contained the original leaflet and envelope no. 2 contained the optimized leaflet; for study group 2, the numbering was reversed.

After they completed the UPIM-Checks, the participants were asked to return them to the isPO-Trust Centre in an enclosed return envelope.

The UPIM-Check form used for the psychometric pilot study contained some additional elements for study purposes. These included demographics such as age, gender and tumour entity. The time efficiency of the UPIM-Check was also measured. Participants used text fields to enter the times when the UPIM-Check was started and completed. This information was used to calculate the completion time in minutes.

The traffic light scale of the UPIM-Check was operationalised as a three-point Likert scale with the following options: 1 = very good; 2 = sufficient; 3 = unsatisfactory. The UPIM-Check total score and the four criteria areas as subscale scores were calculated as the sum of the corresponding items, with a lower score representing a better rating.

Statistical analysis

To explore the psychometric properties of the German UPIM-Check, item acceptance, discriminatory power, internal consistency, and construct validity were tested. All analyses were performed to assess both the initial and the optimized isPO-leaflet.

Item acceptance was assessed by the completion rate; the higher the rate, the greater the acceptance of the item [25]. For each item, the percentage of pilot study participants who answered it was calculated.

Item discrimination is the extent to which the differentiation of subjects within an item corresponds to that within the total score [26]. Thus, the corrected item–scale correlations were computed. This was the correlation between an item and the score of the remaining items [27]. Item–total correlations >0.20 were considered acceptable [28, 29].

Internal consistency is a measure of the inter-relation of items [30]. Hence, Cronbach's α [31] was calculated, with values between 0.0 and 1.0. Values >0.70 were considered acceptable, values >0.80 good and values >0.90 excellent [30].

Construct validity refers to whether an instrument really measures the construct that it claims to measure [30]. As construct validity cannot be directly measured, its assessment comprises the formulation of hypotheses concerning the relationships of constructs [29, 30]. To assess the evidence for the construct validity of the UPIM-Check, the following hypothesis was formulated:

Hypothesis 1: *The UPIM-Check total score correlates highly positively with the four UPIM-Check subscale scores.*

Furthermore, we explored the ability of the UPIM-Check to discriminate between an initial and an optimized PIM, and the time-efficiency of the instrument:

Hypothesis 2: *The UPIM-Check total score on the optimized isPO-leaflet is significantly lower than the total score on the initial leaflet.*

Hypothesis 3: *The UPIM-Check total score correlates positively with the completion time since a lower rating requires more improvement suggestions.*

To test the first and third hypotheses, Spearman's correlation was calculated one-sided and interpreted according to Taylor [32]: 0.0 to 0.35 = weak correlation; 0.36 to 0.67 = moderate correlation; 0.68 to 1.0 = high correlation. For the second hypothesis, the Wilcoxon test was performed as a non-parametric test for dependent samples.

To test the hypotheses, a significance level of $\alpha = 0.05$ was assumed and adjusted to $\alpha = 0.0125$ for hypothesis 1 and to $\alpha = 0.025$ for hypothesis 3 according to the Bonferroni correction.

Data input, preparation and analysis were performed using IBM SPSS Statistics 27. The data were input manually by the first author, and they were checked by another author, using a dual control principle. For missing values, pairwise deletion was applied.

Results

The UPIM-Check – Structure and application

The final UPIM-Check is an instrument for both assessing and optimizing the quality of PIM. It has 31 items, which are divided into four quality areas: *Q1: Correctness and validity of content* (9 items), *Q2: Readability of content* (8 items), *Q3: Structural readability* (4 items), and *Q4: Graphical readability* (10 items).

To map *Q1*, items were developed to assess the information basis of the PIM. The relevance of such information is decisive for the end-users, as well as whether the PIM gives concrete recommendations for action. *Q2* focuses on whether the PIM is designed in such a way that the end-users are specifically addressed and the linguistic design corresponds to the end-users. Delimited from this superordinate level, *Structural Readability* (*Q3*) focuses on features at the word and sentence levels. *Q4* takes up the graphic design of the PIM. This refers to the information provided by illustrations and to the visual design and structuring of the text.

The items of the UPIM-Check represent concrete criteria and contain questions to help users assessing the criterion. The evaluation itself is quantitative, using a traffic light scale with the levels *very good* (green), *sufficient* (yellow) and *unsatisfactory* (red). For its function as an optimization tool, the UPIM-Check provides an open text field for suggestions for improvement for each criterion. The field can be used if a criterion is rated yellow or red. Figure 3 shows an excerpt from the English version of the UPIM-Check.

Figure 3. Excerpt from the User-Friendly Patient Information Material Checklist (UPIM-Check) English version

Quality criteria		very good	suffi-cient	unsatis-factory	Suggestions for improvement
Q1: Correctness & validity of content – Does the content seem to be correct? Does the information appear to be valid?					
Q1.1	**Up-to-date & technically correct** (references, expertise of the authors, date) *Does the information appear to be up-to-date? Is the information correctly cited?*	☐	☐	☐	
Q1.2	**Transparency** (author of the PIM; contact person, contact & logo) *How clear is the information?*	☐	☐	☐	
Q1.3	**Information is relevant for the target group** (social evidence) *Is the information relevant for the target group?*	☐	☐	☐	
Q1.4	**Contextual integration into patient's situation** (experience, emotions, burden) *How does the information fit the patient's situation?*	☐	☐	☐	

Available at https://www.imvr.de/wp-content/uploads/UPIM-Check_English.pdf, accessed on 18 August 2021

On the first page of the UPIM-Check, information about the assessment process itself can be given: (1) name of the PIM, (2) role of the rater (e.g. patient/patient representative, researcher/project staff, care provider), and (3) information on where and how the end-users come into contact with the PIM. Section 2 is intended to support the cooperation of persons with different perspectives in the development, assessment and optimization of PIM, and Section 3 aims to classify the PIM within a communication strategy. That is, if several PIMs with different objectives and different end-users were to be used in a project. The UPIM-Check is freely available at https://www.imvr.de/wp-content/uploads/UPIMCheck_English.pdf, accessed on 18 August 2021.

Preliminary psychometric properties of the UPIM-Check German version

A total of 18 cancer survivors took part in the psychometric pilot study, although one person completed the UPIM-Check only on the optimized leaflet. Pilot study participant characteristics are presented in Table 1.

Table 1. Participant characteristics of the UPIM-Check German version psychometric pilot study

Characteristic	***M (SD)***	**Range**
Age (years)	65.28 (9.49)	42–79
	f	**%**
Gender		
female	5	27.8
male	13	72.2
Tumour entity		
Bladder	11	61.1
Head and Neck	6	33.3
Other	1	5.6

Item acceptance ranged from 88.2% to 100% for the initial leaflet and from 83.3% to 100% for the optimized leaflet (Table 2). The item with the lowest acceptance was *Q2.8 Use of empowering words*.

The corrected item–total correlations ranged between -0.175 and 0.943 for the initial leaflet and between -0.395 and 0.626 for the optimized leaflet. A total of 26 items for the initial leaflet and 17 items for the optimized leaflet had a corrected item–total correlation of >0.20 (Table 2). Three items were removed from the reliability analysis of the optimized leaflet because their variance was zero. These were *Q2.4 Neutral language*, *Q3.1 Sentence length* and *Q4.7 Font size*. Cronbach's α was 0.927 for the initial leaflet and 0.655 for the optimized leaflet.

The mean UPIM-Check total score was M = 44.08 (SD = 10.86) for the initial leaflet and M = 38.36 (SD = 4.48) for the optimized leaflet. Corresponding information on the subscale scores can be found in Table 2. On average, participants needed 25.18 min (SD = 28.09 min) to complete the UPIM-Check for the initial leaflet and 21.18 min (SD = 20.27 min) to complete the UPIM-Check for the optimized leaflet.

Table 2. Item and score characteristics of the UPIM-Check German version according to the rating of the initial and optimized isPO-leaflet

Item/Score	Initial Leaflet					Optimized Leaflet				
	M	***SD***	**Fill-In rate (%)**	**Corrected Item-Total Correlation**	**Cronbach's α**	***M***	***SD***	**Fill-In rate (%)**	**Corrected Item-Total Correlation**	**Cronbach's α**
UPIM-Check total	44.08	10.86			0.927	38.36	4.48			0.655
Q1: Correctness and validity of content	12.63	3.65			0.806	11.76	2.33			0.594
Q1.1 Up-to-date and technically correct	1.24	0.56	100	0.052		1.39	0.70	100	0.047	
Q1.2 Transparency	1.06	0.24	100	0.263		1.47	0.72	94.4	0.381	
Q1.3 Information is relevant for the target group	1.13	0.50	94.1	0.727		1.11	0.32	100	0.376	
Q1.4 Contextual integration into patient's situation	1.56	0.81	94.1	0.791		1.22	0.43	100	0.626	
Q1.5 Focus	1.35	0.61	100	0.897		1.06	0.24	94.4	0.309	
Q1.6 Adequate presentation	1.65	0.79	100	0.665		1.33	0.59	100	0.626	
Q1.7 Motivation and increase of self-efficacy	1.41	0.62	100	0.736		1.22	0.43	100	0.472	
Q1.8 Recommendation for action	1.53	0.62	100	0.736		1.24	0.56	94.4	−0.174	
Q1.9 Further literature/points of contact	1.59	0.80	100	−0.058		2.06	0.80	100	0.145	
Q2: Readability of content	11.42	4.21			0.929	9.47	1.68			0.625
Q2.1 Aim of the PIM and target group is identifiable	1.31	0.60	94.1	0.897		1.06	0.24	94.4	0.309	

Item/Score	Initial Leaflet					Optimized Leaflet				
	M	*SD*	Fill-In rate (%)	Corrected Item-Total Correlation	Cronbach's α	*M*	*SD*	Fill-In rate (%)	Corrected Item-Total Correlation	Cronbach's α
Q2.2 Clarity of content	1.44	0.63	94.1	0.943		1.29	0.59	94.4	0.359	
Q2.3 Simple, clear language	1.29	0.59	100	0.897		1.11	0.32	100	0.309	
Q2.4 Neutral language	1.24	0.56	100	0.727		1.06	0.24	100	[a]	
Q2.5 Target group-specific language	1.53	0.74	88.2	0.603		1.39	0.70	100	0.626	
Q2.6 Use of numbers	1.13	0.35	88.2	0.263		1.18	0.39	94.4	0.023	
Q2.7 Language that can be understood without prior medical knowledge	1.75	0.78	94.1	0.795		1.44	0.62	100	0.070	
Q2.8 Use of empowering words	1.60	0.74	88.2	0.895		1.40	0.63	83.3	.292	
Q3: Structural readability	5.19	1.76			0.822	4.59	1.12			0.803
Q3.1 Sentence length	1.18	0.39	100	0.068		1.17	0.51	100	[a]	
Q3.2 Sentence difficulty/complexity	1.24	0.44	100	0.264		1.12	0.33	94.4	−0.146	
Q3.3 Word length	1.29	0.59	100	0.374		1.17	0.38	100	−0.146	
Q3.4 Word difficulty	1.56	0.73	94.1	0.248		1.39	0.61	100	0.177	
Q4: Graphical readability	13.67	3.54			0.803	12.33	2.50			0.607
Q4.1 Layout/overall visual appearance	1.59	0.71	100	0.226		1.33	0.49	100	0.412	
Q4.2 Eye-catching	2.00	0.73	94.1	0.452		1.59	0.80	94.4	0.208	
Q4.3 Appropriate overall text length	1.35	0.70	100	0.576		1.28	0.58	100	0.316	
Q4.4 Structure and context	1.12	0.33	100	0.263		1.33	0.69	100	0.330	
Q4.5 Illustrations	1.76	0.83	100	0.590		1.69	0.95	88.9	0.425	
Q4.6 Coloured headings and highlighting of key points	1.24	0.44	100	−0.175		1.22	0.43	100	−0.160	
Q4.7 Font size	1.19	0.54	94.1	0.724		1.00	0.00	94.4	[a]	
Q4.8 Font colour	1.18	0.39	100	−0.061		1.06	0.24	94.4	−0.271	
Q4.9 Font type	1.18	0.39	100	0.620		1.11	0.32	100	−0.395	
Q4.10 Corporate design	1.25	0.58	94.1	0.825		1.33	0.59	100	0.286	

Note. [a]Item was removed from reliability analysis because it has a variance of zero.

The scores on the Wilcoxon test were significantly lower for the total score for the optimized leaflet than for the initial leaflet (Z = -2.606; p = 0.009). This showed that the UPIM-Check could discriminate PIM versions of different quality.

The Spearman's correlations of the UPIM-Check total score with the subscale scores for the initial leaflet ranged from r = 0.594 to r = 0.923. The correlations with the subscales *Q1: Content correctness and validity* and *Q2: Content readability* were significant (p < 0.001) (Table 3). Regarding the optimized leaflet, the correlations ranged from r = 0.301 to r = 0.753, with

significant correlations with subscale Q1 (p = 0.001) and subscale Q2 (p = 0.006). The correlation with subscale *Q4: Graphic Readability* was also significant (p = 0.004).

Table 3. Spearman's correlations of the UPIM-Check total score with subscale scores according to the initial and optimized isPO-leaflet

Subscale Score	UPIM-Check Total Score (Initial Leaflet)		UPIM-Check Total Score (Optimized Leaflet)	
	r	***p***	***r***	***p***
Q1: Correctness and validity of content	0.919 *	<0.001	0.753 *	0.001
Q2: Readability of content	0.923 *	<0.001	0.645 *	0.006
Q3: Structural readability	0.637	0.013	0.301	0.148
Q4: Graphical readability	0.594	0.021	0.679 *	0.004

Note. * Significant correlation according to α = 0.0125

The respective correlations of the UPIM-Check total score with the duration of completion for the two versions of the leaflet showed a significant positive correlation for the initial leaflet (r = 0.685; p = 0.010) and the optimized leaflet (r = 0.606; p = 0.014).

The results show that the UPIM-Check is a precise instrument and efficient to use.

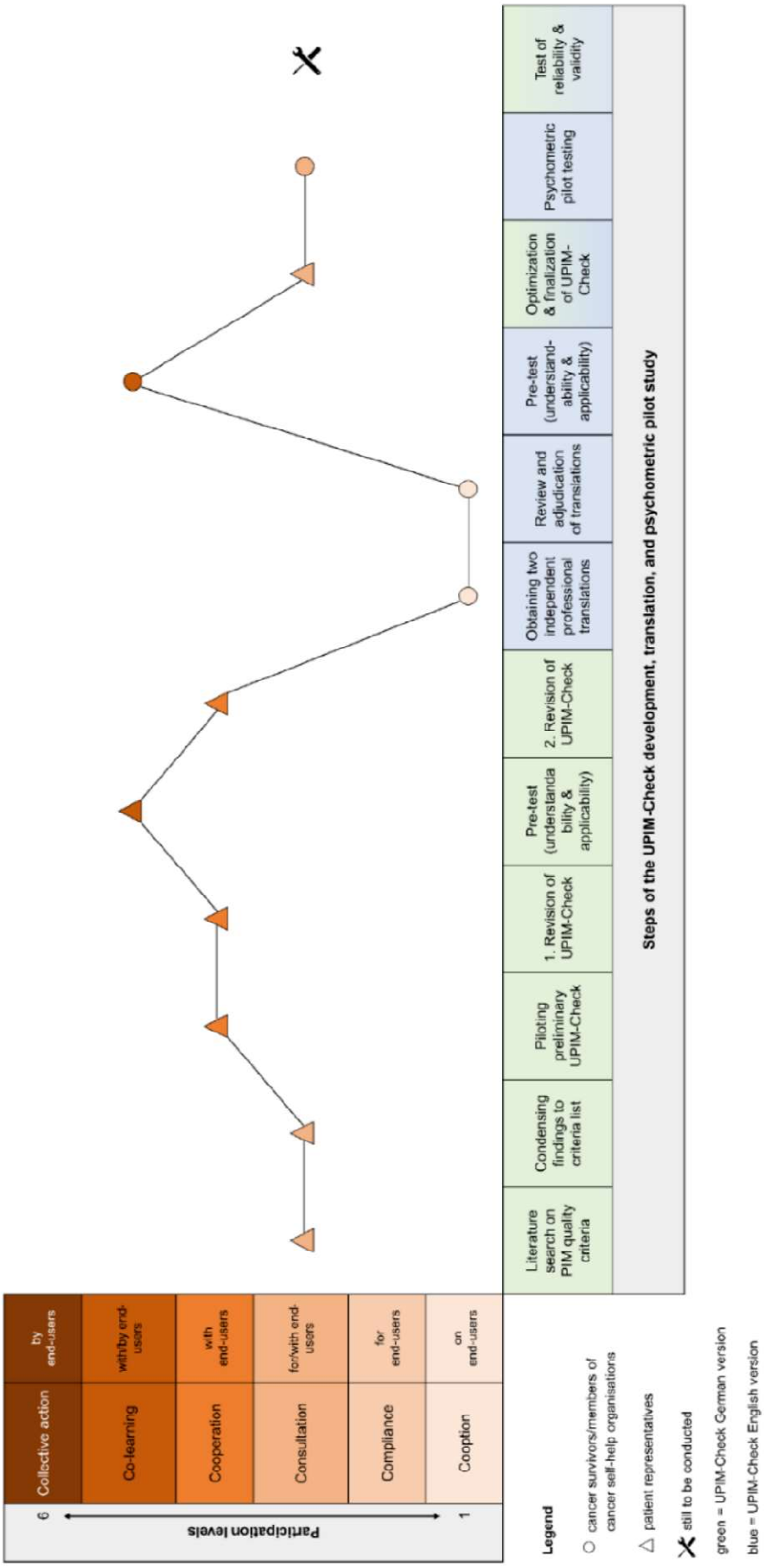
Discussion

This work shows how an end-user-friendly quality instrument for written PIM (UPIM-Check) was developed with ongoing end-user engagement (Figure 4). Besides, it serves as a structured assessment and optimization tool for PIM. The availability of the instrument in German and English widens its usability. Preliminary data on the psychometric properties of the German version were presented first. Validation of the English version is still to be conducted, for which we are looking for interested cooperation partners.

The UPIM-Check was developed to be (1) intuitively usable by all PIM end-users, (2) applicable for both assessment and optimization of PIM and (3) based on scientific criteria for the quality of PIM.

All isPO-PIM team members found their team composition (patient representatives, cancer care experts, and researchers) to be fruitful and enlightening. In particular, the end-users were strengthened in their roles as co-researchers, so that collaboration took place on an equal footing. Moreover, exploring three different perspectives provided a valuable impetus to make the UPIM-Check scientifically and linguistically appropriate, and applicable for end-users. Patient representatives offered the following observations: *'The checklist covers a lot of aspects, so you get a "close up" of the material'*. There is a *'reasonable assurance that patients would be able to comprehend the checklist'*.

Figure 4. Levels of end-users' participation (according to Cornwall (1996)) within the steps of the UPIM-Check development and translation process and psychometric pilot study



Nevertheless, the PHR approach also involves some bottlenecks. Krieger et al. [33] found that communication between different groups was very resource-intensive. Knowing this beforehand, we carefully planned and implemented the communication channels between the isPO-PIM team members. It was essential to provide an equal level of information to all team members, as 'knowledge is power', and the PHR approach demands power balance [34]. Also, recruiting people from the end-user group during the COVID-19 pandemic was challenging, e.g. in studies with older people and in oncological trials [35, 36].

In the psychometric pilot study, an initial and an optimized leaflet for the psycho-oncological care programme isPO were assessed with the UPIM-Check by cancer survivors of various patient organizations representing different tumour entities. Thus, diversity of perspectives was achieved.

While the *internal consistency* of the initial leaflet was excellent, it was just below an acceptable value for the optimized version. However, comparability was limited because only 28 of the 31 items were included in the analysis of the optimized leaflet because some variances were zero. This could lead to an underestimation of reliability [37]. The low dispersion in the evaluation of the optimized leaflet could also indicate a high rater agreement, so PIM of very high quality could be achieved especially for three criteria (*Q2.4 Neutral language, Q3.1 Sentence length, Q4.7 Font size*).

The values of the item–total correlations as measures of item discrimination were acceptable for 26 items (initial leaflet) and 17 items (optimized leaflet), respectively. Four items had a very low item –total correlation of <0.20 for both leaflets. These were: *Q1.1 Up-to-date and technically correct; Q1.9 Further literature/points of contact; Q4.6 Coloured headings and highlighting of key points; Q4.8 Font colour*. If these results are replicated in a representative validation study, items with no acceptable discrimination will have to be removed from the UPIM-Check, as they make no contribution to measure the construct [29].

Regarding *construct validity* (hypothesis 1), it was particularly restrictive that *Q3: Structural readability* was not significantly related to the overall rating. There might be a separate construct that should be addressed with comprehensibility tests [3]. The low acceptance of the empowering language criterion might be related to the average age of the pilot study participants (M = 65.28 years) and less familiarity with such formulations (e.g. post-war generation). The empowerment approach is relatively recent, especially in health care [38].

Hypotheses 2 (*discrimination ability*) and 3 (*time-efficiency*) were accepted. This showed that the UPIM-Check could distinguish between an initial and an optimized leaflet. Because of the open text fields, which were completed in the case of low scores, it is plausible that a worse overall score is associated with a longer completion time. Although data were collected by both scale and open text fields, the UPIM-Check proved to be very time-efficient and manageable.

Strengths and limitations

The UPIM-Check was developed in an ongoing project (isPO). By pursuing the bottom-up PHR approach, we avoided a research-to-practice gap [34]—in contrast to the top-down development of the initial isPO-PIM. Despite all the constraints (e.g. scarce resources, experts' scepticism), the participatory procedure was indispensable for optimizing the PIM to create a tailored fit for end-users (cancer patients) and usability in care. The process had to be conducted as quickly as possible to facilitate further programme implementation and enhance patients' programme acceptance with optimized PIM. Due to this highly practical setting and bottom-up approach on the one hand, and the rarity of similar development processes on the other hand, not every UPIM-Check development step was approached systematically, such as the selection of criteria/items based on a systematic review on PIM quality criteria.

With a sample size of n = 18 and two assessed leaflets, the results of this study are not representative. They only give first indications on the psychometric properties of the UPIM-Check German version, so a comprehensive validation still has to be conducted. However, as the UPIM-Check's observation units are PIM and not people, especially the number of assessed PIMs has to be increased. For example, reliability testing for the DISCERN was conducted by only two raters assessing 31 PIM [17].

The UPIM-Check has been used only in the context of psycho-oncology so far, but its open format implies a high likelihood that it can be applied in a wide variety of care areas. This could generate larger PIM samples for future validation studies like for DISCERN [17] and PEMAT [13]. Also, the full potential of user groups in validating has not yet been realized.

Moreover, construct validity of the UPIM-Check was explored within the instrument, instead of testing the relationships with other PIM assessment instruments (convergent validity) [29, 30].

Besides participatory development (Figure 4), the mixed-methods response format consisting of a traffic light scale and open text fields is a unique feature of the UPIM-Check, e.g. in comparison to DISCERN and PEMAT. Knapp et al. [39] conducted PIM optimization based on quantitative user assessments and qualitative user interviews. They achieved a significantly higher understandability and acceptability of the improved PIM, whereas top-down PIM optimization using solely quantitative assessments resulted in minor differences in recruitment rates [40].

Unlike DISCERN and PEMAT, the items of the UPIM-Check do not cover a special area of PIM quality criteria. They consider content-related, structural and graphical requirements, whereas DISCERN focuses on reliability and completeness of information, and PEMAT on understandability and actionability. In contrast to UPIM-Check, DISCERN and PEMAT already have been validated [13, 17]. Moreover, the items of DISCERN were notably formulated to assess

PIM on treatment choices [2]. Such a specification was avoided in the UPIM-Check. Therefore, it can be applied for various PIMs, e.g. on diagnostics and care programmes.

Dissemination and accessibility of the UPIM-Check are guaranteed on the websites of all developers. The instrument is available for international use, as an English version was created following a recognized translation procedure [23, 24].

Conclusions

The participation of the end-users was essential for the precise definition of the PIM quality criteria and the development of an end-user-friendly PIM quality instrument. The resulting UPIM-Check was rated as valid by experts and user-friendly by patients in both language versions. Through the quantitative and qualitative response format, the UPIM-Check enables both the assessment and optimization of PIM. Since both can be conducted with the same instrument, it is also very time-efficient. This was observed in the psychometric pilot study by the end-user group. However, patients often experience that they are hardly involved beyond the participation level of consultation [9, 41, 42]. With the PHR approach, end-users engaged in the UPIM-Check's development and psychometric pilot study (Figure 4), assisting the process with their specific knowledge.

With the UPIM-Check, a PIM quality instrument tool has become universally available, which appeared in a pilot study to be reliable and valid. It had already been used for optimizing and developing PIM [8, 43], and it proved to be very end-user-friendly. It is aimed to support all groups involved in the development, optimization or evaluation of PIM, i.e., patients, relatives, patient representatives and professionals in health care, research and policy. The intuitive applicability enables end-users, in particular, to evaluate PIM according to scientific criteria. This empowers them to engage in PHR towards co-learning and collective action [9]. In this way, end-users are strengthened in their role as co-researchers.

Author contributions

Conceptualization, S.S., J.M. and T.K.; Formal analysis, S.S., J.M., C.H., N.C., S.H., A.A., A.G., K.S. and T.K.; Investigation, S.S., J.M., C.H., N.C., S.H., A.A., A.G., K.S. and T.K.; Methodology, S.S. and T.K.; Project administration, T.K.; Resources, C.H., S.H., A.A., A.G. and K.S.; Supervision, A.D.; Validation, S.S., C.H., N.C., A.D., H.P., N.S. and T.K.; Visualization, S.S.; Writing—original draft, S.S.; Writing—review and editing, J.M., C.H., N.C., A.D., S.H., A.A., A.G., K.S., H.P., N.S. and T.K. All authors have read and agreed to the published version of the manuscript.

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Institutional review board statement

The study was performed according to the Declaration of Helsinki. The ethics committee of the Medical Faculty of the University of Cologne has approved the isPO project and its study design (No. 18-092; date of approval: 15 October 2018). The relevant national and European data protection regulations were considered for data collection. The isPO project study is registered in the German Clinical Trials Register (No. DRKS00015326).

Informed consent statement

All participants received oral and written information regarding the aim of the study and its voluntary nature and provided written consent to participate.

Data availability statement

The data presented in this study are available on reasonable request from the corresponding author. The data are not publicly available due to ethical and legal restrictions (participants of this study did not agree for their data to be shared publicly).

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Conflicts of interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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Chapter 8

Dissertation Project 4

Published as:

Integrating one-to-one peer support into psycho-oncological care in Germany: Multi-perspective, mixed-methods evaluation of the isPO onco-guide service

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Abstract

Purpose: One-to-one peer supporters called isPO onco-guides (isPO OGs) are an integral part of the new German psycho-oncological form of care 'integrated, cross-sectoral Psycho-Oncology' (isPO), additionally to professional care. The isPO OGs are cancer survivors with experiential knowledge, offering information on local support services and answering questions 'all around cancer' to newly diagnosed cancer patients. We aimed to evaluate the isPO OG service from three perspectives: patients, isPO OGs, and professional service providers.

Methods: A mixed-methods approach was pursued. We conducted interviews and focus groups with the three person groups, and applied qualitative content analysis on the reported resources, processes and outcomes regarding the isPO OG service. Relations with patients' utilisation and isPO OGs' work satisfaction were identified with regression and correlation analyses of questionnaire and isPO care data. We compared isPO care networks (CN) with X^2-tests or ANOVA. Qualitative and quantitative results were integrated during interpretation phase.

Results: Qualitatively, the three person groups agreed on the benefits of the isPO OG service. The implementation's maturity differed between the CN concerning established processes and resource availability. Attitudes of professional service providers appeared to be crucial for patients' utilisation of the isPO OG service. Quantitative results emphasised the differences between the CN.

Conclusion: Beyond differences in the CN, the isPO OG service has two psychosocial benefits: providing relevant, reliable, and understandable information; and offering the encouraging example that surviving and living with cancer is possible.

Trial registration: The study was registered in the German Clinical Trials Register (No. DRKS00015326) on 30.10.2018.

Background

In addition to the physical burdens of medical treatment, cancer patients can be affected by psychological, social, and financial strains [1]. It is estimated that 52% suffer from psychological distress [2]. Moreover, cancer patients have high information needs throughout their trajectory [3]. Unfortunately, psychological and informational demands are the most unmet need domains in cancer patients [4–6].

Since 2003, healthcare institutions in Germany have been able to gain a certificate as cancer centres from the German Cancer Society; accordingly, psycho-oncological care provision is required [7]. Nevertheless, psycho-oncological services are still insufficiently integrated into routine cancer care. In 2008, the German Federal Ministry of Health set thirteen aims in the National Cancer Plan (NCP) [8]. Aim no. 9 clarifies that 'all cancer patients receive appropriate psycho-oncological care if needed' [8]. The NCP also demands that 'for all cancer patients low-threshold, target-group specific, and quality assured information are available' (aim no. 11b). Finally, in 2014, the German S3 guideline 'Psycho-oncological diagnostics, counselling and treatment of adult cancer patients' [9] was published. In addition to professional psycho-oncological care, the German NCP and guideline oblige that 'peers are closely involved in care provision' (NCP aim no. 7) [8], as peer support is considered an integral part of the psychosocial care of cancer patients [9].

Peer support in cancer care

In healthcare, peer support is differentiated into different types like emotional, informational, and practical support [10–12]. Furthermore, peer interventions can be distinguished based on their aims, such as providing information as an education-based intervention [12], facilitating health outcomes through social support [11, 12], or increasing self-efficacy so that patients are empowered to engage in beneficial health behaviours [10, 12]. One of the most frequent peer support mechanisms is based on "experiential knowledge" [13], which incorporates practical information and advice while authentically capturing the patient's individual situation and needs. Peer supporters also differ from professional service providers in their ability to talk to patients in ways they understand [13]. Watson [14] identified the 'use of lived experience' as the strongest mechanism of peer support. Sharing emotions makes patients feel understood, as they recognise that others have the same experiences, which facilitates hope [11, 14]. Furthermore, shared experiences define peer supporters' credibility and authenticity. Patients feel trust and a connection as long as communication with the peer supporter is on equal footing [14], and, therefore, they can open up to the peer supporter [11].

Peer support for cancer patients is mostly done in face-to-face group settings [15]. The offers found in the literature address especially breast cancer patients [15, 16]. In Germany, a

systematic integration of peer support into cancer care is still pending [15]. Nevertheless, the psychosocial benefits of peer support for cancer patients are described similarly across different studies. It has been reported that patients gained experienced-based knowledge of cancer and its treatment (informational support) [15, 17–19], were more confident when interacting with professional service providers [17, 19], felt less isolated (social support) [17, 18], improved their coping strategies [15, 17–19], and experienced increased self-efficacy [15, 19].

Regarding the different types of peer support, Hoey et al. [20] found one-to-one, face-to-face peer support to be one of the most effective peer support models. Systematic reviews concerning one-to-one peer support in cancer care and mental healthcare reveal high patient satisfaction [16, 21, 22]. They also indicate that this type of intervention can reduce anxiety [21] and emotional distress [16] and increase empowerment [22].

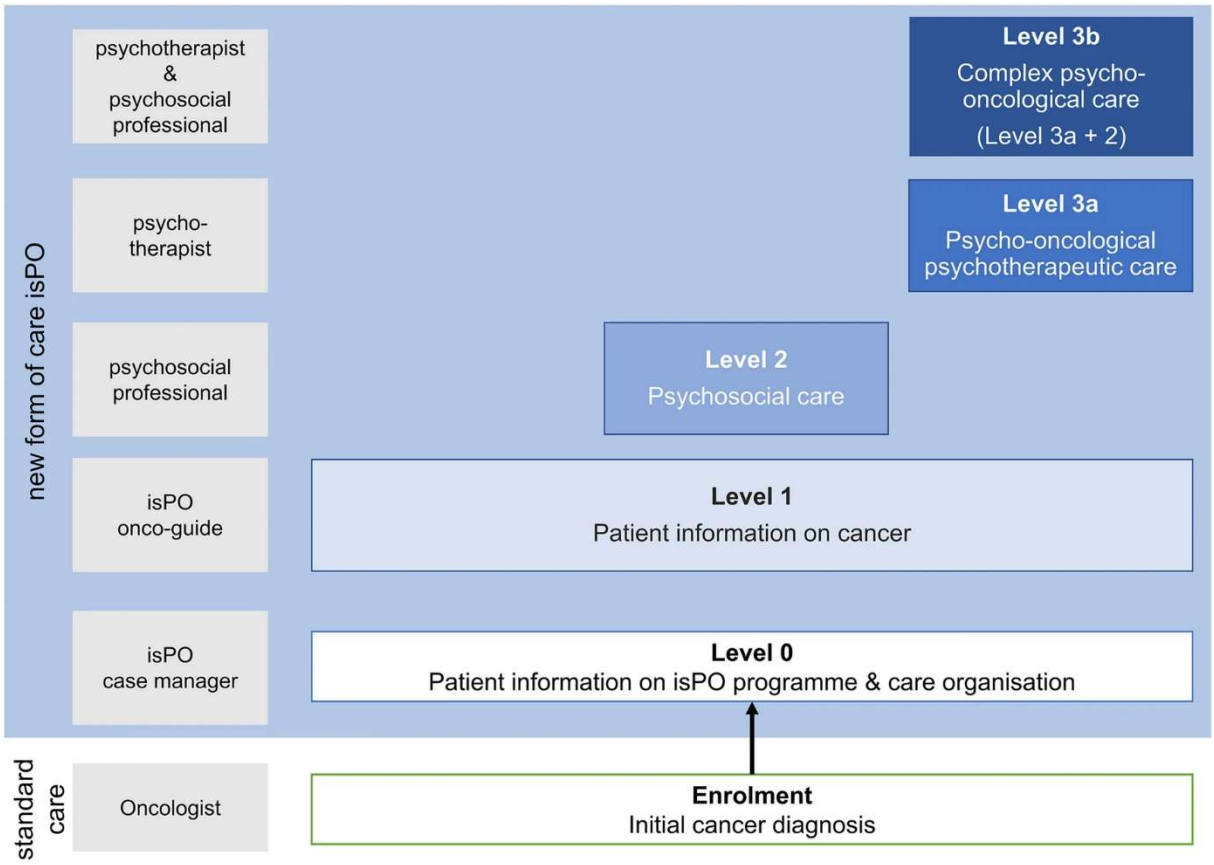
Despite the requirements of the German NCP and the psycho-oncological guideline, and the evidence for the benefits of one-to-one peer support in cancer, the number of programmes that systematically include such support is quite limited in Germany. They are mostly restricted to offers in the inpatient sector [23] or for adolescents and young adults [24, 25].

The new German form of care, 'integrated, cross-sectoral Psycho-Oncology' (isPO) [26], uses one-to-one peer supporters called isPO onco-guides (isPO OGs) as an integral part of psycho-oncological care in order to fill this gap. In the isPO project (10/2017–03/2022), the eponymous new form of care was developed and implemented. It was comprehensively externally evaluated (prospective, formative, and summative) by a multidisciplinary team [27–32].

The isPO onco-guide: a psycho-oncological one-to-one peer support

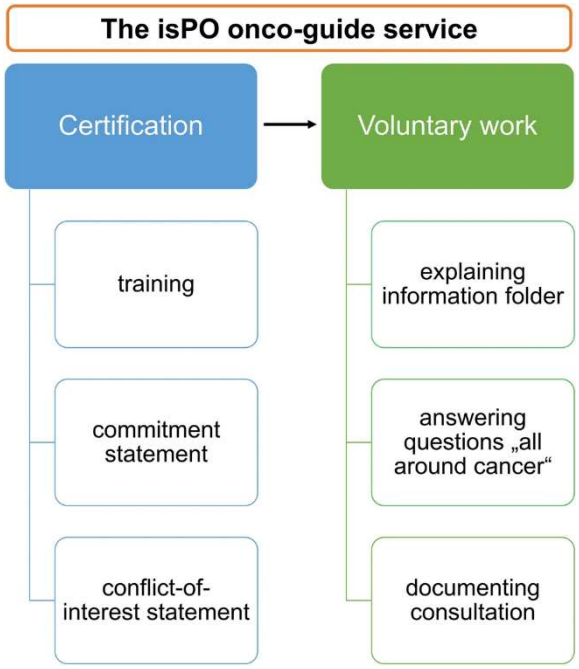
Within isPO, newly diagnosed cancer patients receive psycho-oncological care for up to twelve months in a stepped-care approach. At the beginning of the care trajectory, every patient is assigned to a specific care level in accordance with the individual depression and anxiety level captured with the Hospital Anxiety and Depression Scale (HADS) [33] and the psychosocial care needs measured with the newly developed and validated psychosocial risks scale [34]. Figure 1 displays the isPO care levels and their corresponding service provider groups.

Figure 1. The isPO care levels and service providers. Adapted from Salm et al. (2022)



The new form of care isPO was implemented in January 2019 in four care networks in North Rhine-Westphalia, Germany. Every isPO care network comprises a cancer centre hospital and adjoint oncological outpatient practices. The hospitals differed in their location (metropolis, big city, middle city), their size (hospital of maximum care or standard care), and their teaching status (e.g. university hospital, academic teaching hospital). All of the hospitals offer acute care. Care level 1 is offered to every enrolled patient independent of the patient's depression and anxiety level, which makes it a low-threshold service. It contains the provision of psychosocial support information by an isPO OG. isPO OGs are cancer survivors whose cancer treatment goes back at least one year. They are trained and certified for their voluntary work (Figure 2). Services at levels 0, 2, 3a, and 3b are delivered by professional service providers (isPO case managers, psychosocial professionals, and psychotherapists) who are staff in the cancer centre hospitals of the care networks.

Figure 2. Overview of the isPO onco-guide certification requirements and voluntary work tasks



isPO OG certification

The isPO OG training consists of a five-hour seminar and covers four topics: (1) the new form of care isPO; (2) the role of the isPO OG; (3) exercises to facilitate conversation; and (4) documentation of the isPO OG consultations. The training was conducted by a patient representative of the cancer self-help umbrella organisation, House of Cancer Patient Support Associations of Germany (HKSH-BV), and a psychotherapist from the isPO development team. Aside from completing the training, cancer survivors must sign a commitment and a conflict-of-interest statement to obtain the certification as an isPO OG. The HKSH-BV oversees the acquisition, training, and certification, and was involved in developing the isPO OG care concept. The umbrella organisation forwards the data of certified isPO OGs to the respective isPO care network where the isPO OG wants to do their voluntary work.

isPO OG voluntary work

According to the isPO care concept, isPO OGs can offer up to two face-to-face consultations to every newly diagnosed cancer patient enrolled in the isPO programme. An isPO case manager who serves as a contact person for the patient throughout the 12 months in isPO coordinates the appointment between the patient and the isPO OG (Figure 1). This consultation should be conducted in the cancer centre hospital as soon as possible after enrolment into isPO, and it should last a maximum of 45 min. The isPO case manager is also responsible for preparing the consultation-relevant documents. These consist of a conversation guideline and documentation sheet for the isPO OG and an information folder for the patient, which contains information on community-based psychosocial support services (according to the patient's postal zip code),

contact information for non-profit peer support groups, and services offered by the patient's statutory health insurance.

During the consultation, the isPO OG provides the information folder and reviews it with the patient for a comprehensive orientation. Moreover, patients' questions 'all around cancer' are answered except regarding medical and social legal advice. If the patient requests, the isPO OG may reflect upon their cancer care trajectory and experiences. In addition to providing information, the isPO OG acts as an authentic example that living with cancer is possible. Furthermore, they enable a conversation on equal footing. As the isPO OG service provides general information that may be relevant to all cancer patients, matching isPO OGs with patients with the same cancer type is not mandatory.

After the consultation, the isPO OG conducts the documentation on the prepared sheet and assesses their personal experience of the consultation's quality. The written documentation is forwarded to the isPO case manager, who inputs the data into the isPO-specific IT documentation and assistance system CAPSYS^{2020}. If no certified isPO OG is available for a specific appointment, an isPO case manager who has obtained the isPO OG training may conduct the appointment. This is also true for patients who do not want a consultation with an isPO OG, so information provision is secured for all patients.

Objectives

Beyond the evaluations of one-to-one peer supports in cancer care in Germany [23, 24], we aimed to evaluate the isPO OG service as an integrated peer support within a psycho-oncological care programme. The evaluation design of the entire isPO programme and, thus, of the isPO OG service was based on the Medical Research Council framework for the evaluation of complex interventions [27, 28, 35]. The focus is therefore on (1) implementation facilitators and barriers, feasibility and reach of the isPO OG service, (2) the acceptance and satisfaction of patients, isPO OGs, and professional service providers, (3) the different isPO care networks as the context, and (4) the health outcomes at patient level.

Methods

The evaluation of the isPO OG service was part of the comprehensive evaluation of the overall isPO programme [27]. Therefore, all the methods mentioned below—apart from data collections with the isPO OGs—were aimed at the isPO programme as a whole and not solely focused on the isPO OG service. The evaluation followed a mixed-methods approach with a concurrent qualitative and quantitative design (QUAL + QUANT) [36]. The perspectives of three different groups were considered: (1) isPO patients (end-users), (2) isPO OGs (peer service providers), and (3) professional isPO service providers. Integrating multiple perspectives and methods

permits thorough insights into the different experiences, opinions, and processes in implementation reality [37–39]. Different data sources on the isPO OG service were utilised for the three groups, as shown in Figure 3.

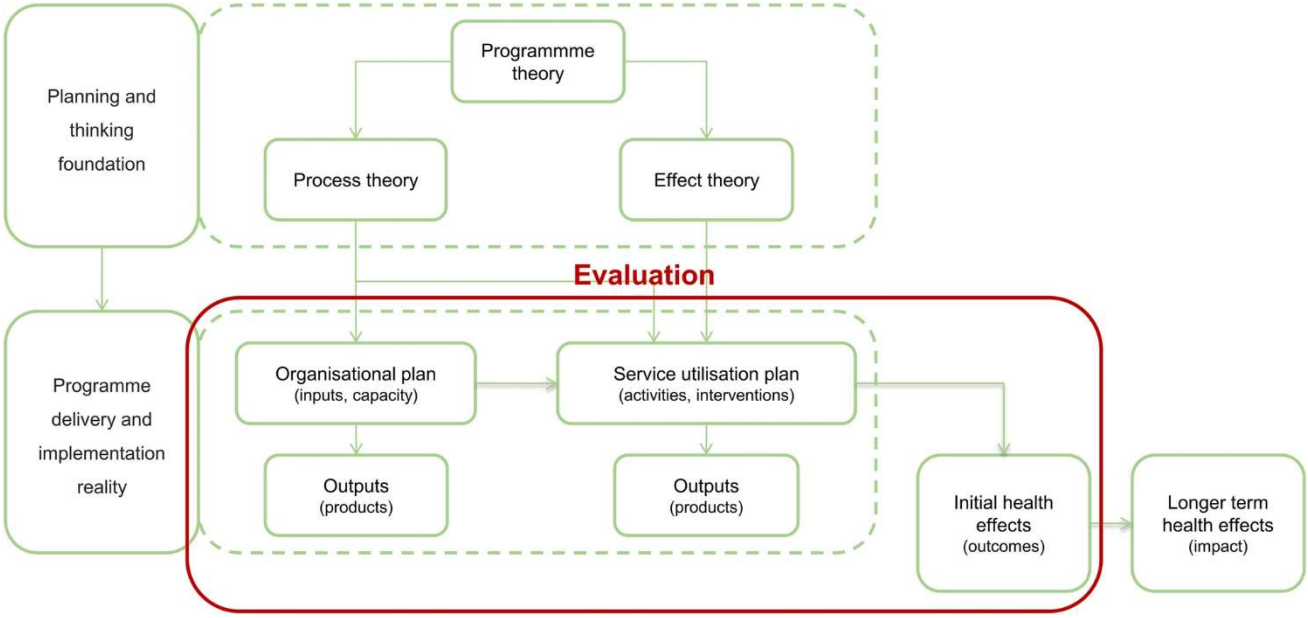
Figure 3. Data sources of the multi-perspective isPO onco-guide evaluation

Perspective	End-users		Comparison of end-users' and peer service providers' outcome assessment		Peer service providers		Professional service providers
Person group	newly diagnosed cancer patients		newly diagnosed cancer patients	isPO onco-guides	isPO onco-guides		isPO case managers, psychosocial professionals, psychotherapists, network coordinators, head psycho-oncologists
Data source	QUANT	QUAL	QUANT		QUANT	QUAL	QUAL
	Survey (n = 996) isPO care data (n = 1.757)	Semi-structured interviews (n = 23)	isPO care data (n = 1.757)	isPO care data (n unknown due to anonymization)	Survey (n = 17)	Semi-structured interviews (n = 5) Focus group (n = 8)	Semi-structured interviews (n = 8) 6 Focus groups (n = 34)
Focus	Care quality of isPO (satisfaction) Utilisation and assessment of isPO OG consultation	Experiences with isPO care programme	Assessment of isPO OG consultation from both perspectives		Care quality of isPO (training, satisfaction with voluntary work)	Experiences with voluntary work as isPO OG	Experiences with implementation and care provision in the isPO care programme

Cancer patients could be enrolled into the isPO programme if they met the following inclusion criteria: new cancer diagnosis in one of the four isPO care networks, legal age ≥ 18 years, statutory health insurance, sufficient knowledge of the German language, and a clinical situation that enabled isPO care to be provided.

The following will report the methodological procedures separately for the qualitative and quantitative methods. They were also analysed independently and will be compared and integrated into the discussion [38]. The analysis and integration process were guided by the programme theory of Issel and Wells [40] as the development of the new form of care isPO was based on this framework (Figure 4).

Figure 4. The programme theory of Issel and Wells with the embedded evaluation



According to Issel and Wells [40], the evaluation of a health programme incorporates the assessment of (1) the resources that are required, for example, personnel (Organisational plan), (2) the processes needed to provide the care services like patient acquisition and work flows (Service utilisation plan), and (3) the health outcomes induced by care provision (Initial health effects). Moreover, the components 'Organisational plan' and 'Service utilisation plan' are divided into 'Inputs' and 'Outputs'. Inputs are the resources and processes that are available, while outputs describe the results. An input at the level of 'Organisational plan' is, for example, the number of recruited staff; and a possible output is the work satisfaction. Regarding the 'Service utilisation plan', an exemplary input is the plan for care provision and an output might be the intervention coverage.

Results from qualitative and quantitative methods which belong to the same dimension were contrasted to examine if the results corroborate or contradict each other, or whether quantitative results can be explained with the help of qualitative findings.

Qualitative methods

Sampling

The qualitative methods of the isPO OG evaluation contained the analysis of semi-structured interviews and focus groups with patients, isPO OGs, and professional isPO service providers. The acquisition of participants followed purposeful sampling [41] according to the completion of the isPO care programme, the coverage of the isPO care networks, and the coverage of the different service provider roles. This means for the patient interviews that participants should have had already completed their 12-month isPO care trajectory. Moreover, participants should

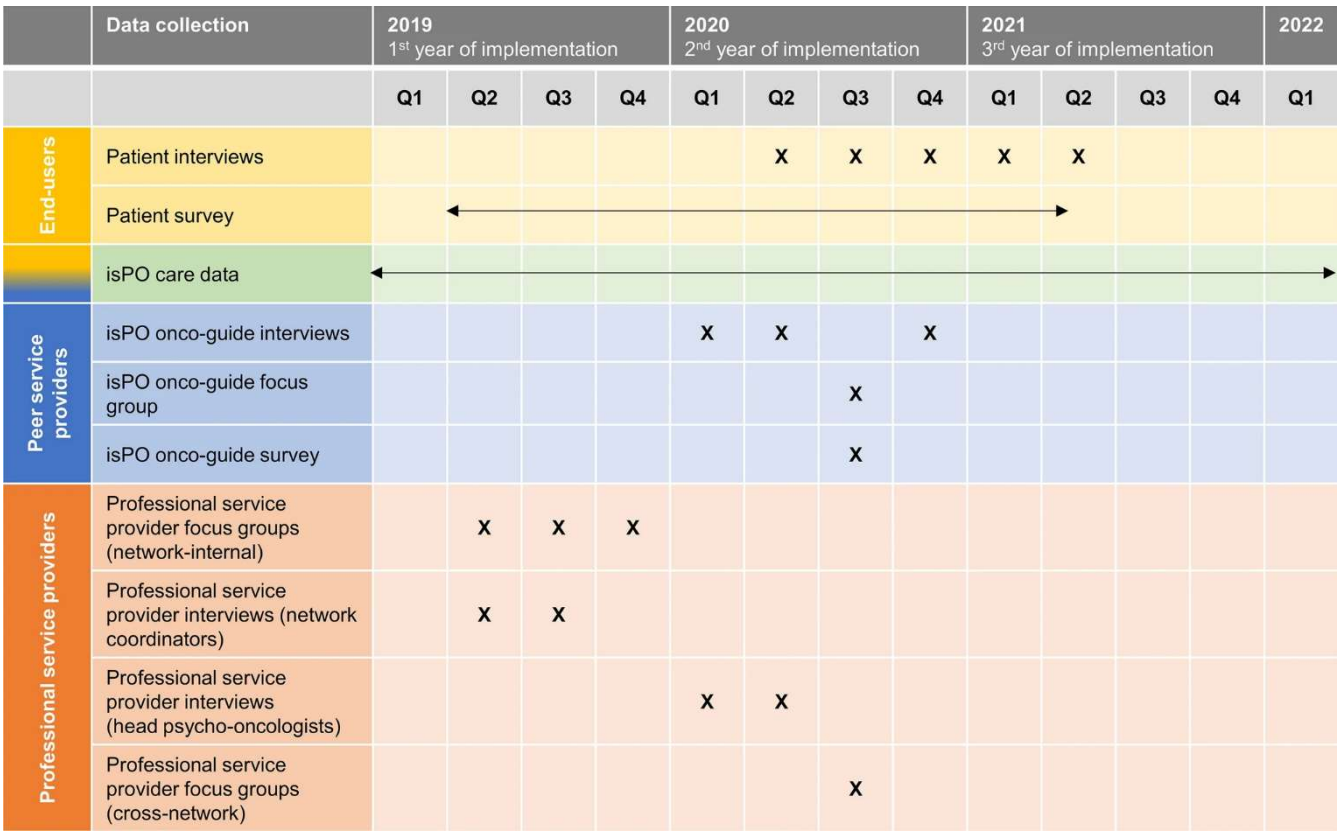
cover all four isPO care networks. This also applied to the interviews and the focus group with certified isPO OGs, the focus groups with professional isPO service providers on the care level (isPO case managers, psychosocial professionals, and psychotherapists), and the interviews with professional service providers on the managerial level (network coordinators and head psycho-oncologists of the isPO care networks).

Patients who were able to participate in an interview were acquired with the help of the care networks' psycho-oncologists. Then, the psycho-oncologists provided contact information for these selected patients to the isPO Trust Centre. The isPO Trust Centre ensured that the data exchange in the project was compliant with data protection regulations. It managed contact information of patients and service providers as well as pseudonyms for the different data sources to make data linkage possible. It was a unit within the institute responsible for the external evaluation of isPO but separated from the researchers both spatially and by personnel. For the interviews with isPO OGs, network coordinators and isPO case managers were asked to look for participants in their respective care network and provide their contact information. According to the isPO OG focus group, the HKSH-BV forwarded an invitation email from the evaluators to all certified isPO OGs so they could announce their participation to the isPO Trust Centre. The evaluators contacted the network coordinators and head psycho-oncologists directly. The network coordinators discussed within the team of the respective care network which members would participate in the focus groups with professional isPO service providers on care level and announced them to the evaluators. According to the purposeful sampling, it was requested that the participants cover professional service providers on all isPO care levels (isPO case managers, psychosocial professionals, and psychotherapists).

Data collection

Data collection for the isPO OG evaluation started from the beginning of programme implementation. The time sequence of all data collection activities is illustrated in Figure 5. All interviews and focus groups were conducted by the researchers of the external evaluation team. They were not involved in the development, implementation, and service provision concerning the isPO programme.

Figure 5. Time course of the data collections used for the isPO onco-guide evaluation



Patients

Patient interviews were conducted via telephone, as they took place during the COVID-19 pandemic in the second and third years of implementation. A semi-structured interview guideline was developed with the key topics 'from diagnosis to participation in isPO', 'assessment of the care programme', and 'overall assessment' (the key questions for all interview guidelines can be found in Online Resource 1). Four evaluators conducted the interviews, each responsible for one respective care network.

isPO onco-guides

Like the patient interviews, the interviews with isPO OGs were conducted via telephone by one evaluator (first author). A semi-structured interview guideline was used. The first author also functioned as head moderator of the isPO OG focus group and was supported by evaluation team members acting as co-moderator and recorder during data collection. The focus group took place in a seminar room in one of the care network hospitals. The same interview guideline was applied to the focus group and the telephone interviews. It contained questions on the topics of 'admission and training', 'tasks and experiences', 'assessment of the isPO OG concept', and 'assessment of isPO'. The interviews and focus groups were conducted in the second year of implementation.

Professional service providers

For each of the four isPO care networks, a focus group with the network-internal professional service providers on the care level took place in the respective care network hospitals. Moreover, all four network coordinators were interviewed during an isPO quality workshop or in their network hospital. Two members of the evaluation team, acting as head and co-moderator, conducted these eight data collections within the first year of implementation. The semi-structured interview guidelines were similar and primarily contained questions on the implementation of the new form of care isPO and the communication and cooperation within isPO. The data collection described in the following occurred in the second year of implementation. The interviews with the four head psycho-oncologists occurred during the COVID-19 pandemic and were conducted via telephone. Topics of the interview guideline were 'communication', 'assessment of the isPO care concept', and 'evaluation of changes due to the implementation of isPO'. The same evaluator conducted the four data collections per person group (professional service providers, network coordinators, and head psycho-oncologists).

Finally, one cross-network focus group each was performed with professional isPO service providers on the care level and the managerial level. Due to the COVID-19 pandemic and high workload, the participants could not travel on business for the focus groups. Therefore, they were conducted using video conferencing. In addition to the semi-structured interview guideline, a PowerPoint presentation was prepared with slides for each key question. The prepared topics were 'experiences towards the implementability of isPO during the different phases', 'facilitators for implementation', 'barriers for implementation', and 'prerequisites for the dissemination of isPO into routine care'. Three evaluators conducted the focus group: (1) a head moderator, (2) a recorder who filled in the PowerPoint presentation with keywords from the participants' statements, and (3) a technical supporter who also managed the chat posts.

Before every data collection, participants were informed about the procedure, and written consent was obtained. All interviews and focus groups described above were audiotaped. A professional service transcribed the audio material verbatim. For the focus groups, protocols for a change of speaker were created to facilitate the transcription. Before data analysis, transcripts were anonymised using replacements for names of persons and network locations; for example, [name of psycho-oncologist].

Data analysis

Content analysis was performed for all transcripts of the interviews and focus groups [42] using MAXQDA. First, a deductive coding system was developed. The head codes were 'Description of the isPO OG service', 'Facilitators', 'Barriers', and 'Suggestions for optimisation'. These four

categories were, in turn, divided into the components of the programme theory of Issel and Wells [40] for evaluation: 'Organisational plan—Inputs', 'Organisational plan—Outputs', 'Service utilisation plan—Inputs', 'Service utilisation plan—Outputs', and 'Initial health outcomes'. Then, all text passages in the patient and service provider data material that refer to the isPO OG service were identified. One network-internal focus group with professional service providers, one interview with a network coordinator, and two interviews with head psycho-oncologists could not be considered for further analysis because they did not contain statements on the isPO OG service. Sub-codes were derived inductively from the identified text passages and classified into the programme theory-driven coding system. Concerning the isPO OG interviews and focus group, sub-codes of the already performed analyses for the formative evaluation of isPO were also used and classified in the aforementioned coding system. Two evaluators were involved in the data analysis, consenting the coding system each time after the data material was coded for a certain perspective and after the coding was conducted for all transcripts (see Online Resource 2). Coded text passages were condensed, and connections between Input and Output sub-codes were identified.

Quantitative methods

Sampling

The quantitative methods considered the perspectives of isPO patients and isPO OGs.

All isPO patients who met the aforementioned inclusion criteria and gave consent to participate in the isPO study were considered for the evaluation. The network coordinators sent the contact information of all patients to the isPO Trust Centre on a monthly basis, as patients were enrolled into the isPO programme ongoing from 1/2019 to 3/2021.

Concerning the isPO OGs, all persons who obtained the training and had been certified were invited to the survey, regardless of whether they had already conducted conversations with patients (n = 45). As the HKSH-BV holds the contact information of all certified isPO OGs, it sent an invitation email to the isPO OGs on behalf of the evaluators. Persons who decided to participate in the survey shared their postal addresses with the isPO Trust Centre (n = 22).

Data collection

Three data sources were used for the quantitative methods of the isPO OG evaluation: 1) isPO care data of the IT documentation and assistance system CAPSYS^{2020}, 2) survey data of patients (three months after enrolment), and 3) survey data of isPO OGs (18 months after implementation beginning). The survey data used were collected cross-sectionally, whereas the isPO care data are longitudinal and stem from the isPO care documentation (secondary data).

isPO care data

The isPO care data were extracted quarterly from the isPO IT documentation and assistance system CAPSYS^{2020} by the network coordinators and transferred encrypted to the isPO data warehouse at the Institute of Medical Statistics and Bioinformatics, University of Cologne. The data exports from the four care networks were merged at the isPO data warehouse and the data was comprehensively processed to make it usable for research purposes. The prepared isPO care data were again transmitted encrypted from the data warehouse to the evaluators. The isPO care data contain information on sociodemographic characteristics, psychosocial situation, psycho-oncological screenings (e.g. HADS [33]), and the isPO care trajectory of all isPO patients participating in the study who completed their 12-month care in isPO. The isPO care data also include evaluation data on the isPO OG service from the perspectives of isPO OGs and patients. The isPO OGs conduct their assessment right after an appointment together with the consultation documentation, which the isPO case manager inputs into CAPSYS^{2020}. The patients receive a questionnaire by mail with the same items four months after enrolment during their intermediate psycho-oncological screening. After completion, they send the questionnaire back to their isPO case manager who enters the data into CAPSYS^{2020}. The items concerning the isPO OG service have been newly developed and are guided by the three dimensions of sense of coherence (comprehensibility, manageability, and meaningfulness) [43]. There is one item each for orientation, coping, and confidence.

Patient and isPO onco-guide survey

The surveys with patients and isPO OGs were conducted as paper–pencil questionnaires sent by the isPO Trust Centre to the participants along with a consent form. The questionnaire and consent form were filled in and returned to the Trust Centre in separate envelopes. According to Dillman's Total Design Method [44], up to three contact attempts were made. The isPO patient survey three months after enrolment contained, among others, items on the care by the different service providers, including a newly developed scale concerning satisfaction with the isPO OG service. This scale showed an excellent internal consistency (Cronbach's $\alpha = 0.904$). Furthermore, two validated scales on social support were used: OSS-3 [45] and BS6 [46]. Due to pseudonymisation, isPO care and survey data could be linked as an exact matching [47].

The isPO OG survey was conducted 18 months after the implementation of the new form of care isPO into the care networks started. The questionnaire contained newly developed items on the training, the conditions of the voluntary work, and work satisfaction (according to the short scale on life satisfaction by Beierlein et al. [48]), as well as a validated scale on the work-related sense of coherence (Work-SoC) [49].

All survey questionnaires were scanned using the software Teleform to create SPSS data files. These pseudonymised data were transmitted to the evaluators for processing and analysis. The time sequence of the isPO care data collection and the surveys is shown in Figure 5.

Data analysis

The following characteristic values describing the isPO OG service were computed from the variables of the isPO care data: percentage of patients who utilised the isPO OG service; date difference between enrolment and isPO OG consultation; percentage of patients who received an isPO OG consultation with a peer service provider; percentage of patients per reason isPO OG service was not conducted by a peer service provider; appropriateness of consultation timing; duration of the isPO OG consultation; percentage of patients who requested a second isPO OG consultation; to what extent the consultation helped in coping with cancer; to what extent it gave confidence; and to what extent it provided orientation.

For all these key figures, comparisons between the isPO care networks were conducted. X2-tests were computed for categorical variables and ANOVA for continuous variables. If variance homogeneity was not met, Welch statistics and Games-Howell post hoc tests were analysed.

Moreover, logistic regression analyses for the predication of utilisation were performed. Therefore, the isPO care data were linked with the patient survey data. The tested models were created according to the elements of Andersen's model of health services use: predisposing characteristics, enabling resources, and needs [50].

Model 1 (predisposing factors) contains the variables of age group, gender, and educational level, according to the International Standard Classification of Education [51]. We used age groups instead of an interval-scale age variable to identify possible non-linear relations.

Model 2 (enabling factors) consists of the predictor variables of partnership status, type of household, social support, and isPO care network.

Model 3 (need factors) takes into account tumour entity, depression and anxiety at the time of enrolment, and the assigned isPO care level.

For the items of the isPO OG assessment, which both patients and isPO OGs answered, paired t-tests were conducted to compare the perspectives. This covered the variables of the appropriateness of consultation timing, coping, confidence, and orientation.

From the patient survey, the scale 'satisfaction with isPO OG consultation' was analysed using ANOVA to compare isPO care networks.

The data of the isPO OG survey were analysed descriptively considering the volunteers' activity status, their workload in hours per week, their subjective workload, satisfaction with training, and satisfaction with the voluntary work.

According to the latter, Spearman's correlations were conducted for person-related and work-related variables. In the person-related analysis, age, gender, employment status, and level of previous experiences in cancer peer support were examined. The work-related analysis considered the objective and subjective workload, the number of consultations conducted, satisfaction with training, and work-related sense of coherence.

Analyses comparing the isPO care networks were not carried out for the isPO OG survey data, as the number of cases was insufficient.

To be able to present and interpret the results of the quantitative analyses according to Issel and Wells' programme theory [40], the key figures described above were assigned to the programme theory components (Table 1).

Table 1. Key figures of the isPO onco-guide evaluation located into the programme theory components stratified after patients' and isPO onco-guides' perspective

	Component of programme theory				
	Organisational plan – Input	Organisational plan – Output	Service utilisation plan – Input	Service utilisation plan – Output	Initial health effects
Perspective	**Key figures**				
Patients	-	-	Utilisation rate Time span between enrolment and consultation Consultation with peer service provider Reasons for consultation without peer service provider	Timing of consultation Request for further consultation Satisfaction with consultation	Coping Confidence Orientation
isPO onco-guides	Activity status	Objective workload Subjective workload Satisfaction with training Satisfaction with voluntary work	-	Timing of consultation Duration of consultation	Coping Confidence Orientation

All analyses were conducted using IBM SPSS Statistics 28.

Results

Qualitative results

The results of the qualitative analysis are based on 23 interviews with patients, five interviews and one focus group (n = 8) with isPO OGs, and five interviews and five focus groups (n = 30) with professional isPO service providers. The interviews took approximately 30–90 min; the focus groups lasted 1.5–3 h. The ages of participating patients ranged from 32 to 65 years; 69.57% were female, and 30.43% were male. Participating isPO OGs were 42–69 years old; 69.23% were female, and 30.77% were male. Due to data protection requirements, sociodemographic characteristics of professional service providers were not collected.

Organisational plan (Resources)

Acquisition, training, and certification

Most of the isPO OGs had previous experience in cancer self-help or patient representation. This was one of the motivations for becoming an isPO OG, but the aspect of giving something back was also important. One isPO OG recalled how difficult it was to find relevant information as a cancer patient; therefore, they would now like to help others. To be suitable for voluntary work as an isPO OG, one must be "*psychologically stable*" (isPO OG; Interview; ID1; care network 1) and have "*overcome one's cancer*" (isPO OG; Interview; ID3; care network 2). How the cancer survivors became aware of the isPO OG voluntary work opportunity are manifold and include mail distribution lists of self-help organisations, personal enquiry, or knowing an already active isPO OG.

Completing a training course is a basic requirement for the certification as an isPO OG. Many isPO OGs described the course as "*superficial*" (isPO OG; Focus group; ID; care network 1) and "*too short*" (isPO OG; Interview; ID7; care network 1), even though they stated that the provided conversation guideline was helpful. They desire the expansion of topics such as conducting a conversation and the provision of continuous training. The way patients and professional service providers reflect on the experience with the isPO OGs in their voluntary work makes their training satisfying.

Infrastructure and human resources

According to the isPO OGs, the infrastructure available differs depending on the care network. In care network 2, the isPO OGs have a designated room for consultations with prepared information folders in individual patient bags. In care networks 1 and 3, room facilities are scarce, which was also mentioned by the professional service providers, or the consultations take place in different hospital departments. In this case, the information folders are either deposited on the corresponding ward or must be collected from the isPO case management at a fixed location.

Whether the isPO OGs receive an allowance for their work also depends on the care network. From care network 1, it was reported that no costs were covered; in care networks 2 and 3, travel costs were reimbursed, or a voucher for the staff canteen was handed out.
Patients and professional service providers of all care networks reported situations when no isPO OG was available for a consultation. Additionally, the isPO OGs asked for the expansion of the isPO OG teams in their respective care network so "*that one can provide even better support for every patient*" (isPO OG; Focus group; ID4; care network 3). From care network 4, it was reported that no isPO OG was active, although two persons were trained and certified. isPO case managers from care networks 3 and 4 described that they take over the isPO OG consultations on a regular basis.

Coordination and cooperation lines

According to professional service providers, isPO case management coordinates the scheduling of appointments between the patient and the isPO OG in most care networks (1, 2 and 3). As the isPO OGs are volunteers and not regular staff, WhatsApp groups were created out of necessity to facilitate this process. An isPO OG from care network 2 reported that they support the isPO case management as a contact person from the isPO OG team concerning the coordination. From this care network, the isPO OGs stated that they feel considered as part of the psycho-oncological team of the hospital:

> "*So, we as isPO OG, we get along very well, but also [names of isPO case managers] - all is so well integrated. We don't feel like an annoying appendage that simply has to be done, but we really feel very valued. Also, when there are things to be done in the hospital, we are heard at least and can also give our voice to some extent*" (isPO OG; Interview; ID2; care network 2).

The professional service providers from care network 2 also reported that cooperation was established between the isPO case management and the isPO OGs. Furthermore, joint quality management circles have been conducted.

In care network 1, the team of isPO case managers is so large that the isPO OGs complained of not knowing every person and feeling less supported and valued. Therefore, they suggested that there should be a permanent contact person for the isPO OGs.

Another mentioned barrier for the cooperation between the isPO case management and isPO OGs in care network 3 was confusion about the distinct roles and tasks within isPO itself:

> "*For a long time, we weren't able to say concretely what we were going to do and when*" (Professional service provider; Focus group; ID1; care network 3).

This resulted in a sceptical attitude towards the isPO OG concept and its implementability in general, which also applies to care network 4.

At the level of the organisational plan, the isPO OGs of all care networks have repeatedly expressed the wish to increase the possibilities for exchange. This concerns, on the one hand, meetings with professional (psycho-)oncological service providers as well as (group) supervision with psycho-oncologists and, on the other hand, the exchange between the isPO OGs, which does not yet take place in an organised way.

Based on the results presented above, connections are made between the sub-codes of the categories 'Organisational plan—Input' and 'Organisational plan—Output'. These are summarised in Table 2.

Table 2. Identified consequences between 'Organisational plan—Input' and ‚Organisational plan—Output' sub-codes

Organisational plan – Input		Organisational plan – Output
Further training for isPO OGs	→	Accurate and continuous training
Number and availability of isPO OGs	→	isPO case manager acting as isPO OG
Cooperation lines between isPO OGs and professional service providers	→	Integration of isPO OGs in isPO service provider team Exchange between isPO OGs and isPO case managers Support of isPO OGs by professional service providers Optimisation of cooperation with professional service provider team
Lack of clarity on isPO OG role and tasks	→	Reservations of professional of service providers towards isPO OG service

Service utilisation plan (Resources)

Coordination

The isPO OGs describe different processes for the care networks regarding the coordination of consultations. In care network 1, the isPO case management calls the isPO OG to ask whether they can take over a particular appointment. In care network 2, an isPO OG as a representative receives the appointment requests from the isPO case management and forwards them to a WhatsApp group of the isPO OGs so that the volunteers can answer. In care network 3, the process is similar, but the isPO case management forwards the appointments to a WhatsApp group. The professional service providers from care network 2 report that their workflow is well established. According to the professional service providers from care network 3, the coordination of the isPO OG consultations is very time-consuming and "*costs effort*", so it is

perceived as "*more efficient*" if the isPO case managers themselves carry out the "*consultations in 15 min*" with the patient (Service provider; Focus group; ID5; care network 3).

Timing, duration, and frequency

The timing of the isPO OG service within the care trajectory varies depending on the patient's preference and understanding of this voluntary service offer; therefore, timing is perceived differently in its appropriateness. The isPO OGs report that most patients have already started biomedical oncological treatment before they receive the isPO OG consultation. From the patient's perspective, different timings were reported depending on the care network. In care networks 1 and 3, the consultation took place shortly before discharge from the hospital; in care network 2, at the beginning of oncological care. Particularly regarding information provision, the isPO OGs welcome the earliest possible timing as specified in the care concept. On the other hand, some patients report that the timing was too early for them to make contact with a peer and that they, therefore, rejected the isPO OG consultation. The professional service providers of care network 4 also mentioned that it was "*too much*" (Service provider; Interview; ID4; care network 4) for the patients.

Regarding the duration of the consultations, the isPO OGs of care networks 1, 2, and 3 state that they are at least 45 min and sometimes up to 90 min. According to the isPO OGs, adequate time is needed to understand the patient's situation and needs. Therefore, the limitation to a maximum of 45 min, as stated in the training, is viewed critically.

The experiences of the isPO OGs are mixed as to whether, according to the concept, one or a maximum of two consultations are sufficient. It depends on the needs of the individual patient. Therefore, they suggest keeping the frequency of consultations flexible, similar to the duration.

Communication and understandability

Another reason patients refused to utilise the isPO OG consultation was that they did not understand what this care offer was about. For example, patients reported that they assumed it was a self-help group or that it was explicitly about the isPO OG sharing their experiences and medical history rather than providing general information. An important prerequisite is that the professional service providers inform the patients about the isPO OG consultation accordingly. Two patients from care network 4 stated that they were not informed about the isPO OG service at all. Additionally, it can be seen from the patients' descriptions that misunderstandings occur among the professional service providers, which are then passed on to the patients, leading to refusal:

> "*It (Note: the isPO OG service) was introduced to me immediately at the first appointment by my counsellor, that this exists. She had, I think, two ladies, but*

> *they both had breast cancer and I have a completely different disease, so that it would probably not fit with me in terms of the topics we would talk about. She informed me about it and said that she could of course establish contact if I wanted to, but she also said that it probably wouldn't be a good fit in terms of the disease and the topics that we would deal with. I saw it the same way, so I didn't make use of it.*" (Patient; Interview; ID9_2; care network 4)

Utilisation experiences

When the isPO OG consultation takes place, patients appreciate that they are provided with information on support services as explained by the isPO OG. Several isPO OGs report that such a folder with relevant, reliable, and accurate information would have helped them at the time of their cancer diagnosis.

In this way, the isPO OGs act as authentic gatekeepers for psycho-oncological care and other support services for newly diagnosed cancer patients:

> "*That this consultation is also the beginning for some people: 'OK, to what extent can I perhaps open up or may I face my fears or what is coming up for me?' That sometimes people don't even think about the possibilities beforehand and that through these consultations, this is consolidated or perhaps a bit of encouragement is given as to the direction in which it can go to get help.*" (isPO OG; Interview; ID4; care network 3)

For the isPO OGs, the consultation does not consist exclusively of the provision and explanation of the information folder, even though the isPO care level 1 is called "*patient information*". Rather, the information folder is the entry point into the consultation because it then "*often leads to very personal questions that are asked, or people tell us how they have been. So, it often becomes more personal, I think*" (isPO OG; Interview; ID4; care network 3).

By condensing the qualitative data to the level of 'Service utilisation plan' as just presented, the conclusions between 'Input' and 'Output' sub-codes shown in Table 3 are drawn.

Table 3. Identified consequences between 'Service utilisation plan—Input' and 'Service utilisation plan—Output' sub-codes

Service utilisation plan – Input		Service utilisation plan – Output
Initiation and coordination of isPO consultation	→	Established workflow Service coordination
Predefined duration of consultation	→	Duration of consultation per patient
Frequency of consultations per patient (according to care concept)	→	Frequency of consultations per patient (as needed by patients)
Timing of isPO OG service/within care trajectory	→	Refusal by patients
Lack of understanding by professional service providers Missing information by professional service providers	→	Lack of understanding by patients Refusal by patients
Provision of relevant, reliable, and accurate information	→	isPO OGs as gatekeeper for psycho-oncological care Importance of information folder

Initial health effects

Through the isPO OG consultation, patients can talk to someone who has had authentic cancer experiences (peer). This brings the potential for new, supportive social contacts. Unlike professional service providers, the isPO OGs have their experiential knowledge, so the patients feel understood. As cancer survivors, the isPO OGs are an encouraging example that living and coping with cancer is possible. Patients, isPO OGs, and professional service providers shared this view (Table 4).

Table 4. Interview/focus group quotes from different perspectives regarding the category 'Initial health effects'

Exemplifying quotes for the category 'Initial health effects'		
Patients	**isPO onco-guides**	**Professional service providers**
"It was somehow very reassuring for me to see this person (*Note: the isPO OG*) in front of me, who you would never have thought had been through such a difficult time, who is just shining, looking healthy, being there with full concentration to conduct this consultation. That was just a very, very wonderful experience." (ID2_2; care network 1)	"And I notice that they (*Note: the patients*) get a bit of hope, that they think 'Ah, maybe I'll be lucky too. There's someone sitting here who has made it and why shouldn't I be able to achieve the same?'" (ID1; care network 1)	"'I recognise someone for whom it has moved on, so it can also move on well for me.' That's comforting to know." (Focus group; ID3; care network 2)

Quantitative results

In total, 1,757 newly diagnosed cancer patients participated in the isPO study. Their age ranged from 18 to 93 years (*M* = 57.34 years; *SD* = 13.36 years); 61.9% were female, and 38.1% were male. The majority of patients had an upper secondary education level (68.7%). The most frequently documented tumour entity was breast cancer (24.9%). Participant characteristics are presented in detail in Table 5. Of 1,599 patients invited, 994 took part in the survey (response rate: 62.2%).

Table 5. Characteristics of isPO patients per care network

Care network (CN)	Total (*n* = 1,757)	CN 1 (*n* = 1,036)	CN 2 (*n* = 235)	CN 3 (*n* = 257)	CN 4 (*n* = 229)
Characteristic	%	%	%	%	%
Age group (years)					
18-29	3.4	5.1	0.9	1.2	0.4
30-39	7.9	11.1	3.8	2.7	3.5
40-49	12.7	15.0	8.5	8.9	10.9
50-59	29.4	29.2	32.3	28.0	28.8
60-69	29.0	24.4	35.3	33.5	38.4
70-79	14.3	12.1	17.9	19.8	14.8
≥ 80	3.3	3.2	1.3	5.8	3.1
Gender					
female	61.9	58.4	52.8	73.9	73.4
male	38.1	41.6	47.2	26.1	26.6
Educational level					
Primary education	1.9	1.3	4.1	2.0	2.7
Lower secondary education	7.3	7.3	5.9	6.9	9.0
Upper secondary education	68.7	64.0	80.6	75.5	71.2
Bachelor or equivalent	6.7	7.6	2.3	6.1	8.1
Master or equivalent	14.0	18.2	6.3	8.6	8.1
Doctoral or equivalent	1.3	1.7	0.9	0.8	0.9
Tumour entity					
Head and neck	3.8	5.0	6.2	0.0	0.0
Oesophagus/stomach	6.4	9.4	1.8	3.2	0.0
Colon/rectum	6.0	4.9	7.5	9.7	5.4
Liver	1.2	1.4	0.9	2.0	0.0
Pancreas	2.7	3.7	2.6	0.8	0.0
Lung	10.1	5.2	22.9	25.4	2.0
Malignant melanoma	5.7	9.1	1.8	0.0	0.0
Breast	24.9	15.0	17.2	50.4	52.0
Female genital organs	5.7	6.2	2.2	4.4	8.4
Prostate	3.2	2.4	4.0	0.0	10.9
Kidney/urinary tract	1.1	0.5	1.8	0.0	5.0
Bladder	1.7	0.4	6.6	0.0	4.5
Hematologic malignancies	11.3	14.9	11.9	3.2	2.0
Other	16.2	21.9	12.8	0.8	9.9

Seventeen isPO OGs took part in the survey (response rate: 77.3%). The mean age was 56.35 years (*SD* = 10.65 years; range: 37–72 years). 70.6% of the participants identified as female, and 29.4% as male. Most isPO OGs were employed full time (41.2%) and have been actively involved in cancer self-help for 1–2 years (47.1%) (Table 6).

Table 6. Participant characteristics of the isPO onco-guide survey (*n* = 17)

Characteristic	***M* (*SD*)**
Age (years)	56.35 (10.65)
	%
Gender	
female	70.6
male	29.4
Employment status	
full-time employed	41.2
part-time employed	5.9
marginally employed (e.g., so-called 450 € job)	5.9
retired due to reduced earning capacity	17.6
retiree	29.4
Actively involved in cancer self-help for…	
< 1 year	11.8
1-2 years	47.1
3-5 years	11.8
6-10 years	17.6
> 10 years	11.8

Organisational plan (Resources)

Of the 17 certified isPO OGs who participated in the survey, 13 conducted consultations with isPO patients. This resulted in an activity status rate of 76.5%. The mean number of conducted consultations was 17.69 (*SD* = 14.14; range: 1–45). The isPO OGs report that they engage up to two hours per week in their voluntary work (92.9%; objective workload). Most of them state that they perceive this workload as "just right" (58.5%; subjective workload), while 5.9% assessed the workload as "too high" and 11.8% as "too low".

A proportion of 76.5% would have liked more training for the isPO OG work. The item that asked whether the previous training was sufficient was answered as follows: 21.4% reported "little", 64.3% "quite", and 14.3% "totally".

The scale of the satisfaction with the isPO OG voluntary work ranged from 1, "totally dissatisfied" to 10, "totally satisfied". The mean value was 6.31 (*SD* = 2.81; range: 1–10).

Table 7 presents the results of the Spearman's correlation analyses for work satisfaction with person-related and work-related variables.

Table 7. Results of Spearman's correlation analyses of the isPO onco-guides' work satisfaction and person-related and work-related variables

Variable	r_S	p
Person-related variables		
Age	.117	.704
Gender	-.216	.478
Employment status	.142	.642
Activity in cancer self-help	-.059	.847
Work-related variables		
Objective workload (hours per week)	.197	.518
Subjective workload	.354	.235
Number of conducted consultations	.011	.971
Request for further training	.175	.568
Sufficiency of training	.277	.360
Work-related sense of coherence	.618	.024*
Work-related sense of coherence – comprehensibility	.431	.142
Work-related sense of coherence – meaningfulness	.337	.260
Work-related sense of coherence – manageability	.625	.022*

Notes. *$p < 0.05$

While no significant linear correlations could be observed for person-related variables, significant positive correlations were found with the overall work-related sense of coherence score and its manageability subscale. The higher the work-related sense of coherence and manageability, the higher the work satisfaction and vice versa.

Service utilisation plan (Processes)

The percentage of isPO patients who made use of the isPO OG consultation (utilisation rate) ranged from 61.9% (care network 1) to 96.6% (care network 2). Care network 2 was also the network with the highest rate of consultations conducted by an actual isPO OG peer service provider (84.1%); care network 4 had the lowest rate (3.4%). Across all care networks, the most frequent reason for a consultation not having been conducted by a peer service provider but instead by a professional service provider was "no isPO OG available" (86.0%). The highest rates were observed for care networks 3 and 4 (99.3% and 94.6%, respectively). It was documented that most patients did not request a further consultation (68.9%). The distribution across care networks was significant for all the aforementioned key figures with $p < 0.001$. Details on the analyses are presented in Table 8.

Table 8. Results of the X^2-test and ANOVA for comparison of isPO care networks towards Service utilisation plan key figures

Care network (CN)	Total (*n* = 1,757)	CN 1 (*n* = 1,036)	CN 2 (*n* = 235)	CN 3 (*n* = 257)	CN 4 (*n* = 229)		
Key figure	**%**	**%**	**%**	**%**	**%**	X^2	*p*
Utilisation rate	70.9	61.9	96.6	90.3	63.8	168.60	< .001
Consultation with peer service provider	*n*=913	*n*=343	*n*=201	*n*=224	*n*=145	297.70	< .001
yes	50.8	66.2	84.1	28.1	3.4		
no	49.2	33.8	15.9	71.9	96.6		
Reasons for consultation without peer service provider	*n*=315	*n*=35	*n*=8	*n*=142	*n*=130	212.16	< .001
Peer service provider not wanted	14.0	91.4	50.0	0.7	5.4		
No isPO OG available	86.0	8.6	50.0	99.3	94.6		
Request for further consultation	*n*=456	*n*=219	*n*=169	*n*=63	*n*=5	23.23	< .001
yes	31.1	41.5	23.7	17.5	0.0		
no	68.9	58.4	76.3	82.5	100		
Key figure	***M* (*SD*)**	***M* (*SD*)**	***M* (*SD*)**	***M* (*SD*)**	***M* (*SD*)**	**Welch statistic**	***p***
Time span between enrolment and consultation (days)	*n*=1,173 51.50 (58.54)	*n*=591 69.12 (63.72)	*n*=227 34.15 (45.31)	*n*=219 51.62 (51.77)	*n*=136 3.65 (8.51)	261.69	< .001
Duration of consultation (minutes)	*n*=738 39.93 (19.86)	*n*=308 44.00 (24.61)	*n*=200 40.11 (16.11)	*n*=98 40.79 (16.01)	*n*=132 29.51 (8.10)	44.70	< .001
Satisfaction with consultation	*n*=689 3.39 (0.60)	*n*=356 3.38 (0.62)	*n*=122 3.24 (0.65)	*n*=143 3.49 (0.57)	*n*=68 3.54 (0.44)	6.06	< .001

Comparisons of care networks were also significant for the continuous variables 'Time span between enrolment and consultation', 'Duration of consultation', and 'Satisfaction with consultation (Table 8). Care network 4 had the lowest time span, with an average of 3.65 days, and care network 1 had the highest, with 69.12 days. Post hoc tests revealed significant differences between all care networks with $p > 0.001$. The average duration of consultation was lowest for care network 4 (29.51 min), which could also be observed in the post hoc tests in significant differences to the other three networks ($p < 0.001$ in each case). The newly developed scale on satisfaction with the consultation contains items with answers from 1 "totally disagree" to 4 "totally agree". Mean values of the satisfaction scale ranged from 3.24 for care network 3 to

3.54 for care network 4. Post hoc tests revealed significant differences between care networks 1 and 4 (p = 0.040), care networks 2 and 3 (p = 0.007), and care networks 2 and 4 (p = 0.001).

In addition to the analyses described above, logistics regressions for the utilisation rate were computed with regression models according to Andersen's model of health services use [50]. Model 1 with predisposing factors was significant (X^2 = 22.49; p = 0.004) with a variance explanation of Nagelkerke's R^2 = 0.019. Analyses of the odds ratios revealed gender and educational level as not significant, although die odds ratios of utilising the isPO OG consultation were at least two times higher for all age groups except > 80 years in comparison with the age group 18–29 years (Table 9).

Table 9. Results of the logistic regression analysis for the utilisation of the isPO onco-guide consultation

Regression models with predictors	OR	95% CI	*p*
Model 1: Predisposing factors (*n*=1,705)			
Age group (years)			
18-29[a]	-	-	-
30-39	2.03	1.08-3.82	.028*
40-49	2.24	1.24-4.07	.008*
50-59	2.77	1.59-4.83	< .001*
60-69	3.14	1.80-5.49	< .001*
70-79	2.33	1.29-4.20	.005*
≥ 80	1.80	0.85-3.80	.124
Gender			
female[a]	-	-	-
male	1.02	0.82-1.27	.890
Educational level	0.97	0.91-1.03	.334
Model 2: Enabling factors (*n*=905)			
Partnership status			
without a stable partnership[a]	-	-	-
in a stable partnership, living in the same household	0.95	0.46-1.95	.889
in a stable partnership, not living in the same household	1.61	0.74-3.51	.232
Type of household			
One-person household[a]	-	-	-
Couple/family household	1.14	0.55-2.37	.729
Multi-family household/shared living	0.48	0.18-1.27	.141
Other type of household	446565728.2	-	.999
Social support			
OSS-3	1.03	0.95-1.11	.530
BS6	0.98	0.94-1.03	.504
Care network			
1[a]	-	-	-
2	821995742.5	-	.995
3	16.24	6.53-40.38	< .001*
4	0.80	0.50-1.28	.346

Regression models with predictors	OR	95% CI	*p*
Model 3: Need factors (*n*=1,690)			
Tumour entity			
Head and neck	0.83	0.40-1.75	.629
Oesophagus/stomach	0.34	0.18-0.62	< .001*
Colon/rectum[a]	-	-	-
Liver	0.43	0.16-1.19	.104
Pancreas	0.63	0.29-1.39	.253
Lung	1.02	0.55-1.86	.962
Malignant melanoma	0.43	0.23-0.80	.008*
Breast	0.99	0.58-1.69	.968
Female genital organs	0.40	0.21-0.76	.005*
Prostate	1.73	0.68-4.39	.246
Kidney/urinary tract	0.76	0.25-2.37	.638
Bladder	1.22	0.41-3.62	.719
Hematologic malignancies	0.47	0.27-0.82	.008*
Other	0.46	0.27-0.80	.005*
HADS total score	0.99	0.97-1.01	.349
isPO care level			
1[a]	-	-	-
2	0.99	0.63-1.54	.960
3a	1.24	0.69-2.20	.474
3b	0.91	0.50-1.63	.740

Note. [a]Reference category *$p < 0.05$

Model 2 with enabling factors was also significant and had the highest variance explanation of all three models ($X^2 = 164.84$; $p < 0.001$; Nagelkerke's $R^2 = 0.250$). However, partnership status, type of household, and social support are not significant predictors. The odds ratio analysis showed a 16.24 times higher chance of utilisation for care network 3 than care network 1 (Table 9).

Model 3 (need factors) was significant as well ($X^2 = 72.78$; $p < 0.001$; Nagelkerke's $R^2 = 0.060$). Although the HADS total score and the isPO care level were not significant predictors, the chances to utilise the isPO OG service were significantly lower for patients with the tumour entities oesophagus/stomach, malignant melanoma, female genital organs, haematologic malignancies, and others compared to the reference entity colon/rectum (Table 9).

The isPO OGs and the patients assessed the appropriateness of the timing of the consultation. The scale ranges from 0, "too early" to 2, "too late". The mean value of the isPO OGs was slightly higher than those of the patients ($M = 1.14$ ($SD = 0.42$) and $M = 1.05$ ($SD = 0.60$), respectively). The paired t-test revealed the mean difference as significant ($t = 2.62$; $p = 0.009$).

Initial health effects

Along with questions regarding the timing of the consultation, patients and isPO OGs answered three assessment items concerning the consultation's effects on coping, confidence, and orientation. The scales ranged from 0, "totally disagree" to 5, "totally agree". For each of the three items, the isPO OG's mean value was higher than the patient's (Table 10). All paired t-tests were significant ($p < 0.001$).

Table 10. Results of the paired *t*-tests for isPO OG's and patient's assessment of the consultation effects

Variables	*M* (*SD*)	Mean difference	*t*	*p*
Coping – isPO OG	4.10 (0.91)	0.87	10.23	< .001
Coping – Patient	3.23 (1.40)			
Confidence – isPO OG	4.43 (0.83)	0.72	9.56	< .001
Confidence – Patient	3.71 (1.25)			
Orientation – isPO OG	4.02 (0.94)	0.56	6.60	< .001
Orientation – Patient	3.46 (1.43)			

Discussion

This study aimed to comprehensively evaluate the isPO OG one-to-one peer support by capturing the perspectives of patients, isPO OGs, and professional service providers, following a mixed-methods approach and the programme theory model of Issel and Wells [40]. To our best knowledge, this is the first study that applied this approach and thus offered insightful knowledge regarding the benefit of one-to-one peer support for newly diagnosed patients.

Figure 6 provides an overview of the positive and negative results of integrating the isPO OG service as one-to-one peer support according to the model components of Issel and Wells [40].

Figure 6. Condensed results of the isPO onco-guide evaluation

Organisational plan

The training for the isPO OGs was one of the relevant topics at the Organisational plan level. Both qualitative and quantitative results revealed that isPO OGs required more accurate and *comprehensive basic training*, particularly in facilitating conversation and deepening the topics in further courses (for example, differentiation from the concerns of the patients as a means of self-protection). The importance of the training was also underlined by the significant correlation between the work satisfaction of isPO OGs and the work-related sense of coherence scale manageability. Charles et al. [52] identified in their systematic review the most relevant topics for initial training of peer supporters in mental healthcare, including, for example, communication and peer support of worker well-being. These results correspond to the demands of the isPO OGs and underline their importance. In addition, appropriate training helps to prevent volunteers from burnout so that they can pursue their work for longer and, thus, secure the service in the long term [53, 54]. We recommend optimisation of the training curriculum due to the requirements in the field and ongoing supervision and intervention on a professional basis.

Across all perspectives and isPO care networks, there is agreement that the *size of the isPO OG teams* and the availability of volunteers for appointments are crucial factors for implementing the isPO OG service, which corresponds to one-to-one peer support programmes in the UK [55, 56]. Thus, the participatory development of a suitable, context-specific acquisition strategy, as well as measures of outreach and commitment of the isPO OGs to the voluntary work, is of particular importance to secure isPO OG service provision to avoid high staff turnover in the isPO OG team and to distribute the workload among all volunteers [57]. Regular and flexible supervision in the event of stressful patient conversations is considered helpful in this context [58]. Although the HKSH-BV, as a patient representative organisation, was assigned to the acquisition, among other things, its role, according to the project application, was to be exclusively advisory, which was also reflected in the approved personnel resources. We recommend allocating sufficient resources to these organisations to foster sustainability and make the service available to other care centres.

In contrast, the quantitative analyses revealed that some certified isPO OGs have not yet been appointed to any consultation. This may make them feel unappreciated, which could decrease their motivation to engage as an isPO OG in the future [59]. The ways of cooperation and the available *resources*, such as premises and allowances for the isPO OGs, are described very differently between the care networks. In care network 2, for example, the professional service providers have established a corresponding infrastructure. This may be due to their particular motivation and the convincing nature of the isPO OG service, as it was reported that the isPO OGs were involved in decisions towards implementation. Furthermore, joint quality

management circles were conducted, which were not even prescribed by the isPO care concept. Such team building and decentralised decision-making strategies express the readiness for change in this care network [60]. Nevertheless, it would have been necessary to involve the service providers in the development of the isPO programme to achieve a tailored implementation and sustainable changes in all four care networks [61]. We recommend establishing the isPO OG quality management circles introduced by care network 2 as a cross-network activity so that the isPO OGs and care networks can learn from each other to overcome challenges and reservations.

Service utilisation plan

Based on the reports of the professional service providers and the patient descriptions of the information about the isPO OG service, it appears that in care network 4, the voluntary service was not understood correctly and not perceived as an integral part of the isPO care programme. The particularly low utilisation rate also indicates this. Identified misunderstandings referred, for example, to the fact that matching a patient and isPO OG with the same tumour entity is not intended since the aim is to pass on information relevant to all newly diagnosed cancer patients. Patients' understanding of a complex intervention is considered a 'prerequisite for decision-making' [62]. However, these misunderstandings about the isPO OG service may, in turn, lead to a sceptical attitude that influences whether and how patients are informed about the service. Consequently, care network 4 had a significantly lower utilisation rate than the other three isPO care networks. Furthermore, the period from enrolment to isPO OG consultation was significantly shorter in care network 4 because the isPO case managers took over consultations, and, therefore, no appointment coordination between the patient and isPO OG was required. However, this procedure is inadequate for a one-to-one peer support concept.

Since the attitude towards a complex intervention is a relevant implementation factor [63], we recommend that the identification of respective barriers and facilitators and the involvement of the professional service providers should take place in the development phase. In this way, low commitment and resistance due to insufficient participation [28] and training [64] might be mitigated, while a tailored and stepwise implementation will be fostered [61].

Almost all other age groups had a significantly higher chance of utilising the isPO OG consultation than 18–29-year-olds. However, this age group is only represented to a very small extent in the sample. Another reason is that young adults may have specific questions and needs [65] that they would prefer to discuss with peers of the same age.

Patients with tumour entities with a significantly lower probability of using the isPO OG service were treated almost exclusively in care network 1. In this hospital, patients with particularly complex and demanding cases are treated. Moreover, it has a large coverage area

and short lengths of stay, which may lead to patients being unable to use the isPO OG service depending on distance and mobility. An extension of the service to local outpatient options such as cancer counselling centres and online support via an app could be supportive.

The *timing* of the isPO OG consultation within their individual cancer care trajectory was an aspect that led to a refusal by some patients [17, 66]. Patients explained that a conversation with a peer shortly after cancer diagnosis was “too early and therefore might not do any good”. They assumed that the isPO OG must necessarily share their medical history, although this only happens upon the patient's request. The isPO OGs were undecided about the “right” timing and pleaded for a flexible approach based on the needs of the patients, which Campbell et al. [17] identified as a benefit of cancer peer support. We recommend that the *frequency and duration* of the conversations should also be handled in a flexible, patient-oriented manner.

Within the four care networks, we identified different implementation and normalisation processes caused by varying resources for the organisation and coordination of the isPO OG consultations. When a corresponding infrastructure was expanded, the coordination lines between the isPO OGs and the professional service providers were jointly experienced and adapted where necessary. These interactions and optimisation attempts led to a maturation of the isPO OG service as an integral part of the isPO care provision. If resources were low, the required processes were considered burdensome. In these care networks, the proportion of conversations conducted by an isPO case manager instead of a peer service provider is significantly higher. This demonstrates that implementation factors like ‘resource availability’ and ‘organisational change’ are interrelated [60]. Therefore, we recommend establishing the necessary resources (personnel and infrastructure) to carry out the processes [40].

Initial health effects

At the level of *initial health effects*, there exists a high level of qualitative agreement among the perspectives and care networks; quantitatively, the isPO OGs rate the effects significantly higher than the patients. This could reflect the fact that isPO OGs evaluate the peer support service retrospectively, including their experiences from their care trajectory. At the same time, isPO patients are still close to their diagnosis, which is reminiscent of the response shift in patient-reported outcomes [67, 68]. A different understanding of the isPO OG service is also important. In addition, the isPO OGs have several consultations as a basis for evaluation, which they may use for comparison. Overall, the decisive factor was that the isPO OGs are a living example that cancer can be overcome in such a way that even demanding volunteer work can be practised. In addition to authentic and plain information provision, encouragement is the central core of the isPO OG service. This was evidenced both qualitatively and quantitatively, as the assessment on the item "confidence" showed the highest mean value among patients and isPO OGs.

This puts the isPO OG service in line with the effects identified in systematic reviews of one-to-one peer support in cancer care and mental healthcare [16, 21, 22].

Strengths and limitations

Applying a mixed-method study design resulted in several advantages. While the quantitative analyses provided a general view of experiences and opinions, the qualitative analyses helped to understand the underlying reasons and conditions. The different data sources supported the multiplicity of perspectives so that the isPO OGs and the patients and professionals service providers articulated their views and experiences. Furthermore, a multi-contextual understanding was gained, as all isPO care networks were considered, and their similarities and differences were elaborated. The ability to synthesise these results helped draw useful recommendations for actions.

The individual methods and data sources, respectively, contain strengths and limitations. Although the isPO care data contain representative data on the entire isPO care trajectory, they can also be afflicted with documentation gaps and errors. Moreover, the isPO OGs are obliged to conduct their assessment directly after the consultation, whereas the patients do so four months after enrolment in isPO. However, the data linkage with the patient survey data provided relevant information on the topics of satisfaction with the isPO OG consultation and social support. In addition, the quantitative patient data helped gain an overview of all patients, as they were not interviewed in focus groups, unlike the isPO OGs and professional service providers, and not all the patients interviewed had utilised an isPO OG consultation. The number of isPO OGs surveyed by questionnaire was very small in absolute terms. Hence, no parametric statistical evaluations were possible, but isPO was implemented in only four care networks during the project phase so that the population of isPO OGs is statistically small. No quantitative data on the isPO OG service was available for the professional service providers. Therefore, the qualitative data was a necessary complement to capture comprehensive insights from all perspectives. The qualitative data helped classify and explain the quantitative results. For example, the different utilisation rates in the care networks could be explained by the fact that, according to the qualitative investigations, there were different resources and attitudes on the part of the professional service providers, which in turn influenced the patient information on the isPO OG service and, thus, the utilisation decision of the patients.

The isPO programme was implemented in only four care networks with a limited number of service providers. This resulted in partly the same participants within the interviews and focus groups. However, they took part in qualitative data collections at different time points so changes between the different implementation phases could be reflected.

The mixed-methods design allowed for comprehensive evaluation [69]. However, only one-group post-test data were available for the initial health effects. Thus, in the sense of Issel and Wells, this is an outcome documentation [40]. Since the isPO OG service is one of several care levels in the isPO programme, it is questionable to what extent an outcome evaluation only at the level of the isPO OGs would be meaningful due to interactions.

In addition, within the project duration of four years, isPO was not only developed but also implemented and optimised. This means that the isPO OG service only reached a high degree of maturity at the end of the project. Thus, short-term health effects could be observed, but not medium- and long-term ones. Moreover, depending on the assigned care level, patients took up further interventions in isPO, so it is very difficult to differentiate the effects of the individual interventions and, thus, also that of the isPO OG service after completion of the 12-month care. Therefore, qualitative data were also used to supplement the initial health effects key figures. For future projects on complex interventions, we recommend a two-step approach. First, a project should be carried out that includes implementation and formative evaluation. After reaching high maturity, the summative evaluation should take place as a separate project. For this, appropriate funding programmes are necessary that enable such an approach.

Practical implications

The isPO OG consultation offers low-threshold psychosocial support for newly diagnosed cancer patients. The hope-giving and encouraging aspects empower patients and may have a positive impact on adherence to cancer treatment [70]. Thus, peer service providers may amplify the interconnection between patients and professional service providers [22]. Besides the clinical benefits, the isPO OG service may be cost-effective. As the experiences of isPO OGs are the focus of their work, they need far less comprehensive training than professional service providers. Furthermore, they work as volunteers rather than paid staff. However, in order to retain the volunteers and, thus, ensure the sustainability of the isPO OG service as a whole, clear regulations on financial allowances for the isPO OGs are essential [71].

Moreover, the isPO OG service complements the peer support of cancer self-help groups who are mostly entity-specific and can be attended throughout the cancer care trajectory. With the provided information, isPO OGs make patients aware of self-help group offers and, thus, encourage participation.

Conclusion

The isPO OG service is an integral part of the new psycho-oncological form of care isPO. It is offered to newly diagnosed cancer patients on a voluntary basis and engages cancer survivors as peer service providers. The isPO OG consultations embody a low-threshold offer for information

provision (orientation towards support services) and the gift of courage and hope to newly diagnosed patients. With these two main characteristics, the programme fulfils the requirements of the German NCP and psycho-oncological guideline [8, 9]. This gives the programme the potential to be implemented as an independent form of care.

Overall, the initial health effects were described as psychosocially beneficial. However, resource, process, and utilisation differences were detected within the isPO care networks. These indicate that both flexibility and adaptation of the care concept are required at the organisational level, provision, and individual level. The perfect conceptual fitting, timing, frequency, and duration of the consultations should follow the actual patient needs in everyday care.

To optimise new forms of care like the isPO OG service, we recommended early involvement and participation of all relevant stakeholders, including patients or their representatives, professional service providers at the care and managerial level, and the isPO OGs. With its positive outcomes and low-threshold healthcare offer, the isPO OG service can serve as a blueprint for one-to-one peer support in other healthcare domains, such as stroke. The key elements of such integrated peer support are providing relevant and accurate information and demonstrating how to overcome or live with a disease soon after the diagnosis.

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Author contributions

SS conducted the conceptualisation, development of the study design, data analysis, interpretation, data visualisation, and writing the original draft. SH contributed to the acquisition of participants. NCS contributed towards the investigation. AD was a supervisor and contributed to the process of conceptualisation. HP and NS were supervisors during the study and acquired the funding. TK contributed towards the conceptualisation, interpretation, and was a project manager. SH, NCS, AD, HP, NS, and TK reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest

The authors have no relevant financial or non-financial interests to disclose.

Ethical approval

The ethics committee of the Medical Faculty of the University of Cologne has approved the isPO project and its study design (No. 18–092).

Consent to participate

Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

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Supplementary information

Supplementary file 1

Key questions of the interviews and focus groups with patients, isPO onco-guides, and professional isPO service providers

Interviews with patients who completed the isPO care programme
Please briefly describe how you felt after you were diagnosed.
How did you first learn about the isPO programme?
How do you think patients should learn about the programme?
How would you describe isPO to a friend in short words?
In what ways have you received support within the isPO programme?
The isPO programme was newly implemented, i.e., the hospital had to establish new structures and procedures. Did you ever feel that these changes were apparent in your contacts?
How professional did you perceive the various service providers in the isPO programme to be?
To what extent has isPO met your individual support needs?
To what extent did organisational challenges arise during your care process?
What did you particularly appreciate about the isPO programme?
How did you feel about the 12-month care period?
What did you find unusual, unpleasant or in need of improvement?
Looking back, would you say that participating in the isPO programme was beneficial for you?
What would you wish for isPO in the future?
Is psycho-oncological support needed beyond the one-year isPO programme?
Interviews and focus group with isPO onco-guides
To what extent have you made use of cancer peer support services yourself or been active in peer support outside of isPO? How long have you been certified as an isPO onco-guide and how long have you been active in the field? How many cancer patients have you supported (approximately) since then? *Just for the interviews:* How do you evaluate the role of the isPO onco-guide or peer support as an integral part of psycho-oncological care? *Just for the focus group:* What do you associate with isPO?
How did it come about that you became an isPO onco-guide in the first place? Please describe the path from learning about the isPO programme for the first time to your certification.
If you were to describe your work to a self-help colleague, how would you describe the schedule of a "typical working day" as an isPO onco-guide?
How do you experience the consultations with the patients?
Just for the focus group: How do you experience working an isPO onco-guide through Corona?
To what extent were your expectations of the work as an isPO onco-guide fulfilled?
Just for the interviews: Please comment on this statement: “Just passing on an information folder, anyone can do that. Why is the isPO onco-guide needed?”
How do you evaluate the innovative concept of the isPO onco-guide overall?
How do you evaluate isPO?
What wishes do you have for the training and design of the work as an isPO onco-guide?
What do you wish for the future of isPO?

Supplementary file 2

Coding system for interviews and focus groups with patients, isPO onco-guides (isPO OG), and professional isPO service providers

Component of programme theory					
Head codes	Organisational Plan – Input	Organisational Plan – Output	Service Utilisation Plan – Input	Service Utilisation Plan – Output	Initial health effects
			Sub-codes		
Description of the isPO OG service	Previous experiences in peer support Motivation Requirements of potential isPO OG Acquisition as isPO OG Expectations towards the isPO OG work Cooperation lines between isPO OG and professional service providers Matching of patient and isPO OG	Amount of training Topics/content of training Time between certification and work as isPO OG Reasons for not being occupied as isPO OG Number of isPO OG Infrastructure Workload for isPO OG Allowance for isPO OG work Integration of isPO OG in professional isPO service provider team Support of isPO OG by professional service providers isPO case manager acting as isPO OG Network-internal exchange between isPO OG Focus of isPO OG work Authentic empathy and experience level	Initiation and coordination of isPO OG consultation Timing within care trajectory Time between patient enrolment and isPO OG consultation Preparation and follow-up of isPO OG consultation Setting Changes due to COVID-19 pandemic	Frequency of consultations per patient Duration of consultation per patient Content of isPO OG consultation Importance of information folder for consultation Subjective perception of patient needs Consultations with presence of relatives Attitude of patients towards isPO OG service Developing openness as patient Trust of patients through openness of isPO OG Perceived benefits for isPO OG Strain for isPO OG Individual coping strategies for stressful consultations	Perceived benefits for patients New social contact Emotional empowerment
Facilitators	isPO-experienced patients as new isPO OG	Emotional stability of isPO OG Training in conducting a conversation Satisfaction with training Established resources Additional resources for psycho-oncological care Allowance for isPO OG Age matching Atmosphere in isPO OG team Exchange between isPO OG and isPO case managers	Frequency of consultations per patient Timing within care trajectory Composition of information folder Provision of relevant, reliable, and accurate information Flexibility in matching isPO OG and patients Acceptance of patients Acceptance of professional service providers	Established workflow Optimisation of care quality isPO OG as gatekeeper for psycho-oncological care Presence of relatives	Feeling understood Encouragement/empowerment
Barriers	Eligibility criteria for isPO OG Lack of clarity on isPO OG role and tasks Number and availability of isPO OG Diversity of isPO OG for matching with patients COVID-19 pandemic	Experience of isPO OG Amount of training Topics/content of training Lack of resources Resource expenditure for hospital Working hours of staff and isPO OG Compatibility with hospital structures Allowance for isPO OG Reservations of professional service providers towards isPO OG service Support of isPO OG by professional service providers	Lack of understanding of professional service providers Missing information by professional service providers Competing with other peer support services Timing of isPO OG service Predefined duration of consultation Availability of information material Composition of information folder Importance of information folder Mobility of patients Length of stay in hospital COVID-19 pandemic	Refusal by patients Lack of understanding of patients Service coordination Frequency of consultations per patient Connection between patient and isPO OG Focus on self-help group organization	Noticeability of effects
Suggestions for optimisation	Selection procedure for isPO OG Further training for isPO OG Expansion of isPO OG teams	Accurate and continuous training Allowance for isPO OG Increasing appreciation of isPO OG work Regular (group) supervisions Optimisation of cooperation with professional service provider team Regular exchange between isPO OG	Content and design of information folder Flexible consultation offers (timing, duration, frequency) Establishing as consultation for patients	Support in transforming isPO OG information into action	-

Chapter 9

Discussion

Discussion

9.1 Findings of the doctoral projects concerning patient involvement and engagement

The aim of this thesis is to outline at which levels and how patient involvement and engagement (PIE) can be realised in health services research (HSR) projects in Germany, exemplified in the context of psycho-oncological care. Therefore, a tool for reflecting the levels, processes, and results of PIE was compiled of appropriate components of PIE frameworks and models in HSR (Patient Involvement and Engagement Profile - PIE PRO). In the following, the filled in PIE PRO tools give an overview on PIE in the four dissertation projects (DP) and will be discussed. Each DP represents a task area of HSR.

9.1.1 Patient involvement and engagement in dissertation project 1 – Investigation of everyday healthcare

In DP 1 [1], the prevalence of mental disorder diagnoses (depression disorder, anxiety disorder, adjustment disorder, post-traumatic stress disorder) in newly diagnosed cancer patients as well as the utilisation rates of outpatient psychotherapy and pharmacotherapy were determined. In addition, predictors for diagnosis and mental health service utilisation were investigated. For this purpose, health insurance claims data were analysed. Cancer patients were neither involved in the development of the study design nor in the data preparation, analysis, interpretation, and dissemination (level 1 – cooption) (Figure 1). Thus, patient empowerment and knowledge integration were not realised in this study. Since administrative data were analysed, these were not even generated by the insured persons themselves. Exploring a field of research [2], the chosen approach can be helpful for orientation. The analysis of health insurance claims data offered the advantage of retrospectively gaining a rapid insight into the healthcare situation of newly diagnosed cancer patients with mental disorders without the need to collect new data, thereby reducing recall and selection bias [3]. PIE is often poor in studies with epidemiological questions because professional researchers typically control the process [4]. However, the extent to which PIE can be incorporated without scientific training, especially concerning the data type and analytical procedures used in this DP, remains a question. It becomes apparent that PIE cannot and does not have to take place at an identical level in every phase of a project. Nevertheless, patients in epidemiological studies, for example, can contribute to the study design and the interpretation of the results and guide the dissemination to the general public [5]. This approach empowers patients to influence the design and implementation of epidemiological HSR studies based on their experiences and needs, facilitating the integration of their knowledge into the development of care concepts derived from the study results [6].

Figure 1. Patient Involvement and Engagement Profile of dissertation project 1

9.1.2 Patient involvement and engagement in dissertation project 2 – Development of complex interventions

The second DP dealt with the prospective external evaluation of the new form of care 'integrated, cross-sectoral Psycho-Oncology' (isPO), i.e. the assessment of potential facilitators and barriers, the comprehensibility and maturity before implementation [7]. For this purpose, the perspectives of end-users (newly diagnosed cancer patients), isPO designers, and service providers were captured. Since there was obviously no experience with the new psycho-oncological care programme available before implementation, the patient perspective was reflected by a patient representative. They were an employee of the House of the Cancer Patient Support Associations of Germany (HKSH-BV). This umbrella organisation was a consortium partner within the isPO project and, according to the project proposal, was to act in an advisory role. The patient representative took part in a focus group with isPO designers as part of the prospective evaluation and wrote a statement on the isPO project from the patient's perspective at the end of the first project year. This reveals two levels on which PIE could be discussed – the prospective evaluation as a DP and the isPO project as a whole. These different levels will also affect the following DPs 3 and 4. In the context of this thesis, PIE will be reflected on the basis of the publications with reference to the DPs. Whenever concrete references to PIE in the overall isPO project can be found in the publications, these will be examined exclusively with regard to the respective DP.

The researchers of the external evaluation of isPO were responsible for the development of the evaluation design. PIE was not realised in this work step (level 1 - cooption) (Figure 2). The data collection, in turn, took place at the level of consultation (level 3) or cooperation (level 4). The participation of the patient representative in the focus group had the higher degree of PIE, since an exchange with the isPO designers occurred. From the patient's perspective, the potentials of the new form of care isPO, but also the barriers with regard to the adoption into routine care, were discussed. This insight gave the isPO designers valuable suggestions for the further maturation of the new form of care, so that it could be developed according to patients' needs. A needs-driven development captures the aspect of acceptance, which was discussed on many levels within the focus group, as the attitude towards an intervention is decisive for its implementation success [8]. The advisory role was also fulfilled by the patient representatives through the preparation of a written statement at the end of the first project year. It was integrated into the prospective evaluation report and placed in relation to the other evaluation results which was done solely by the researchers (level 1 - cooption). In addition to this integration of knowledge at the patient level, the written statement revealed an increased PIE within the entire isPO project. The HKSH-BV was in charge of the conceptualisation of the isPO onco-guide peer support (chapter 8) beyond the advisory role agreed in the proposal and was

responsible for the acquisition and training of isPO onco-guides. Early involvement of patient knowledge and expertise is recommended for the development of complex interventions [9, 10] as it helps to generate evidence relevant for patients [11], and facilitates patient acquisition in the implementation phase [12]. The dissemination of the results of the prospective evaluation was done indirectly to the patient representative. The prospective evaluation report was submitted to the project leader who in turn decided which recommendations and work assignments would be addressed to the individual consortium partners (level 2 - compliance). This procedure may create a break in communication and sovereignty over the results which is why direct and independent feedback to the respective responsible consortium partners is considered more effective [13] and strengthens empowerment.

Figure 2. Patient Involvement and Engagement Profile of dissertation project 2

9.1.3 Patient involvement and engagement in dissertation project 3 – Implementation and optimisation of complex interventions

The setting for the third DP [14] was the participatory optimisation of patient information material (PIM) in the isPO project [15]. This was inspired by feedback from the early implementation phase of isPO service providers. They claimed the isPO PIM to be too extensive, partly redundant and difficult to understand [15]. The optimisation of the isPO PIM was not envisaged in the project proposal but seemed urgent to increase the acceptance of the new form of care isPO and thusly the number of enrolled patients. For a participatory and iterative process to optimise the isPO PIM, it was necessary for all persons involved and engaged to be able to systematically evaluate the initial isPO PIM and to make suggestions for optimisation. Therefore, a PIM assessment and optimisation instrument (User-friendly Patient Information Material Checklist – UPIM-Check) was developed in a participatory manner.

Compared to DP 1 and 2, the manuscript title of DP 3 already indicates that it is designed with PIE. In addition, several patient roles can be recognised in the reflection (Figure 3) – cancer survivors and patient representatives. The latter were employees of the isPO consortium partner HKSH-BV and were members of the participatory research team developing the UPIM-Check and optimising the isPO PIM. The cancer survivors were members of (inter-)national cancer self-help organisations and were involved in the pre-testing of the UPIM-Check English version and the psychometric pilot testing of the German version.

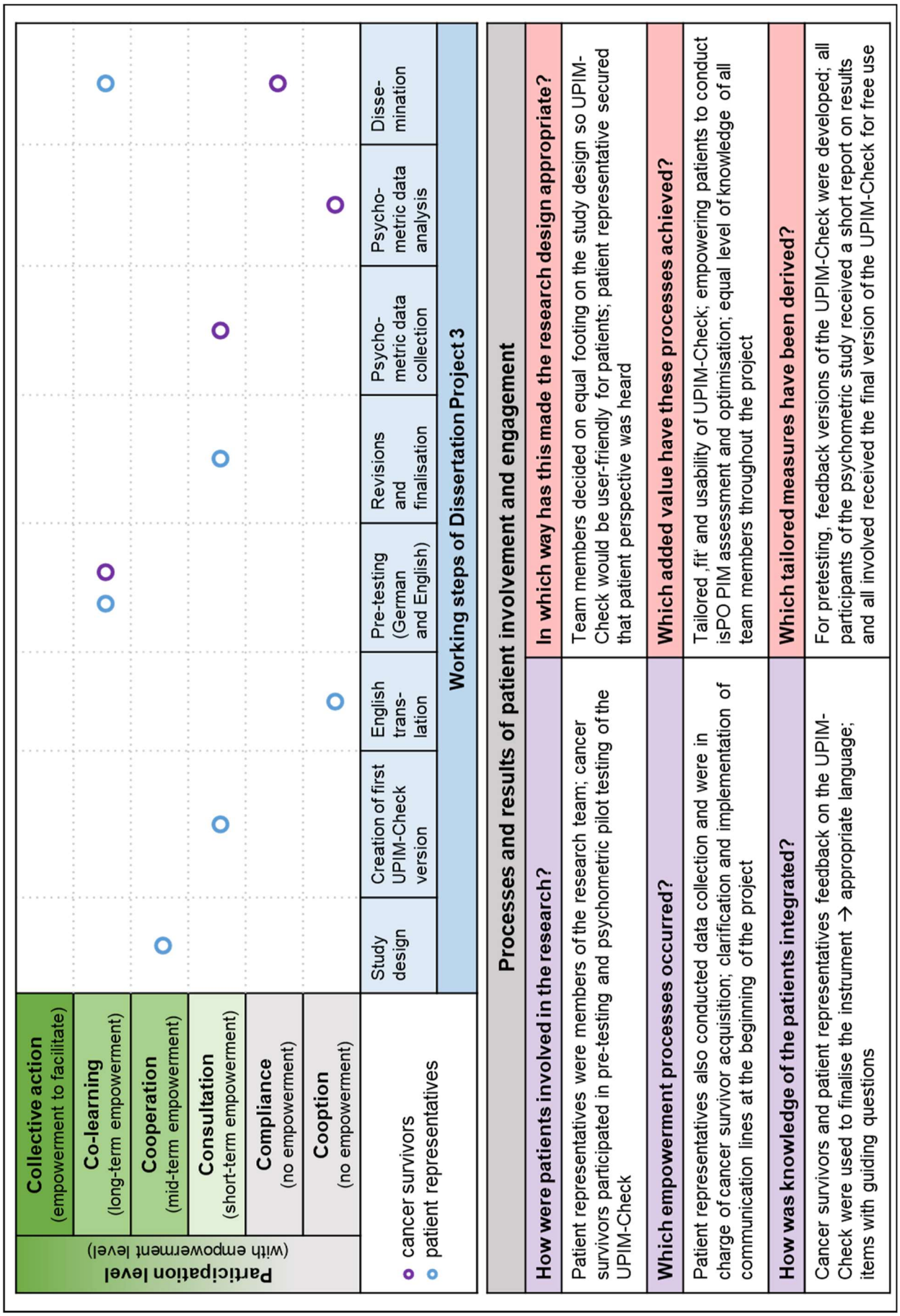
As the participatory team was formed at the beginning of the process, the study design was defined jointly (level 4 - cooperation) so that the developed instrument could also be used by patients. Professional researchers led the process in creating a first version of the UPIM-Check. Through their access to scientific literature, they were able to compile an evidence-based list of criteria for PIM. This was supplemented with criteria that are relevant from the perspective of the patient representatives (level 3 - consultation). In this context, the relevance of the component of accessibility according to Chudyk et al. [16] comes apparent (chapter 2.2.1). If the patient research partners do not have access to scientific literature, it reduces their possibilities for participation on an equal footing and for empowerment. The publication of scientific articles in open access journals can only be part of the solution because there are still high demands on their comprehensibility. Establishing so-called lay summaries in publications may increase the outreach of scientific knowledge into the public [17] and would be useful for patient research partners.

Concurrently to the development of the UPIM-Check as an original German-language instrument, an English version was prepared. A professional service was commissioned for the translations and the consensus was reached in a team of professional researchers (level 1 - cooption). The influence of patient representatives and cancer survivors was particularly high

during the pre-testing of the two language versions of the UPIM-Check. For this purpose, special feedback versions were created so that the application of the UPIM-Check could not only be tested but also that suggestions could be made for the adaptation of the individual items. The knowledge of the patient representatives and cancer survivors has contributed significantly to the understandability of the UPIM-Check and has influenced the item format (level 5 - co-learning). Previously, these only contained a short description of the associated criterion; after the pre-test, each item includes guiding questions to facilitate assessment. The adjustments and finalisation were implemented by the professional researchers and accompanied by the patient representatives' advisory (level 3). After the UPIM-Check development process, a pilot-testing of the psychometric properties of the UPIM-Check German version was conducted. Patients who neither know the UPIM-Check nor the isPO project were asked to participate. The preliminary validation was based on the initial and the optimised version of the isPO leaflet. With the help of the team members of the HKSH-BV, cancer survivors were acquired from the associated cancer self-help organisations. The participants received two UPIM-Check forms and were asked to evaluate the initial and the optimised isPO leaflet. In this way, the cancer survivors supported the data collection (level 3 - consultation). The psychometric analysis was again the sole responsibility of the researchers (level 1 - cooption). The participants received a short report on the results (level 2 - compliance). For further dissemination of the results of the development process and the preliminary psychometric analysis, a patient representative contributed to the publication as a co-author. In particular, they contributed to the classification of the participation levels for the patient representatives and cancer survivors, resulting in an exchange on how participation was experienced from the different perspectives (level 5 - co-learning).

As mentioned above, the optimisation of the isPO PIM and the development of the UPIM-Check were not part of the project planning, so no additional financial and time resources were available which made the conduction challenging [18–21]. After the team of patient representatives, cancer care experts, and professional researchers had gathered, agreements were made on how to work together and how to organise communication in order to make the collaboration efficient. Overall, the composition of the team with its different perspectives and expertise was found to be beneficial [14]. The created 'product' - the UPIM-Check – has the potential to empower patient research partners beyond the DP as it can be used in future studies enabling patients to develop, evaluate, and optimise information materials addressed to them.

Figure 3. Patient Involvement and Engagement Profile of dissertation project 3



9.1.4 Patient involvement and engagement in dissertation project 4 – Evaluation of complex interventions

The DP 4 with its examination of the isPO onco-guide service [22] serves as an example of the evaluation of a complex intervention or new form of care. The isPO onco-guide service is a one-to-one peer support for newly diagnosed cancer patients. The isPO onco-guides are former cancer patients offering one to two consultations about information on local support services which are also handed out as a patient information folder. Furthermore, isPO onco-guides answer questions 'all around cancer'. The evaluation of the isPO onco-guide service was conducted in a mixed-methods design, considering the perspectives of isPO patients, isPO onco-guides, and professional isPO service providers.

Turning to PIE, three patient roles can be identified in the publication of the DP 4: newly diagnosed cancer patients who utilised the isPO programme, the isPO onco-guides as peer service providers, and patient representatives of the HKSH-BV (Figure 4). Concerning the HKSH-BV, it was already observed in the prospective evaluation that, contrary to the application, it was jointly responsible for the development of the isPO onco-guide concept and for the acquisition, training, and certification of isPO onco-guides (chapter 9.1.2). The attribution 'peer service providers' adds a level of PIE in HSR that, strictly speaking, does not refer to patients as research partners but is of high importance. In the background (chapter 2), it was stated that patient involvement in healthcare in Germany occurs particularly in the form of shared decision-making and patient representation in committees in the healthcare system. The isPO onco-guides, in contrast, pursue tasks as service providers and are considered a part of the psycho-oncological team. Thus, PIE in HSR is widened beyond research activities which can be regarded as a special feature of the research field [23, 24].

As part of the evaluation of the isPO onco-guide service, isPO patients participated in a paper-based survey and in telephone interviews at the end of 12 months of care. In addition, the patients evaluated the isPO onco-guide consultation in the course of an interim screening (four months after the start of care). These data were part of the IT-based documentation (isPO care data). The isPO onco-guides also participated in a survey and telephone interview. In addition, a focus group with isPO onco-guides was conducted. For the documentation, the isPO onco-guides evaluated the consultation directly afterwards with the analogous items as the patients. A patient representative participated in the evaluation of the isPO onco-guide service in the course of dissemination. The patient representatives of the HKSH-BV also supported the acquisition of isPO onco-guides for the survey and focus.

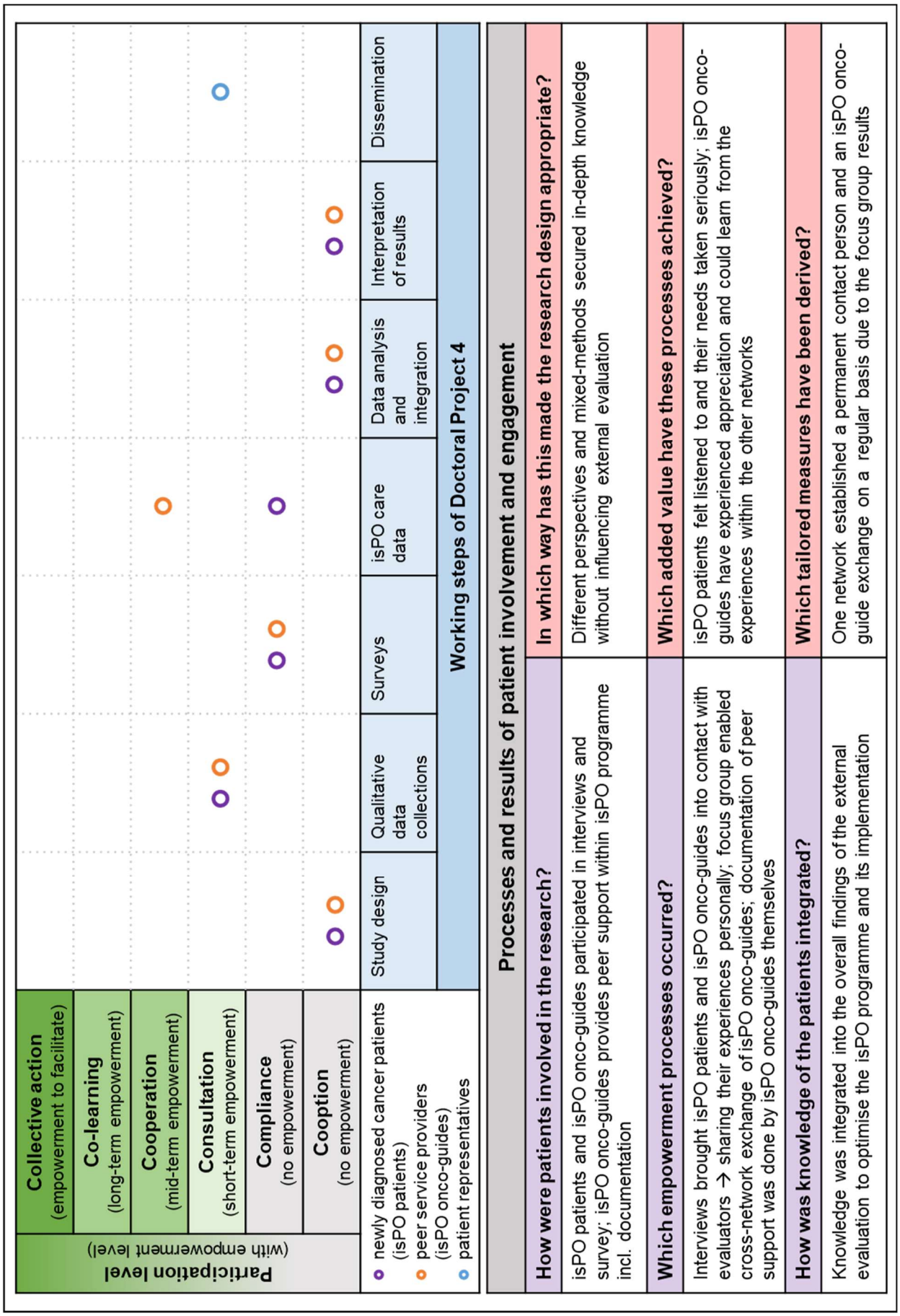
A look at the PIE in Figure 4 shows similarities in the participation levels to DP 2 (prospective evaluation of the isPO development). The study design was as well developed by the external evaluation (level 1 - cooption). From the perspective of professional researchers, it is often the

study design step that seems less suited for PIE [12, 18, 25]. However, PIE does not require that responsibility and decisions on methodological appropriateness are delegated the patient research partners. Rather, they can help to ensure study feasibility and that the defined outcomes address patient values [12, 16, 18, 25]. In the isPO project proposal, no interviews and focus groups with isPO onco-guides were planned. With the adaptation, it was possible to obtain in-depth information also from their perspective (level 3 - consultation). Otherwise, direct contact between isPO onco-guides and external evaluators as well as between isPO onco-guides of the different isPO care networks probably would not have been established. This is similar to the interviews with isPO patients. Even if the isPO care had already been completed, it was possible to give space to the patients' experiences and needs. Furthermore, it was possible to explain ambiguities about the new form of care isPO and thus clarify the importance of their participation. Principles of interpersonal relationships such as transparent communication and trust are a crucial part of PIE in HSR [16].

In contrast to qualitative interviews, surveys can be used to capture opinions and attitudes, but without any explanations or exchange why they were assigned a reduced participation level (level 2 - compliance). The same applies to the evaluation of the isPO onco-guide consultation by patients within the interim screening. For the isPO onco-guides, the evaluation of the consultations is in contrast linked to the documentation of their volunteer work as peer service providers and is communicated to the isPO case managers (level 4 - cooperation). As in the three previous DPs, the data analysis and interpretation of results was carried out by the professional researchers without PIE (level 1 - cooption) which appears frequently in HSR studies [26] (chapter 9.1.5). The publication on the isPO onco-guide service evaluation was co-authored by a patient representative who, however, was no longer working at the HKSH-BV at the time of writing, so that due to the lack of time resources only reviewing was possible (level 3 - consultation). Comparable to the limited accessibility to scientific information described in DP2, lack of resources resulted in a reduced participation level concerning dissemination. This underlines the importance of the respective PIE in HSR principles according to Chudyk et al. [16]

The additional qualitative data collections with isPO onco-guides in particular made it possible to broadly explore this one-to-one peer support as one of the care levels of isPO and thus to embed the findings in the further results of the external evaluation [27–29]. At the focus group with isPO onco-guides, a staff member of the isPO case management of an isPO care network was present as a silent listener. From personal communication it is known that this led to the establishment of a permanent contact person and a regular exchange format for the isPO onco-guides in accordance with the discussion contents. This is a substantial example of how participation, conjugated with the appropriate addressing of needs, can bring about change.

Figure 4. Patient Involvement and Engagement Profile of dissertation project 4



9.1.5 Patient involvement and engagement across the four dissertation projects

In the examination of PIE in the individual dissertation projects, first similarities and differences have already been identified. The corresponding working steps are characterised by similar participation levels. The development of the study design was the full responsibility of the professional researchers in three DPs. This is rather unusual in an international comparison, as a frequently mentioned example of PIE is the selection of patient-relevant outcomes [12, 25, 30]. In contrast, the lack of PIE in data analysis and integration and interpretation of results which was observable across all DPs, appears to be typical [26]. A rare example of participatory data analyses in HSR is the analysis of qualitative interviews in a coding team of patient research partners and professional researchers [31]. Although in this study patients were involved at the level of cooperation in data collection and data analysis [19, 31], they are not credited as co-authors. PIE in the dissemination of research results seems to receive little attention overall [26]. Here, the four DPs vary widely, as there are publications with and without co-authorships by patient representatives, as well as indirect dissemination via the project management. Furthermore, the co-authorships were also characterised by different participation levels, depending on whether content input was provided or the publication was only reviewed due to lack of resources.

What is hardly addressed, especially in systematic reviews of PIE in HSR, are different patient roles [12, 16, 26, 32, 33], i.e. whether PIE includes people who are currently in treatment or former patients, or patients who contribute their own experiences as private individuals or patient representatives who act on behalf of an entire patient collective [34]. In the DPs, a wide variety of patient roles could be identified: insurees, patient representatives, members of self-help organisations (cancer survivors), patients as current service users (isPO patients), and peer service providers (isPO onco-guides). For the insured persons, PIE was consistently at the level of cooption, provocatively put, they were merely ‘data providers’. The patient representatives were involved in many ways and most frequently in the DPs but mostly at least at the consultation level up to co-learning. The particularity is that they were active as researchers (DP 3) as well as interviewees (DP 2). It should be emphasised that the patient representatives belonged to the staff of a patient organisation, one person even with a position within the isPO project. Appropriate resources therefore enable higher levels of participation. In comparison, the volunteers (cancer survivors and isPO onco-guides) and the patients in the isPO programme are more likely to be not involved or only at the preliminary stage of participation.

It is striking that the highest participation was observed for DP 3 which was participatory in its design from the beginning. This suggests that PIE does not just "happen" but requires accordingly planning and action. Routen et al. [5] emphasise that new ways of knowledge generation, as are possible with PIE also require new methodological ways. For example, they

cite examples of participatory epidemiological studies in which Delphi studies and qualitative methods are conducted, when quantitative methods, such as routine data analyses, are typically used.

Altogether, it becomes apparent that PIE is not a dichotomous characteristic. It is rather the question to what extent patients are involved or engaged [35]. This requires researchers to critically reflect on their own actions and to prevent tokenism. In all phases of the research process, it should be clarified with all involved in the research team who is participating and when, and to what degree [35–37]. It is important to remember that not all persons involved want or are able to participate equally across all phases and should therefore be able to decide on their participation [36]. It is perfectly normal for participation levels to vary over the course of a project [38] like it came apparent within DPs 2 to 4 as well as between all DPs (Figures 1-4).

9.2 Methodological considerations

This thesis has not only addressed PIE in HSR on the basis of a single project, but considered the range of task areas in HSR. Additionally, all DPs are situated in the same care context of psycho-oncology. This made it possible to understand and compare how PIE is characterised in HSR in different phases and task areas. However, this raises the question of to what extent the findings on PIE in psycho-oncological HSR can be transferred to other care areas, such as general medicine which is structured very differently in terms of patient representation than oncology and cancer self-help.

Another scope of this work is reflected in the variety of research methods which cover the two methodological origins of HSR – clinical epidemiology and social sciences [39]. This allowed to show which data collection methods already enable (pre-)stages of PIE through study participation, such as interviews and focus groups. Moreover, it demonstrates how patients as research partners can be involved and engaged by jointly selecting methods and outcomes or by patient research partners collecting and evaluating data themselves.

Usually, PIE is only reflected on in research projects if the use of a participatory approach was planned from the beginning. Ideally, reflection should be continuous throughout the research process [40]. For this thesis, a retrospective evaluation of PIE within HSR projects was conducted regardless of whether the projects were planned with PIE or not. This made it possible to compare the processes projects that claimed to be participatory and those that do not. Furthermore, with regard to the isPO project, it became visible how the degree of participation of the consortium partner HKSH-BV increased from the project proposal (advisory role) to the development (responsibility for isPO onco-guide concept, acquisition, and training/certification) and implementation/optimisation (research partner).

In accordance with the doctoral student's own contribution, the evaluation of PIE in the DPs was carried out exclusively from the perspective of a professional researcher. However, this contradicts the purpose of reflecting on participatory research processes [2, 40]. Tools such as the Participation Web [2] are explicitly designed to be used intuitively by all members of a participatory research team and to reflect on and discuss involvement and engagement from each perspective. On their own initiative, staff members of the HKSH-BV have written an article on how they perceived their PIE as patient representatives in the isPO project [41].

A disadvantage of assessing the PIE in an HSR project on the basis of publications is that this depends on how transparently the processes are presented. Otherwise, the basis for assessment is insufficient or incorrect conclusions are drawn. Therefore, the GRIPP2 checklist is recommended, which is a guiding tool for reporting PIE in research [42].

To systematically evaluate PIE in the DPs, a tool called PIE PRO was created. Neither the design nor the application was carried out with PIE so that only the scientific perspective came into action as described above. Accordingly, the PIE PRO is based on existing frameworks and models for PIE in health (services) research. Since the DPs are situated in the German healthcare system, only frameworks and models that have been adapted for the German-speaking context or those that are originally in German were used. Due to the different foci, it is recommended to use frameworks as appropriate for the respective purpose [16, 43]. Therefore, to answer the research questions of this thesis, the PIE PRO contains a part for assessing the participation levels for each working step. These can be specified freely, in contrast to the Participation Web, in order to take account of the diversity of projects. Furthermore, it is possible to differentiate according to patient roles. These are often mixed in the literature in general terms such as patients and the public (e.g. Concannon et al. [26]). In chapter 9.1.5, however, it was shown that there are differences in the involvement and engagement of patients as individuals and patient representatives or volunteers and staff in self-help which underlines the relevance of differentiation. As the mere description of the participation level does not say anything about how the PIE was realised, the PIE PRO also contains reflection questions to describe the involvement and engagement processes and their results.

9.3 Implications for research and practice

Despite the heterogeneity of the DPs, similar challenges and questions emerged with regard to resources, patient roles, how PIE can be realised in HSR projects, and with which aim. Therefore, the implications will relate to what conditions HSR requires to be able to implement PIE and what benefits PIE has for HSR and healthcare.

The resources for supporting participatory processes are such a central aspect that Chudyk et al. [16] classify them simultaneously as principle, core element, context, and action of PIE in

HSR. Governmental funders play a crucial role for the financing of HSR projects with PIE. Strategic recommendations from participatory researchers in Germany state that funding programmes should require for research proposals to include a statement on participation [44, 45], as already required by the German Federal Ministry of Education and Research (BMBF) and the Innovation Committee [46, 47]. However, this does not mean that PIE is obligatory in order to receive research funding. It is rather a matter of promoting and demanding health services researchers' critical reflexivity with regard to their scientific practice. If PIE should actually be realised, necessary financial resources need to be taken into account in the application process. The efforts of patient research partners as well as travel costs and indirect costs should be adequately planned for and remunerated [36, 37, 44, 45, 48, 49]. This is even more important because with the growing number of participatory HSR projects, patient and self-help organisations receive an increasing number of requests for participation from research institutions. The screening of documents, decision-making, and communication with the applicants are already almost impossible to manage with the existing human resources. The fact that funding for the coordination of patient organisations was discontinued by the German Federal Ministry of Health at the beginning of 2023 [50] exacerbates the precarious situation. Therefore, research funders have to ensure that patient organisations can also apply for participatory HSR projects as main applicants and that they have equal chances of receiving funding as research organisations [51]. This would also lay the foundation for so-called user-controlled research [51] (participation level 6 - collective action) according to which patients advance their own research ideas and involve professional researchers as partners or commission them with the research.

So, if PIE is initiated by health services researchers, one of the challenges is to find patient research partners. The acquisition should be based on the research question and thus the target group of the project, but sometimes pragmatic selection criteria (e.g. availability) are needed [12]. Existing collaborations can be advantageous, or 'institutionalised' PIE in the form of patient advisory boards (as established in cancer or general practice research [52, 53]) whose members are involved/engaged or who can be a starting point for further networking.

In any case, the teamwork of patients and professional researchers should be characterised by an open atmosphere, trust, and respect so that patients consider themselves as equal research partners [16, 36, 37]. This means that in the conduction of HSR projects with PIE it is jointly agreed on what the role and tasks of patients are; skills, knowledge, and experience of research partners are valued and listed in publications [36, 37, 48, 49], the same applies to the type and measures of PIE. Patients should be involved in decisions about the recruitment strategy of study participants and how to inform participants about the research process [33, 48, 49]. This is

followed by agreeing with patient research partners how to disseminate research findings to the public in a way that is accessible and understandable [48, 49].

In addition to funding and an adequate number of people in the participatory research team, training and support are also important resources [16]. Therefore, patients need to have access to appropriate training for their role as research partners and receive support, e.g. mentoring, to enable and facilitate their participation [33, 36, 37, 48, 49]. Similarly, professional researchers ensure that they are qualified and trained to involve patients as research partners [33, 37, 48, 49]. In addition, reviewers for research funders need support to adequately evaluate applications for participatory projects [44, 45]. Accordingly, the range of further training and handouts is growing in Germany, aimed at professional researchers as well as patient and patient representatives and other stakeholders [53–57]. The memorandum 'Participatory Health Services Research', which is currently being prepared (co-written by the author of this thesis), will complement these offers for HSR. With regard to professional researchers, there are ideas for integrating participatory research into research education and training [51] in order to address the increased demands on project and team management [58].

To make the previous efforts on PIE in HSR sustainable and to learn from the experiences of others, networking of participatory researchers should be promoted [37, 44, 45]. This includes professional researchers, patients, and other possible research partners. In Germany, participatory researchers are mainly connected through the ‘Network Participatory Health Research’ and the working group 'Participatory Health Services Research' of the German Network Health Services Research. Networking and visibility could be further realised through a database on participatory HSR projects [59]. Furthermore, a future task for PIE in HSR lies in the establishment of supporting research infrastructures [51]. For example, the Berlin Institute of Health QUEST Center established a team on Patient & Stakeholder Engagement [60]. A department to strengthen and further develop PIE and to bring together professional researchers and patients as well as other stakeholders with similar research interests would be an asset for every university hospital.

The term stakeholder as well as the four DPs show that in addition to patients and patient representatives, other groups of people are also important for participation in HSR projects. Thus, service providers will also be included in the newly developed definition of 'participatory health services research' which outlines that it is not only based on the approach of Patient and Public Involvement but on Participatory Health Research as well.

Apparently, numerous measures and ideas exist to implement and strengthen PIE in HSR. But PIE is not a self-purpose which is why there is a demand for formative evaluation of participatory research processes to review and reflect on their quality and impact [37, 44, 45, 51]. However, how PIE can be successfully implemented in HSR and how its impact is assessed

is largely unclear which is why a scoping review is currently undertaken [61]. The reasons for the gaps in knowledge are manifold. There is a lack of a uniform understanding of PIE [62]; questions arise about who should be involved, when and how [12] and how the impact can be captured [63]. A common understanding of impact is considered difficult to achieve due to contextual conditions [18, 64].

For the German-speaking context, a group of members of the 'Network for Participatory Health Research - PartNet' (in which the author of this thesis is engaged) wrote a recommendation for a funding focus on meta-research on the quality and impact of public involvement in health research in October 2022 [65] which also includes PIE in HSR. In fact, the need for meta-research was included in the BMBF's 'Strategy for Participation in Research' published in June 2023 [34] and a corresponding funding call was announced for the end of 2023. This brings the opportunity for HSR in Germany to generate evidence for principles of a fruitful PIE that support participatory researchers, but also funders and reviewers, so that it is no longer necessary to refer to the briefing notes from the UK under the outdated name INVOLVE [66] in calls for proposals. If only English-language manuals are available, patient research partners without the appropriate language skills are excluded from access to relevant and helpful information.

International evidence on the impact of PIE in HSR is already available as is presented in chapter 2.2.2. Summaries of impact characteristics can be found in systematic reviews [16, 18, 33] which usually consider different levels: the patient research partners, the professional researchers, their relationship, the research process, and the healthcare system.

Through the conducted DPs, it could be shown that the patient research partners have experienced an appreciation of their experiential expertise through their involvement/engagement and, in the case of the isPO onco-guides, also of their voluntary work [7, 14, 16, 22]. In addition, PIE strengthened their understanding of research processes in HSR [33] and in DP 3, [14] both the patient research partners and the professional researchers were able to learn how participatory research works [33]. In the collaboration with the patient research partners, the professional researchers were able to strengthen their understanding of the patient research partners' living environments so that they are enabled to change perspectives in the sense of a "*transformative experience*" [16] (p. 9). The exchange between all research partners was experienced as enriching [14]. This strengthens the bond between the team members which is important for subsequent collaborations and future engagement in participatory HSR projects [16]. At best, as indicated above, an existing network can be relied on.

Participatorily developing an assessment and optimisation tool for PIM (UPIM-Check) had the advantage that it is generally understandable and intuitively usable. This will enable patients to systematically evaluate and adapt PIM in the future and the tool can be used not only for the

primary purpose of the isPO project. Thus, this additional effort has a sustainable aspect. Using the UPIM-Check, the isPO PIM were optimised [15]. This supported the patient-friendly addressing of newly diagnosed cancer patients by the service providers for the isPO programme. In some cases, patients proactively asked for isPO after seeing the poster or leaflet. This has increased acceptance of the new form of care, resulting in more patients being enrolled [18] which in turn has led to higher case numbers for the effectiveness analysis. Meaningful results are highly relevant for the decision of the Innovation Committee to adopt a new form of care into routine care. If successful, this means that the investments in HSR based on social security taxes benefit the health system and thus future patients [16, 33]. Although PIE in HSR requires adequate resources as described above, PIE in turn helps to ensure that research funding can be used efficiently and effectively [33]. With regard to the isPO onco-guide peer support service, the expanded role of the HKSH-BV has led to the fact that, starting from the idea of a former executive board member, the conceptualisation and implementation now also came from cancer self-help, and thus ownership remains there. This makes the isPO onco-guide service credible and authentic and strengthens cancer self-help as an actor in psycho-oncological care. For the isPO onco-guides themselves, it was very valuable to exchange ideas with each other in the focus group and to notice that their feedback led to measures for further cooperation with the isPO case management. This strengthens the motivation to continue to engage in this voluntary work which is crucial to maintain the isPO onco-guide service. Thus, PIE in HSR is highly relevant for ensuring patient care.

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Chapter 10

Conclusion

Conclusion

In chapter 2.3, a quote was used according to which stakeholder involvement and engagement are the "holy grail" for the development and implementation of new care concepts and forms (which are task areas of health services research (HSR)) [1].

Per definition, patient involvement and engagement (PIE) then would be a goal for all health services researchers but never will be achieved [2]. This thesis has shown that the term misses the essence and the aim of PIE in many ways. It would not be purposeful if all health services researchers only conduct projects with PIE from now on. Even though PIE is not a method per se, but an approach, a possible realisation requires a PIE study design suitable to the project goals and the available resources. Thus, a reflective consideration of the research process, the aims, and the processes for PIE implementation is required. The latter should not only be done from a purely scientific perspective, but also together with the patient research partners, so that their preferences, expectations, and capacities are part of the basis for mutual decision-making [3, 4].

The above-mentioned term "achieve" implies that there is a “right” or “ideal" form or level of PIE. However, the dissertation projects (DPs) that have been conducted show how multi-faceted involvement and engagement processes are and that their level can vary in the course of a project. But it also came apparent that certain research questions can be answered adequately without PIE [5].

Furthermore, participatory research approaches are characterised by an attitude that values different types of expertise equally, that shares power with patient research partners, and wants to initiate positive changes for health and healthcare [6–8]. In this way, PIE shares similar goals with HSR [9]. One of the key concerns of participatory approaches is that the changes initiated are sustainable. In the long term, however, not only PIE is important but also the involvement and engagement of other stakeholders in the healthcare system in HSR projects. For example, service providers are the ones who implement new forms of care in their organisations so that these should be adapted to the existing structures and processes. Besides the stakeholder group, early involvement and engagement already from the initiation phase facilitate tailored intervention design and implementation strategies. PIE during the implementation and optimisation phase enables patients to participate in systematic processes or to conduct these themselves [10]. The experience of empowerment and appreciation of their engagement is important to motivate research patient partners so they remain committed or are willing to engage in future projects. Concerning patients in the role of research partners as well as service providers, their commitment is crucial for ensuring healthcare [11].

After all, the aim of patient and stakeholder involvement and engagement in HSR is to jointly find suitable, feasible, and sustainable solutions to challenges in everyday healthcare.

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Supporting information

List of abbreviations

AD	adjustment disorders
AND	anxiety disorder
ATC	Anatomical Therapeutic Chemical Classification System
BMBF	Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung)
C	component of the isPO care programme
CAPSYS²⁰²⁰	IT documentation and assistance system for the isPO programme
CFIR	Consolidated Framework for Implementation Research
CN	care network
DD	depressive disorders
DKFZ	German Cancer Research Centre (Deutsches Krebsforschungszentrum)
DP	dissertation project (Dissertationsprojekt)
HADS	Hospital Anxiety and Depression Scale
HKSH-BV	House of the Cancer Patient Support Associations of Germany (Haus der Krebs-Selbsthilfe – Bundesverband e.V.)
HSR	health services research
IF	Innovation Fund of the Federal Joint Committee (Innovationsfonds)
IMVR	Institute of Medical Sociology, Health Services Research, and Rehabilitation Science (Institut für Medizinsoziologie, Versorgungsforschung und Rehabilitationswissenschaft)
isPO	integrated, cross-sectoral Psycho-Oncology (integrierte, sektorenübergreifende Psychoonkologie)
isPO OG	isPO onco-guide
KG-NRW	Cancer Society North Rhine-Westphalia (Krebsgesellschaft Nordrhein-Westfalen)
MD	mental disorder
MHS	mental health services
MRC	Medical Research Council
NCP	National Cancer Plan
NIHR	National Institute for Health and Care Research
PCORI	Patient-Centered Outcomes Research Institute
PEMAT	Patient Education Materials Assessment Tool
PHR	Participatory Health Research
PIE	patient involvement and engagement
PIE PRO	Patient Involvement and Engagement Profile

PIM	patient information material (Patient:inneninformationsmaterial)
PPI	Patient and Public Involvement
PTSD	post-traumatic stress disorder
QPR	quarterly progress report
RQ	research question
SHI	statutory health insurance
UPIM-Check	User-friendly Patient Information Material Checklist
VF	Versorgungsforschung

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Doctoral student's declaration of contribution

1. Mental disorders and utilization of mental health services in newly diagnosed cancer patients: An analysis of German health insurance claims data

Sandra Salm, Katja Blaschke, Peter Ihle, Ingrid Schubert, Antje Dresen, Holger Pfaff, Nadine Scholten

Psycho-Oncology [Impact factor at time of publication: 3.006]

Authors' contributions

The analyses for the manuscript are based on the "Statutory Health Insurance (SHI) Sample AOK Hesse/KV Hesse". Sandra Salm wrote the project outline to apply for permission to analyse the database from the advisory board "SHI Sample AOK Hesse/KV Hesse". The advisory board consists of members of the AOK Hesse, the KV Hesse, the Hessian Ministry for Social Affairs, and the PMV forschungsgruppe. The preparation of the project outline included the conceptualization of the research questions and the statistical analyses. Nadine Scholten supported this process and revised the project outline. Sandra Salm coded and performed the data processing, plausibility checks, and statistical analyses and interpreted the data. Peter Ihle provided the resources for the analyses. Peter Ihle and Katja Blaschke gave technical and scientific support towards the database. Nadine Scholten helped with the refinement of the analyses. Data interpretation was accompanied by Nadine Scholten, Peter Ihle, Ingrid Schubert, Antje Dresen, and Holger Pfaff.

Sandra Salm wrote the original draft of the manuscript and prepared tables and figures. Nadine Scholten, Katja Blaschke, Peter Ihle, Ingrid Schubert, Antje Dresen, and Holger Pfaff critically reviewed the manuscript before submission. Sandra Salm revised the manuscript during peer review.

2. Conducting a prospective evaluation of the development of a complex psycho-oncological care programme (isPO) in Germany

Sandra Salm*, Natalia Cecon*, Imke Jenniches, Holger Pfaff, Nadine Scholten, Antje Dresen, Theresia Krieger

*Sandra Salm und Natalia Cecon contributed equally to this work.

BMC Health Services Research [Impact factor at time of publication: 2.655]

Authors' contributions

The manuscript presents sub-results of the external evaluation within the isPO project (integrated, cross-sectoral Psycho-Oncology) focusing the prospective evaluation phase.

Sandra Salm and Natalia Cecon were responsible for the project conduction and therefore for the conceptualization of the external evaluation and its study design. This process was

accompanied by Imke Jenniches and Theresia Krieger as the project managers of the external evaluation. Sandra Salm, Natalia Cecon, and Imke Jenniches developed the criteria catalogue for the evaluation of the consortium partners' quarterly progress reports and conducted the document analysis. Imke Jenniches designed the interview guideline for the isPO project leader interview and was responsible for its conduction and analysis. Sandra Salm and Natalia Cecon developed the guideline for the focus group with the programme designers. Natalia Cecon conducted the focus group as head moderator and Sandra Salm as co-moderator and recorder. Sandra Salm conducted the additional telephone interview. Sandra Salm and Natalia Cecon analyses the focus group/telephone interview data independently and discussed and consented the coding system afterwards. Sandra Salm was responsible for the quantitative isPO training evaluation. This included the development of the questionnaires, the coordination of data collection, and data analysis. Imke Jenniches reviewed the focus group/telephone interview guideline and training evaluation questionnaires. Sandra Salm and Natalia Cecon integrated and interpreted the results of all beforementioned data analyses. Imke Jenniches supported this process. As a scientific supervisor, Antje Dresen supported the conceptualization and helped with the refinement of the data collection and analysis instruments (focus group and interview guidelines, criteria catalogue for the document analysis). Holger Pfaff and Nadine Scholten were supervisors during the external evaluation of isPO and acquired the funding. Sandra Salm, Natalia Cecon, and Theresia Krieger prepared tables and figures. Sandra Salm and Natalia Cecon wrote the original draft of the manuscript. Theresia Krieger, Imke Jenniches, Holger Pfaff, Nadine Scholten, and Antje Dresen critically reviewed the manuscript before submission. Sandra Salm revised the manuscript during peer review.

3. Participatory development and preliminary psychometric properties of the User-Friendly Patient Information Material Checklist (UPIM-Check)

Sandra Salm, Judith Mollenhauer, Carolin Hornbach, Natalia Cecon, Antje Dresen, Stefanie Houwaart, Anna Arning, Andrea Göttel, Kathrin Schwickerath, Holger Pfaff, Nadine Scholten, Theresia Krieger

International Journal of Environmental Research and Public Health [Impact factor at time of publication: 3.390]

Authors' contributions

The work regarding the manuscript was part of the implementation/optimisation phase in the isPO project and was conducted following the participatory health research approach.

As part of the external evaluation team, Sandra Salm, Judith Mollenhauer, and Theresia Krieger conceptualized the development of the UPIM-Check instrument; Theresia Krieger and Sandra Salm planned the study design. Theresia Krieger conducted the literature search and

condensed the findings to a criteria list. Sandra Salm and Judith Mollenhauer reviewed the literature and edited the criteria list. The preliminary UPIM-Check thus created was piloted by Sandra Salm, Judith Mollenhauer, and Natalia Cecon. The pre-test of the UPIM-Check was conducted by Stefanie Houwaart, Anna Arning, Andrea Göttel, and Kathrin Schwickerath. Sandra Salm analysed the data of the piloting and pre-test revising and finalizing the UPIM-Check accordingly. She coordinated the translation process of the UPIM-Check to English by obtaining the professional translations and managing the review and adjudication involving Theresia Krieger and Natalia Cecon. Sandra Salm contacted cancer patient organizations from English-speaking countries to recruit participants for the pre-test of the UPIM-Check English version. This process was supported by Stefanie Houwaart and Theresia Krieger. Sandra Salm collected the pre-test data, analysed them and finalized the UPIM-Check English version accordingly.

Sandra Salm was responsible for the pilot study on the psychometric evaluation of the UPIM-Check German version. This included the conceptualization, the study design, preparation of data collection materials and instruments, and randomization. Carolin Hornbach helped with participant acquisition, sent the study documents to the participants, and digitally recorded the data from the filled in UPIM-Check instruments. Sandra Salm reviewed the data input, and conducted the statistical analyses and interpretation of the results. She wrote a short report for the participants of the pilot study on the psychometric evaluation. Antje Dresen was a scientific supervisor and therefore supported the conceptualization and investigation. Holger Pfaff and Nadine Scholten were supervisors during the external evaluation of isPO and acquired the funding. Sandra Salm prepared tables and figures, and wrote the original draft of the manuscript. Theresia Krieger, Judith Mollenhauer, Carolin Hornbach, Natalia Cecon, Antje Dresen, Stefanie Houwaart, Anna Arning, Andrea Göttel, Kathrin Schwickerath, Holger Pfaff, and Nadine Scholten critically reviewed the manuscript before submission. Sandra Salm revised the manuscript during peer review.

4. Integrating one-to-one peer support into psycho-oncological care in Germany: Multi-perspective, mixed-methods evaluation of the isPO onco-guide service

Sandra Salm, Stefanie Houwaart, Natalia Cecon-Stabel, Antje Dresen, Holger Pfaff, Nadine Scholten, Theresia Krieger

Journal of Cancer Research and Clinical Oncology [Impact factor at time of publication: 4.322]

Authors' contributions

The manuscript focuses on the formative and summative external evaluation on the isPO care level 1 – the isPO onco-guide peer support.

The overall conceptualization and study design of the external evaluation of the isPO programme was planned by Sandra Salm and Natalia Cecon-Stabel with the support of Theresia

Krieger and Antje Dresen. Sandra Salm conceptualized the evaluation of the isPO onco-guide service as part of the isPO programme according to the programme theory model of Issel and Wells (2017). Theresia Krieger and Antje Dresen helped with the refinement of the study design and reviewed the following described data collection instruments. The qualitative study part of the isPO onco-guide evaluation comprised semi-structured interviews with patients, interviews and a focus group with isPO onco-guides, focus groups with isPO service providers, and interviews with isPO network coordinators and head psycho-oncologists. The guidelines for the patient interviews, the service provider focus groups, and network coordinator interviews were designed by Sandra Salm and Natalia Cecon-Stabel. Furthermore, Sandra Salm developed the guideline for the isPO onco-guide interviews and focus group, and Natalia Cecon-Stabel for the head psycho-oncologist interviews. The patient interviews were conducted by Theresia Krieger, Natalia Cecon-Stabel and Sandra Salm. Sandra Salm conducted the isPO onco-guide interviews, the isPO onco-guide focus group, and network coordinator interviews. Natalia Cecon-Stabel conducted the service provider focus groups and head-psycho-oncologist interviews. Sandra Salm designed the coding system for all beforementioned transcripts regarding the isPO onco-guide service. Theresia Krieger supported this process. Sandra Salm conducted the coding and qualitative content analysis. The quantitative study part contained surveys of patients and isPO onco-guides, and data from the isPO IT assistance and documentation system (isPO care data). Sandra Salm and Natalia Cecon-Stabel designed the patient questionnaire and conducted the necessary literature search. Sandra Salm developed the isPO onco-guide questionnaire based on the results of the isPO onco-guide interviews. She conducted the data preparation for all used data sets and the data linkage of the patient survey and isPO care data. Furthermore, she coded and carried out all quantitative analyses according to the manuscript. Sandra Salm integrated and interpreted the results of the qualitative and quantitative study parts. Theresia Krieger helped with interpretation. Stefanie Houwaart supported the recruitment of participants for the isPO onco-guide interviews, focus group, and survey. Holger Pfaff and Nadine Scholten were supervisors during the external evaluation of isPO and acquired the funding. Sandra Salm prepared tables and figures, and wrote the original draft of the manuscript.

Theresia Krieger, Stefanie Houwaart, Natalia Cecon-Stabel, Antje Dresen, Holger Pfaff, and Nadine Scholten critically reviewed the manuscript before submission. Sandra Salm revised the manuscript during peer review.

Acknowledgements

The aim of a doctorate is to acquire the knowledge and skills to act independently as a researcher. But 'independently' does not mean lonely, especially not when you are engaging in participatory research. Therefore, I would like to thank all the people who have contributed to the completion of this work.

I thank my supervisor Prof. Dr. Holger Pfaff and my co-supervisor PD Dr. Nadine Scholten who have accompanied my path in health services research since the beginning, starting from my master's studies. My tutors PD Dr. Michael Kusch and Dr. Utako Barnikol supported me a lot in my independence as a researcher. Their impulses helped me to challenge myself – always with the confidence that I was on the right track.

A big thank you goes to the isPO team at IMVR, especially Dr. Theresia Krieger, Dr. Antje Dresen, and Natalia Cecon-Stabel. I will always remember how well we complemented each other with our expertise and personalities, overcoming any challenge together. Thank you that our collaboration was also characterised by mutual respect, appreciation, and lots of humour. Theresia, I owe you in particular the enthusiasm I gained for participatory research and thus the focus of this work. You have been a great support to me in my personal development as a researcher.

I thank all co-authors from the IMVR, the PMV forschungsgruppe, the HKSH-BV, and the KG NRW for their cooperation on the manuscripts and their insightful impulses.

I dedicate my work to those people who have the main role - the cancer patients and the volunteers and employees in cancer self-help, without whom this work would not be possible. Thanks to all isPO patients, isPO onco-guides, professional service providers, and isPO designers.

Doing a doctorate meant to be confronted with ups and downs of progress and setbacks and sometimes with social pigeonholes such as "child from a working-class family with migration background" or "woman who dares to pursue a higher degree than her husband". I am extremely grateful that with my family and friends I have people in my life without such prejudices. I thank you all for the carefree hours in which I was able to clear my mind and regain energy. In particular, I thank my parents for following my every path with unconditional support.

My biggest thanks go to my husband Stefan Salm. Already during my bachelor's studies, you were sure that one day I would pursue a doctorate, even though that was never my plan at the time. It is hard for me to admit it – but it seems as if you were right. ;) Thank you for giving me strength whenever nothing seemed to work out and for reminding me to be proud of any success, no matter how small or big.

Curriculum Vitae

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Place of birth	Frankfurt/Main

Professional experience

since 12/2022	Institute of General Practice; Goethe University Frankfurt *Research Associate*
6/2022-11/2022	Institute of Pharmaceutical Biology; Goethe University Frankfurt *Research Associate*
10/2017-4/2022	Institute of Medical Sociology, Health Services Research, and Rehabilitation Science; University of Cologne *Research Associate*
3/2014-7/2015	Logopädische Praxis Mack und Polzin Frankfurt/Main *Academic Speech and Language Therapist*

Education

12/2018-12/2023	University of Cologne *Interdisciplinary Program Health Sciences*
8/2021-8/2022	University Hospital Cologne *Certified training Participatory Health Research*
10/2015-8/2017	University of Cologne *Master of Science Health Services Science*
10/2010-1/2014	University of Cologne *Bachelor of Arts Speech and Language Therapy*
10/2009-9/2010	Goethe University Frankfurt *Bachelor of Science Psychology*
8/2000-6/2009	Carl-Schurz-Schule Frankfurt/Main *General university entrance qualification*

Peer reviews

Journal manuscripts:	Archives of Public Health; BMC Medical Informatics and Decision Making; BMJ Open; Complementary Medicine Research; Journal of Cancer Research and Clinical Oncology; Scientific Reports; Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen
Research proposals:	Federal Ministry of Education and Research

Memberships in research societies

Deutsches Netzwerk Versorgungsforschung e.V.
- → *Working group ‚Partizipative Versorgungsforschung'*
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Krieger T, **Salm S**, Cecon N, Dresen A. Welche Kriterien sind für die Qualität von Patienteninformationsmaterialien wichtig und wie kann die Qualität von der Zielgruppe bewertet werden?: Thematische Einführung am Beispiel des Programms integrierte, sektorenübergreifenden Psychoonkologie (isPO). Paper presented at: 56. Jahrestagung der Deutschen Gesellschaft für Sozialmedizin und Prävention; 2021 Sep 22-24; Leipzig; digital. doi:10.1055/s-0041-1732149.

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Workshops and skills building seminars

Hentschel L, Rohde D, **Salm S**. Ein Haus baut sich nur mit vereinten Kräften: Wie Betroffene als Co-Forschende und die Begleitung durch einen Critical Friend den Unterschied machen. Workshop presented at: 7. Berliner Werkstatt Partizipative Forschung; 2023 Mar 3; Berlin.

Krieger T, **Salm S**, von Peter S. (Un-)möglichkeiten partizipativen Zusammenarbeitens im Rahmen von klinischen Studien und Designs der Versorgungsforschung: Potentiale einer Prozessevaluation. Workshop presented at: PartNet Workshop; 2022 Dec 9; digital.

Krieger T, **Salm S**. Kompaktkurs Partizipative Gesundheitsforschung. Workshop presented at: Haus der Krebs-Selbsthilfe – Bundesverband e.V.; 2022 Sep 17; Bonn.

Krieger T, Dresen A, Cecon N, **Salm S**, Farin-Glattacker E. Wann, wie und warum können partizipative Elemente Evaluationen unterstützen?: Einblicke und Perspektivenvielfalt in Prozessevaluationen. Pre-Conference Workshop presented at: 20. Deutscher Kongress für Versorgungsforschung; 2021 Oct 6-8; digital.

Krieger T, Dresen A, Cecon N, **Salm S**. Weitwinkelobjektiv „Partizipation“ sinnvoll nutzen: Wie können Evaluationen komplexer Gesundheitsprogramme vom gezielten Einbezug Beteiligter profitieren? Workshop presented at: 5. Berliner Werkstatt Partizipative Forschung; 2021 Mar 12; digital.

Krieger T, **Salm S**, Houwaart S. Using participatory health research to optimise psycho-oncological patient information material. Skills-building-seminar presented at: 16th World Congress on Public Health; 2020 Oct 12-17; digital. doi:10.1093/eurpub/ckaa165.1434.

Göttel A, Houwaart S, **Salm S**, Krieger T. Lessons learned bei der Optimierung von Patienteninformationsmaterialien mit dem Partizipativen Gesundheitsforschungsansatz in isPO (integrierte sektorenübergreifende Psychoonkologie). Workshop presented at: 4. Berliner Werkstatt Partizipative Forschung; 2020 Mar 6; Berlin.

Erklärung

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Übersicht der Publikationen

1. Salm S, Blaschke K, Ihle P, Schubert I, Dresen A, Pfaff H, Scholten N. Mental disorders and utilization of mental health services in newly diagnosed cancer patients: an analysis of German health insurance claims data. Psychooncology. 2021;30:312–20. doi:10.1002/pon.5579.
2. Salm S*, Cecon N*, Jenniches I, Pfaff H, Scholten N, Dresen A, Krieger T. Conducting a prospective evaluation of the development of a complex psycho-oncological care programme (isPO) in Germany. BMC Health Serv Res. 2022;22:531. doi:10.1186/s12913-022-07951-1. *Sandra Salm and Natalia Cecon contributed equally to this work.
3. Salm S, Mollenhauer J, Hornbach C, Cecon N, Dresen A, Houwaart S, et al. Participatory development and preliminary psychometric properties of the User-Friendly Patient Information Material Checklist (UPIM-Check). Int J Environ Res Public Health. 2021;18:8773. doi:10.3390/ijerph18168773.
4. Salm S, Houwaart S, Cecon-Stabel N, Dresen A, Pfaff H, Scholten N, Krieger T. Integrating one-to-one peer support into psycho-oncological care in Germany: multi-perspective, mixed-methods evaluation of the isPO onco-guide service. J Cancer Res Clin Oncol. 2023;149:10399–10422. doi:10.1007/s00432-023-04951-4.

Ich versichere, dass ich alle Angaben wahrheitsgemäß nach bestem Wissen und Gewissen gemacht habe und verpflichte mich, jedmögliche, die obigen Angaben betreffenden Veränderungen, dem Promotionsausschuss unverzüglich mitzuteilen.

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