

Evidence-based Guideline Psycho-oncological Diagnostics, Counseling and Treatment of Adult Cancer Patients

2.0 – May 2023

AWMF Registration Number: 032-051OL

Guideline (Long version)

This is new!
This has changed

Important Updates

Key changes in version 2.0

The following topics are new to the guideline:

In [Chapter 8](#) Psycho-oncological Interventions

- 8.4 Psycho-oncological E-health interventions
- 8.5.3 Specific Psycho-oncological interventions in the Palliative Phase
- 8.6 Psycho-oncological Crisis Intervention

In [Chapter 9](#) Psychopharmacotherapy

9.1.3 Sleep Disorders

9.1.4 Special Risks Regarding Side Effects and Interactions of Psychotropic Drugs in Cancer Patients

9.1.5 Psychopharmacotherapy for individuals at Increased Risk of Epileptic Seizures due to Malignant CNS Tumors or Cerebral Metastases

9.1.6 Risk of Bleeding Associated with Antidepressants

In [Chapter 10](#) Specifics of Individual Diagnostic Groups and Their Treatment

10.6 Specific Burdens on Patients with Brain Tumors

10.7 Specific Burdens on Young Adult Cancer Patients (AYAs)

10.8 Specific Burdens on Older Cancer Patients

10.9 Specific Burdens on People Living with a Cancer Diagnosis (Cancer Survivors)

The content of the following chapters has been revised:

[Chapter 8.8](#): This chapter has been revised and divided into separate evidence-based sections for Art Therapy (8.8.1), Music Therapy (8.8.2), Dance and Movement Therapy (8.8.3), and Overlapping Systematic Reviews higher-level reviews (8.8.4).

[Chapter 11](#) This chapter has been completely revised.

For Chapters 3 - 7 there were no changes in content, but only an editorial revision as well as an update of the literature. All editorial revisions of existing recommendations were marked with the note "modified 2023". New recommendations were appropriately identified with the note "new 2023".

Chapter 9.3 ([Chapter 8.3](#)) Physical and Exercise Therapy found in Version 1 was omitted from this Version with reference to the Guideline "Exercise Therapy in Oncological Diseases" which is currently under development.

Table of Contents

Important Updates.....	2
1 Information about this Guideline	8
1.1 Editors	8
1.2 Leading Scientific Societies	8
1.3 Funding of the Guideline	8
1.4 Contact	8
1.5 How to cite.....	8
1.6 Special Comment	9
1.7 Objectives of the GGPO	9
1.8 Additional Documents relating to this Guideline	10
1.9 Composition of the Guideline Group.....	11
1.9.1 Guideline Coordination	11
1.9.2 Involved Professional Societies and Organisations	11
1.9.3 Workgroups.....	16
1.9.4 Patient Involvement	17
1.9.5 Methodological Support.....	17
1.10 Abbreviations Used	18
2 Introduction	21
2.1 Scope and Purpose	21
2.1.1 Objective and Key Questions	21
2.1.2 Target Audience	21
2.1.3 Validity and Update Process	21
2.2 Methodology.....	22
2.2.1 Levels of Evidence (LoE)	22
2.2.2 Grades of Recommendation (GoR)	23
2.2.3 Statements	23
2.2.4 Expert Consensus (EC)	24
2.2.5 Independence and Disclosure of Possible Conflicts of Interest	24
3 Definition and Basic Principles of Psycho-oncology.....	25

3.1	Definition.....	25
3.2	Targets	25
3.3	Tasks and Approaches	26
3.4	Informational Needs and Psychosocial Care	27
4	Requirements for Psycho–oncological Care Settings.....	29
4.1	Inpatient Care Facilities	29
4.1.1	Hospitals	29
4.1.2	Oncology Rehabilitation Facilities	30
4.1.3	Social Services in Clinics.....	30
4.2	Palliative Care Facilities	31
4.3	Outpatient Psycho–oncology Care Facilities.....	32
4.4	Self–help/Peer–Support Groups	34
4.5	Cross–sector Coordination of Psycho–oncology Care	35
5	Psychosocial Distress	36
5.1	Quality of Life and its Assessment	36
5.2	Physical, Mental, Social and Spiritual/Religious Problems	38
5.3	Psycho–oncological Relevant Dysfunctions.....	39
5.4	The Frequency of Subsyndromal Mental Distress.....	40
6	Psychiatric Comorbidity.....	41
6.1	Risk Factors that Promote the Occurrence of Mental Disorders	42
6.2	Mental Disorders According to ICD–10/DMS–IV Classification	44
7	Diagnostics	48
7.1	Tasks and Special Features	48
7.1.1	The Objective of Psycho–oncological Diagnostics	48
7.2	Screening	49
7.3	Diagnostic Procedures	51
7.3.1	Appropriate Screening Methods for Assessing the Need for Psycho–oncological Intervention	51

7.4	Diagnostic Process Steps	56
8	Psycho-oncological Interventions	57
8.1	Concept and General Principles for the Indication of Psycho-oncological Treatment	57
8.2	Relaxation and Imaginative Techniques	63
8.3	Psychoeducation	67
8.4	Psycho-oncological E-health Interventions	72
8.5	Psychotherapeutic Interventions	77
8.5.1	Psychotherapeutic Interventions in Individual and Group Settings	77
8.5.2	Psychotherapeutic Couple and Family Interventions	85
8.5.3	Specific Psycho-oncological Interventions in the Palliative Phase	89
8.6	Psycho-oncological Crisis Intervention	95
8.7	Psychosocial Counseling	97
8.8	Creative Arts Therapies	99
8.8.1	Art Therapy	100
8.8.2	Music Therapy	103
8.8.3	Dance and Movement Therapy	109
8.8.4	Overarching Systematic Reviews	111
9	Additional Therapies	114
9.1	Psychopharmacotherapy	114
9.1.1	Depressive Symptoms and Depression	116
9.1.2	Fears and Anxiety Disorders	117
9.1.3	Sleep Disorders	118
9.1.4	Special Risks Regarding Side Effects and Interactions of Psychotropic Drugs in Cancer Patients	121
9.1.5	Psychopharmacotherapy for Individuals at Increased Risk for Epileptic Seizures due to Malignant CNS Tumors or Cerebral Metastases	122
9.1.6	Risk of Bleeding Associated with Antidepressants	123
9.2	Occupational Therapy	124
10	Specifics of Individual Diagnosis Groups and Their Treatment	128
10.1	Sexual Disorders	128
10.1.1	Sexual Dysfunction Associated with Breast Cancer and Gynecological Tumors	128
10.1.2	Sexual Dysfunction Associated with Urologic Tumors in Men	130

10.1.3	Sexual Disorders associated with Malignant Lymphomas and Leukemias	131
10.1.4	Sexual Dysfunction associated with an Ileostomy, Colostomy, or Urostomy.....	132
10.2	Impairments after High-dose Chemotherapy Followed by Allogeneic Stem Cell Transplantation.....	132
10.3	Impairments After Removal of the Larynx in Laryngeal Carcinoma.....	132
10.4	Specific Burdens Resulting from the Treatment of Patients with Gastrointestinal Tumors	133
10.5	Specific Burdens of Patients with Bronchial Carcinoma after Lung Resection	134
10.6	Specific Burdens on Patients with Brain Tumors	134
10.7	Specific Burdens on Young Adult Cancer Patients (AYAs)	135
10.8	Specific Burdens on Older Cancer Patients	136
10.9	Specific Burdens on People Living with a Cancer Diagnosis (Cancer Survivors)	137
11	Patient-centered Communication.....	139
11.1	Basic Principles and Use of Patient-centered Communication	140
11.1.1	Communicative Preferences of Cancer Patients.....	144
11.2	Definition of Patient-centered Communication	145
11.3	Effectiveness of Patient-centered Communication.....	146
11.3.1	Retention of Information.....	146
11.3.2	Patient Satisfaction	147
11.3.3	Patient Adherence.....	147
11.3.4	Mental Well-being, Psychological Factors, and Quality of Life	147
11.3.5	Effects of Participatory Decision Making	147
11.3.6	Effects of Communicating the Prognosis	148
11.4	Improving Communicative Competences	149
11.4.1	Effectiveness of Communication Trainings	150
12	Quality Assurance.....	152
12.1	Structural Quality	152
12.1.1	Personnel Qualification	152
12.1.2	Personnel Requirements.....	153
12.1.3	Spatial Requirements	154
12.1.4	Treatment Concept	154
12.1.5	Structural Characteristics of the Services	155
12.2	Process Quality.....	156

12.2.1	Screening for Psychosocial Distress	156
12.2.2	Establishment of Counseling or Treatment Goals	156
12.2.3	Networking and Cooperation.....	156
12.2.4	Documentation	157
12.2.5	Patient Reported Outcomes	157
12.2.6	Supervision.....	157
12.3	Outcome Quality	157
13	Quality indicators	158
14	List of Tables.....	163
15	List of Figures.....	164
16	Literature References	165

1 Information about this Guideline

1.1 Editors

The German Guideline Program in Oncology (GGPO) of the Association of the Scientific Medical Societies in Germany (AWMF), the German Cancer Society (DKG), and the German Cancer Aid Foundation (DKH).

1.2 Leading Scientific Societies



PSO. Arbeitsgemeinschaft für Psychoonkologie
in der Deutschen Krebsgesellschaft (DKG)

German Cancer Society (DKG) represented by its working groups

1.3 Funding of the Guideline

This guideline was supported by the German Cancer Aid Foundation (DKH) within the framework of the German Guideline Program in Oncology.

1.4 Contact

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1.5 How to cite

German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): S3-Leitlinie Psycho-oncological Diagnostics, Counseling and Treatment of Adult Cancer Patients, Long version 2.0, 2023, AWMF Registration Number: 032-051OL <https://www.leitlinienprogramm-onkologie.de/leitlinien/psychoonkologie/>; Accessed [tt.mm.jjjj]

1.6 Special Comment

Medicine is subject to a continuous development process, so that all information, especially in regard to diagnostic and therapeutic procedures, can only correspond to the state of knowledge at the time when the guideline is printed. The greatest possible care has been taken with regard to the recommendations given for therapy and the selection and dosage of medications. Nevertheless, users are urged to consult the manufacturers' package inserts and expert information for verification and, in case of doubt, to consult a specialist. In the general interest, any discrepancies should be reported to the OL editorial office.

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1.7 Objectives of the GGPO

By establishing the German Guideline Program in Oncology (GGPO), the Association of Scientific Medical Societies (AWMF), the German Cancer Society (DKG) and the German Cancer Aid Foundation have set out to jointly promote and support the development, updating and use of scientifically based and practicable guidelines in oncology. The program is based on the medical-scientific findings of AWMF and the DKG, the consensus of medical experts, users and patients, as well as the set of rules for the development of guidelines put forth by the AWMF, and the professional support and funding by the German Cancer Aid Foundation. In order to reflect the current state of medical knowledge and advances in medicine, guidelines must be reviewed and updated on a regular basis. The implementation of AWMF regulations is intended to provide the basis for the development of high-quality oncological guidelines. Since guidelines are an important instrument of quality assurance and quality management in oncology, they should be introduced into everyday care in a targeted and sustainable manner. Thus, active implementation measures as well as evaluation programs are an important part of promoting the German Guideline Program in Oncology. The aim of the program is to create a professional and financially secure basis for the development and provision of high-quality guidelines in Germany. These high-quality guidelines not only facilitate the structured transfer of knowledge, but can also play a role in shaping structures of the healthcare system. Evidence-based guidelines provide the foundation for the creation and updating of disease management programs. Quality indicators derived from guidelines can be used in the framework of the certification of organ tumor centers.

1.8 Additional Documents relating to this Guideline

This document is the long version of the S3 Guideline on Psycho-oncological Diagnostics, Counseling and Treatment of Adult Cancer Patients.

In addition to the long version, the following supplementary documents for this guideline are available in German:

- Short version of this guideline
- Patient Guideline (lay version)
- Guideline Report on the preparation of this guideline

The guideline and all additional documents are available on the following websites:

German Guideline Program in Oncology (<https://www.leitlinienprogramm-onkologie.de/leitlinien/psychoonkologie/>)
AWMF (<https://register.awmf.org/de/leitlinien/detail/032-051OL>)
Guidelines International Network (www.g-i-n.net)

Earlier versions of the guideline as well as the additional documents (guideline report, evidence tables, evidence reports, if applicable) are available in the guideline archive at <https://www.leitlinienprogramm-onkologie.de/leitlinien/psychoonkologie/>.

The guideline is also included in the German Guideline Program in Oncology app.
Further information at: <https://www.leitlinienprogramm-onkologie.de/app>



iOS App



Android App



1.9 Composition of the Guideline Group

1.9.1 Guideline Coordination

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Dr. Claudia Gebhardt, Leipzig (until June 30th, 2020)
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1.9.2 Involved Professional Societies and Organisations

The organizations and respective representatives listed in the following table were involved in the preparation of this guideline.

Table 1: Participating professional associations and organizations (alphabetical)

Participating professional associations and organizations (alphabetical)	Representative(s)
Arbeitsgemeinschaft Dermatologische Onkologie in der DKG und DDG (ADO)	Prof. Dr. Carmen Loquai Dr. Frank Meiß
Arbeitsgemeinschaft Gynäkologische Onkologie der DGGG und DKG (AGO)	Prof. Dr. Annette Hasenburg
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Participating professional associations and organizations (alphabetical)	Representative(s)
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Arbeitsgemeinschaft Urologische Onkologie der Deutschen Krebsgesellschaft (AUO)	Prof. Dr. Chris Protzel
Arbeitsgemeinschaft für Psychoonkologie in der DKG (PSO)	Gabriele Blettner PD Dr. Andreas Dinkel
Assoziation Chirurgische Onkologie (ACO)	Prof. Dr. Axel Kleespies Prof. Dr. Wolfgang Thasler
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Bundesarbeitsgemeinschaft für ambulante psychosoziale Krebsberatung (BAK)	Gudrun Bruns Martin Wickert
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Participating professional associations and organizations (alphabetical)	Representative(s)
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Participating professional associations and organizations (alphabetical)	Representative(s)
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Deutsche Gesellschaft für Thoraxchirurgie (DGT)	Dr. Dietrich Stockhausen
Deutsche Gesellschaft für Urologie (DGU)	PD Dr. Désirée Luise Dräger Dr. Ulrike Hohenfellner
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Deutscher Verband Ergotherapie (DVE)	Birthe Hucke Claudia Meiling Isabel Pech
Deutscher Verband für Physiotherapie (ZVK)	Reina Tholen - †

Participating professional associations and organizations (alphabetical)	Representative(s)
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In addition, the German Society of General and Family Medicine (DEGAM) and the German Psychoanalytic Society (DPG) were invited to participate in the update of this guideline. However, due to a lack of personnel resources, they did not take part in the guideline update. The House of Cancer Self-help (Haus der Krebsselbsthilfe, <https://www.hausderkrebsselbsthilfe.de>) was represented by Ms. Jäger and Mr. Olbrich (see above).

1.9.3 Workgroups

Table 2: Composition of Guideline Workgroups

Workgroup	Composition of Workgroup
AG A: Chapter 3 - Definition and Basic Principles of Psycho-oncology; Chapter 4 - Structural Prerequisites of Psycho-oncological Care Settings	Prof. Dr. Joachim Weis Dr. Andrea Benecke, Ruth Curio, Prof. Dr. Stephan Dettmers, Prof. Dr. Pirus Ghadjar, Dr. Sabine Köhler, Dr. Ingrid Rothe-Kirchberger, Dr. Andreas Werner, Dr. Tina Wessels, Martin Wickert
AG B: Chapter 5 - Psychosocial Distress; Chapter 6 - Psychiatric Comorbidity; Chapter 7 - Diagnostics	Julia Hufeld, Prof. Dr. Anja Mehnert-Theuerkauf Dr. Jan Christopher Cwik, Prof. Dr. Stephan Dettmers, Dr. Claudia Gebhardt, Dr. Sabine Köhler, Prof. Dr. Dr. Klaus Mathiak, Dr. Frank Meiß, Dr. Anna Westermair, Prof. Dr. Tanja Zimmermann
AG C: Psycho-oncological Interventions Chapter 8.1 - Concept and General Principles 8.2 - Relaxation and Imaginative Techniques; 8.3 - Psychoeducation; 8.4 - Psycho-Oncology E-Health Interventions; 8.5 - Psychotherapeutic Interventions	Felix Brehm, Prof. Dr. Joachim Weis Prof. Dr. Kristin Härtl, Dr. Elisabeth Jentschke, Dipl.-Psych. Karin Kieseritzky, Prof. Dr. Imad Maatouk, Claudia Meiling, Isabel Pech, Dr. Cornelia Rabe-Menssen, Dr. Carola Riedner, PD Dr. Heike Schmidt, Dr. Friederike Schulze, Reina Tholen, Prof. Dr. Tanja Zimmermann
AG D: Psycho-oncological Interventions Chapter 8.6 - Psycho-oncological Crisis Intervention; 8.7 - Psychosocial Counseling -	Gudrun Bruns Hanna Bohnenkamp, Prof. Dr. Stephan Dettmers, Prof. Dr. Imad Maatouk, Claudia Meiling, Isabel Pech, Dr. Carola Riedner, Dipl. Soz. Päd. Marie Rösler, Günter Tessmer, Dr. Anna Westermair, Martin Wickert
AG E: Psycho-Oncological Interventions - Chapter 8.8 Creative Arts Therapies	Prof. Dr. Harald Gruber Dr. Ruth Hertrampf, Prof. Dr. Sabine Koch, Prof. Dr. Joachim Weis, Prof. Dr. Dorothee Wiewrodt
AG F: Additional Therapies - Chapter 9.1 Pharmacotherapy	Prof. Dr. Imad Maatouk, Prof. Dr. Dr. Klaus Mathiak Dr. Pia Heußner, Dr. Anna Westermair
AG G: Additional Therapies - Chapter 9.2 Occupational Therapy	Claudia Meiling, Isabel Pech Manfred Gaspar, PD Dr. Georgia Schilling
AG H: Additional Therapies - Physical and Exercise Therapy (no longer included)	Reina Tholen Manfred Gaspar, PD Dr. Georgia Schilling

Workgroup	Composition of Workgroup
AG I: Chapter 10 Specifics of Individual Diagnostic Groups and Their Treatment	PD Dr. Friederike Siedentopf Dr. Susanne Ditz, PD Dr. Désirée Luise Dräger, Dr. Sara Marquard, Dr. Norbert Mayer-Amberg, Dr. Dietrich Stockhausen
AG Int: Conflicts of Interest	Dr. Markus Follmann Thorsten Kreikenbohm, Prof. Dr. Joachim Weis
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AG K: Quality Assurance	Prof. Dr. Joachim Weis Dr. Andrea Benecke, Ruth Curio, Prof. Dr. Pirus Ghadjar, Thorsten Kreikenbohm, Prof. Dr. Dr. Klaus Mathiak, Dr. Andreas Werner, Dr. Tina Wessels, Dr. Anna Westermair, Martin Wickert, Prof. Dr. Tanja Zimmermann
AG L: Quality Indicators (External contract)	Prof. Dr. Joachim Weis Martina Jäger, Thorsten Kreikenbohm, Prof. Dr. Dr. Klaus Mathiak, Manfred Olbrich, Dr. Andreas Werner, Dr. Anna Westermair
AG M: Patient Guideline (External contract)	Dipl.-Psych. Beate Hornemann, Martina Jäger, Dipl.-Psych. Karin Kieseritzky, Prof. Dr. Imad Maatouk, Manfred Olbrich, Dr. Ingrid Rothe-Kirchberger, Prof. Dr. Joachim Weis
Workgroup managers are marked in bold.	

1.9.4 Patient Involvement

The guideline was developed with the direct participation of patient representatives (Manfred Olbrich, Martina Jäger). These representatives were involved in the entire process of updating this guideline and participated in the consensus conferences with voting rights.

1.9.5 Methodological Support

Through the German Guideline Program in Oncology:

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 Prof. Dr. med. Ina Kopp, (AWMF), (IMWi), Marburg
 Thomas Langer, (DKG), Berlin
 Gregor Wenzel, (DKG), Berlin
 Simone Witzel, (AWMF), Berlin

Through external contractors:

PD Dr. Simone Wesselmann, MBA; Dr. Johannes Rückher - Update of the Quality Indicators
 Mag. Wolfgang Geissler - Patient Guideline (Gesundheit Österreich GmbH, Vienna)

1.10 Abbreviations Used

Table 3: Abbreviations Used

Abbreviation	Explanation
AG	see below WG Working Group
AOTA	American Occupational Therapy Association
AWMF	Association of the Scientific Medical Societies
AYAs	Adolescents and Young Adults
ÄZQ	German Agency for Quality in Medicine (Ärztliches Zentrum für Qualität in der Medizin)
BAK	Federal Working Group for Ambulatory Psychosocial Cancer Counseling (Bundesarbeitsgemeinschaft für ambulante psychosoziale Krebsberatung e.V.)
CALM	Managing Cancer and Living Meaningfully
CBT	Cognitive Behavioral Therapy
CEBM	Centre for Evidence-Based Medicine (Oxford, UK)
CG	Control Group
CNS	Central nervous system
CST	Communication Skills Training
CYP2D6	Cytochrom P450 2D6
DKG	German Cancer Society
DMT	Dance and Movement Therapy
DSM	Diagnostic and Statistical Manual of Mental Disorders

Abbreviation	Explanation
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition
DT	Distress Thermometer
DVE	German Association of Occupational Therapy (Deutscher Verband Ergotherapie e.V.)
DVSG	German Association for Social Work in Healthcare (Deutsche Vereinigung für Soziale Arbeit im Gesundheitswesen)
DVT	German Society for Behavioral Therapy (Deutscher Fachverband für Verhaltenstherapie)
EC	Expert Consensus
EORTC	European Organisation for Research and Treatment of Cancer
FACT	Functional Assessment of Cancer Therapy
FBK	Questionnaire on Distress in Cancer Patients (Fragebogen zur Belastung von Krebskranken)
GAD-7	Health Questionnaire for Patients – Generalized Anxiety Disorder Module
GGPO	German Guideline Program in Oncology
HADS	Hospital Anxiety and Depression Scale
HSI	Hornheider Screening-Instrument
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IG	Intervention Group
IMCP	Individual Meaning-Centered Psychotherapy
MCGP	Meaning-Centered Group Psychotherapy
MM	Music Medicine
MT	Music Therapy
NCCN	National Comprehensive Cancer Network
OSAS	Obstructive Sleep Apnea Syndrome

Abbreviation	Explanation
PHQ	Patient Health Questionnaire
PICO	Population, Intervention, Comparison, Outcome
PO-Bado	Psychoonkologische Basisdokumentation (Basic Psycho-oncology Documentation)
PO-Bado-KF	Psychoonkologische Basisdokumentation Kurzform (Basic psycho-oncology documentation short-form)
QI	Quality indicator
RCT	Randomized Control Trial
SAPV	Specialized outpatient palliative care
SD	Standard Deviation
SIGN	Scottish Intercollegiate Guidelines Network
SSRI	Selective Serotonin Reuptake Inhibitor
TAM	Tamoxifen
TAU	Treatment as usual
USA	United States of America
WG	Working group

2 Introduction

2.1 Scope and Purpose

2.1.1 Objective and Key Questions

This guideline provides recommendations for psycho-oncological diagnosis, counseling and the treatment of adult cancer patients (≥ 18 years) during the entire course of a cancer illness as well as throughout all sectors of medical care. It provides the basis for implementing of psycho-oncological care services in all sectors. In particular:

The guideline should demonstrate the need for comprehensive psycho-oncological baseline documentation.

The guideline should be aligned with the goals of the National Cancer Plan [1] for psycho-oncological care.

The guideline should encourage regional cross-sector networking.

The quality of psycho-oncological services should be assessed in order to evaluate the work of service providers.

The psycho-oncological concerns of cancer patients under 18 years of age (children and adolescents) are addressed in a separate S3 Guideline for Pediatric Oncology (<https://www.awmf.org/leitlinien/detail/II/025-002.html>). The recommendations for this guideline are based on study data identified through systematic literature searches. In areas where a literature search was not possible, an expert consensus was attained through a formal consensus process.

2.1.2 Target Audience

The guideline is intended for all professional groups working in psycho-oncology and oncology such as physicians, psychologists, psychotherapists, social workers and social educators. Furthermore, patients are an important target group of this guideline, whereby a special patient guideline is offered for this target group within the framework of the German Guideline Program in Oncology.

2.1.3 Validity and Update Process

The S3 Guideline is valid until the next update. The validity period is set at 5 years from the date of publication of the updated version (2.0). Regular updates are planned. Comments and advice for the update process are welcome and can be sent to the following address: psychoonkologie@leitlinienprogramm-onkologie.de

2.2 Methodology

2.2.1 Levels of Evidence (LoE)

The assessment and classification of the studies reviewed, with the exception of studies on screening procedures, was carried out in accordance with the Oxford Centre of Evidence-Based Medicine (see Table 4) system.

Table 4: Evidence Grading Scheme (based on the Oxford Centre of Evidence-Based Medicine scheme [available in full [here](#)]).

Studies on Therapy, Prevention, Etiology		Studies on the Quality of Diagnostic Testing
1a	High-quality systematic review (SR) of randomized controlled trials (RCT) with low risk of bias.	High-quality systematic review (SR) of validation cohort studies with low risk of bias
1b	Single RCT with low risk of bias	Single validation cohort study with low risk of bias
1c	„All or None“ Principle*	Absolute SpPins and SnNouts**
2a	SR of cohort studies with low risk of bias.	SR of exploratory cohort studies
2b	Single cohort study with low risk of bias	Exploratory cohort study
2c	Outcome research; ecological studies	
3a	SR of case-control studies	SR of 3b and better studies
3b	Single case-control study	Cohort study at risk for bias (e.g., nonconsecutive or lacking consistency in reference standards used)
4	Case series	Diagnostic case-control study
5	Expert opinion or based on pathophysiological models or basic experimental research or „basic principles“	

* Dramatic effects, e.g., all patients died before therapy was available and some survived after therapy was introduced.

** An "Absolute SpPin" is a diagnostic finding whose specificity is so high that a positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose sensitivity is so high that a negative result rules-out the diagnosis.

2.2.2 Grades of Recommendation (GoR)

The methodology of the German Guideline Program in Oncology specifies that the grading of recommendation should be assigned by the guideline authors within the framework of a formal consensus process. Accordingly, moderated, nominal group processes or structured consensus conferences were conducted by the AWMF (see AWMF Guidelines Rulebook). During these processes, the recommendations were formally consented upon by the representatives holding the right to vote. The results of the respective votes (consensus strength) are assigned to the recommendations according to the categories listed below in the Table on Consensus Strength .

In this guideline, the level of evidence (see Chapter 2.2.1) of the underlying studies is indicated for each evidence-based statement (see Chapter 2.2.3) and recommendation: in the case of recommendations, the strength is also indicated. Three grades of recommendation are distinguished in this guideline (see the following table) and are reflected in the wording of the recommendations.

Table 5: Scheme of recommendation grading

Grade of Recommendation	Description	Expression
A	Strong recommendation	shall
B	Recommendation	should
O	Open recommendation	can

Table 6: Consensus strength

Consensus Strength	Percentage of Consensus
Strong consensus	> 95% of those eligible to vote
Consensus	>75 – 95% of those eligible to vote
Majority consensus	50 – 75% of those eligible to vote
Dissent	<50% of those eligible to vote

2.2.3 Statements

Statements are presentations or explanations of specific subjects or questions that do not immediately require action. They are adopted in a formal consensus process, much in the same way as the recommendations, and are based either on study data or expert opinion.

2.2.4 Expert Consensus (EC)

Recommendations for which no literature search was conducted are referred to as 'Expert consensus (EC)'. As a rule, these recommendations address procedures of good clinical practice for which no scientific studies are necessary or can be expected. No symbols were used for the gradation of "expert consensus"; the strength of the recommendation results from the wording used (shall/should/can) according to the grading in Chapter 2..2.

2.2.5 Independence and Disclosure of Possible Conflicts of Interest

Funding was provided by the German Cancer Aid Foundation through the German Guideline Program in Oncology (GGPO). These funds were used for personnel costs, office supplies, license fees, and literature procurement, as well as external support for updating the Patient Guideline. The development of the guideline was editorially independent of the funding organization. There were no additional sponsors. A standardized declaration of conflicts of interest was obtained from all participants in the guideline group. These were reviewed and evaluated by members of the WG Conflicts of Interest (Prof. Dr. Joachim Weis, Dr. Markus Follmann, Dipl. Psych. Thorsten Kreikenbohm). In individual cases, a consultation took place with the respective mandate holders. The assessment of the disclosed information demonstrated a minor conflict of interest for all mandate holders. Conflicts of interest of minor relevance could be giving lectures on guideline topics on behalf of pharmaceutical companies, membership in professional associations or societies, as well as funding of research by private donors. Moderate conflicts of interest (only defined as paid consulting activities for companies in the health care industry) as well as high-level conflict of interest (defined as ownership interests) were not found in any of the persons involved. Thus, corresponding countermeasures (moderate relevance: abstention rule when voting; high relevance: abstention from deliberations and voting) were not necessary. The results from the reviewing process can be found in the Guideline Report (<https://www.leitlinienprogramm-onkologie.de/leitlinien/psychoonkologie/>).

We would like to take this opportunity to thank the collaborators for their exclusively voluntary work on the project.

3 Definition and Basic Principles of Psycho-oncology

3.1 Definition

Psycho-oncology, also referred to as „Psychosocial Oncology“, is a specialized field within oncology that addresses the experience and behavior, the specific stresses and coping skills as well as the social resources of cancer patients in connection with their cancer, its treatment and associated problems. The task of psycho-oncology is to scientifically investigate the significance of psychological and social factors and how they interact over the entire course of the illness, i.e. in the development, early detection, diagnosis, treatment, rehabilitation, and follow-up care; to make use of the the knowledge gained in the prevention, early detection, diagnosis, treatment, rehabilitation, outpatient care and palliative care of patients; and to implement this through concrete support and treatment services. In this context, psycho-oncology not only includes the persons directly affected by the disease, but also their relatives and social environment. In addition, the primary medical caregivers (physicians) and nursing staff, as well as all professional groups working in oncology also need basic psycho-oncological skills and are therefore important target groups for continuing education and advanced training as well as supervision [2], [3], [4].

Psycho-oncology is a subfield of oncology that incorporates components from the disciplines of medicine, psychology, sociology, nursing science, practical philosophy and ethics, theology, social work, and education. It is characterized by interdisciplinary and multi-professional cooperation between different professional groups. Thus, psychologists, psychological psycho-therapists, social workers, educators, physicians of different specialties, art therapists, (specialized) nurses, physical therapists, occupational therapists and chaplains of different religious communities work together to provide psycho-oncological care for patients [5].

This guideline deals with the psychosocial aspects of cancer and psycho-oncological measures for the diagnosis, counseling, treatment, rehabilitation and follow-up care of adult cancer patients and their relatives. Psychosocial tasks in the scope of primary prevention in healthy people (prevention of cancer) or in children and adolescents with cancer are not the subject of this guideline (see S3 Guideline "Psychosocial Care in Pediatric Oncology and Hematology", [AWMF register number: 025-002](#)).

3.2 Targets

Psycho-oncological approaches target the psychological and social problems and disorders relating to cancer and its treatment. Their goal is to support the patient's ability to cope with the disease, improve psychological well-being, minimize the problems accompanying and resulting from the medical diagnosis or therapy, strengthen social resources, enable participation, and as a result, help to maintain or increase the quality of life of patients and their relatives [3], [6].

3.3 Tasks and Approaches

3.1	Consensus-based Statement	modified 2023
EC	The central tasks of psycho-oncological care are patient-oriented and needs-based information, psychosocial counseling, the psycho-oncological diagnosis and psycho-oncological treatment of psychological complaints, support in coping with the disease as well as the improvement of psychological, social and functional problems and burdens that arise.	
	Strong Consensus	

Psycho-oncology includes psychosocial interventions such as counseling, providing information, crisis intervention, and psychoeducation, as well as psychiatric, psychosomatic and psychotherapeutic measures, that can be offered as needed during all phases of disease:

- early detection and diagnostics
- full and partial inpatient or outpatient medical treatment
- full and partial inpatient or outpatient rehabilitation
- follow-up care
- palliative or terminal phase.

In addition it focuses on the specific problems and long-term effects faced by cancer survivors. Conceptually, the psycho-oncological treatment approach is characterized by a number of special features: It is primarily patient-centered, resource- and problem-oriented, has a supportive orientation, and focuses on the patient's current disease and life situation. Hereby, problematic processing responses are not pathologized in the sense of a primary psychological disorder, rather they are seen as individual attempts to cope, which, and if dysfunctional, require psycho-oncological intervention. Psycho-oncological psychotherapy is characterized by a cross-method approach and is not limited to one of the classical psychotherapy techniques or methods [\[3\]](#), [\[4\]](#), [\[7\]](#), [\[8\]](#).

The spectrum of psycho-oncological interventions includes:

- relaxation methods, imaginative methods, and mindfulness-based interventions¹
- psychoeducation
- individual psychotherapeutic treatment
- psychotherapeutic group treatment
- psychotherapeutic couple interventions
- psychosocial counselling
- crisis intervention
- special psycho-oncological techniques in the palliative setting (CALM, Dignity Therapy, etc.)
- E-health applications
- art therapy
- psychopharmacological treatment taking into account possible interactions
- occupational therapy

With the exception of relaxation techniques, the mind-body procedures belonging to the field of psycho-oncological interventions, such as yoga or mindfulness-based interventions, are presented in the S3 guideline "Complementary Medicine in the Treatment of Oncological Patients" (<https://www.leitlinienprogramm-onkologie.de/leitlinien/komplementaermedizin>) and are therefore not detailed in this guideline. There, the corresponding recommendations are presented in Chapter 5: Mind-body Methods. Likewise, physical therapy and exercise therapy are not covered in this guideline, rather, a separate guideline is in preparation.

¹ mindfulness-based interventions are discussed in the S3 Guideline Complementary Medicine in the Treatment of Oncological Patients, Chapter 5: Mind-body Methods (<https://www.leitlinienprogramm-onkologie.de/leitlinien/komplementaermedizin>)

3.4 Informational Needs and Psychosocial Care

3.2	Consensus-based Statement	modified 2023
EC	Cancer patients wish for psychosocial support. The psychosocial support of cancer patients is mainly realized by psychologists, psychotherapists, social workers, doctors, nurses, and chaplains as well as through the support of peers (self-help).	
	Consensus	

The findings below are based on the de novo literature search on psychosocial support needs which was conducted together with the de novo search on mental comorbidity during the initial drafting of the 2014 Psycho-oncology Guideline and updated with the current literature through 2021. The update identified 8 new studies [9], [10], [11], [12], [13], [14], [15], [16], [17].

In the current literature, similar values are reported on the frequency of patients' informational needs with usually significantly higher values for information about the disease and treatment (70-90%) compared to the need for psychosocial support (about 35%). On average, the informational need of patients is $M=28.0\%$ ($SD=24.1$) with a $Med=21.5\%$ and a wide range of 1-74.5% [18], [19], [20], [21], [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37], [38], [39], [40], [41], [42], [43], [44], [45], [46], [47], [48], [49], [50], [51], [52], [53], [54], [55], [56], [57], [58], [59], [60], [61], [62], [63], [64], [65], [66], [67], [68], [69], [70], [71], [72], [73], [74], [75], [76], [77], [78], [79], [80], [81], [82], [83], [84], [85], [86], [87], [88], [89], [90], [91].

The literature update also shows that the informational needs of cancer patients hardly change during the average continuum of treatment, i.e. at the time of diagnosis as well as during and after medical treatment. Cancer patients most frequently identify informational needs with respect to dealing with distress and stress, talking to and connecting with other patients, coping with depression and other emotional burdens caused by cancer, sexuality and sexual relationships, self-help/support groups and spiritual support.

Cancer patients most frequently identify the need for support in the following areas: help in dealing with fears about the progression of the disease; with anxiety in

general as well as with depression and sadness; help with concerns about loved ones, family and friends; help in dealing with uncertainty about the future and in dealing with lifestyle changes; help in regaining a sense of control, finding hope and meaning; help in dealing with problems of sexuality and intimacy; help in dealing with fears about pain and the deterioration of their physical condition; help in dealing with fatigue; help in dealing with fears and feelings about dying and death; help in dealing with fears about treatment and in dealing with changes in body image. Furthermore, those affected want advice and support with regard to personal and environment-related resources to ensure their social security (income, housing, work and occupation).

Of the 81 studies, 21 studies [92], [93], [94], [32], [95], [35], [39], [96], [97], [51], [98], [99], [100], [72], [74], [101], [102], [78], [103], [104], [91] show that across all studies an average of 33.9% of patients have a need for psychosocial support (range 15-67.3%). Among them, 13 German studies [25], [34], [35], [39], [42], [55], [72], [74], [105], [102], [11], [101], [106] show an average psychosocial support need among cancer patients of 29.9% (range 13.3-42%).

Systematic reviews show prevalence estimates of up to 93% for unmet information needs, up to 89% for unmet physical support needs, up to 89% for unmet psychosocial support needs, up to 63% for unmet support needs in the domain of sexuality, and up to 51% for unmet spiritual needs, with many of these unmet needs being experienced simultaneously [107].

Patients with rare cancers most frequently reported unmet support needs in the domains health care system and information (up to 95%), followed by mental health (up to 93%) and the domains physical health and daily living (up to 80%). Unmet needs primarily expressed during the follow-up care phase [108].

It should be added that not all patients who were identified as being distressed through screening seek psychosocial support [92], [109], [11]. For example, in a study of 935 acute inpatient cancer patients with various diagnoses, 71.6% of all patients and 53.9% of the distressed patients declined psycho-oncological support services during acute inpatient treatment [110].

According to the literature, a variety of reasons for not taking advantage of psychosocial support services are mentioned such as gender, personality characteristics, previous psychotherapeutic experience, informedness and setting conditions [12], [111], [15], [112], [74], [113], [114], [115]. In this context, [Chapter 7.3](#) points out that in addition to distress screening, the subjective psychosocial support needs should also be asked (see Recommendation 7.5).

4 Requirements for Psycho-oncological Care Settings

Psycho-oncological care is provided within the framework of an organized system of diverse structures and different institutions within the varying sectors of health care.

4.1 Inpatient Care Facilities

4.1.1 Hospitals

4.1	Consensus-based Recommendation	new 2023
EC	In all clinics providing oncological care, psycho-oncological care services shall be provided by specialists qualified in psycho-oncology.	
	Strong Consensus	

Psycho-oncological care in the **hospital** is implemented in all medical departments by the attending physicians and nurses in collaboration with psycho-oncological specialists who are usually organized either in consultation or liaison services, or as integrated specialist services. Psycho-oncological care focuses primarily on the distress associated with the disease and therapy, as well as the individual needs of patients and their relatives that arise as a result of the illness. Psycho-oncological support is based on individual treatment needs and should be determined through standardized distress screening or other appropriate assessment procedures (see [Chapter 7](#)). Furthermore, supporting the patient's communication with relatives and their social environment is a central task in the context of acute care. With regard to relatives and the social environment, the focus of psycho-oncological care is on relieving their burden and activating family and other social resources.

With the target group being health care professionals, the activities of psycho-oncological specialists (see [Chapter 12.1](#)) should not only relieve the burden but also promote communicative skills in dealing with patients and with each other (see [Chapter 11](#)).

Recommendations for the provision of needs-based psycho-oncological care are already available (ONKO ZERT <http://www.onkozert.de/>) through the certification system of for Organ Centers, such as Breast Centers, Gynecological Cancer Centers, Colorectal Cancer Centers, Prostate Cancer Centers, Lung Cancer Centers, Skin Tumor Centers, and Oncological Centers established by the German Cancer Society. In all hospitals that treat cancer patients, psycho-oncological care that meets the needs of the patients must be provided [\[2\]](#). The required staffing/qualifications are described in [Chapter 12.1](#).

4.1.2 Oncology Rehabilitation Facilities

4.2	Consensus-based Recommendation	new 2023
EC	In all inpatient or outpatient oncological rehabilitation facilities, psycho-oncological care services shall be provided by specialists qualified in psycho-oncology.	
	Strong Consensus	

The tasks of psycho-oncology within the scope of diagnosis, therapy and counseling in **inpatient, day-care or outpatient rehabilitation facilities** are broadly diversified since cancer patients here represent almost all stages and phases of the disease: following completion of the primary treatment, which can be very close to the time of diagnosis, after a recurrence, after the appearance of metastases or in a palliative treatment situation. Psychosocial rehabilitation services are primarily in the areas of counseling, psychoeducation, the teaching of relaxation techniques, and short-term psychotherapy and are adapted according to the individual needs of the patients. Additional therapies such as occupational therapy and exercise therapy are also offered. For those patients who are in working life, the question of vocational reintegration and regaining the ability to work must be clarified, the necessary assistance for this is offered in cooperation with social services.

If functional and cognitive disorders such as neuropsychological performance limitations are present or for psychological pain therapy, appropriate services are to be implemented or initiated.

Furthermore, the improvement of the quality of life and participation, physical and mental stabilization, the promotion of the patient's self-responsibility, support for self-help, and resource orientation are regarded as being primary goals of the rehabilitation [\[116\]](#).

4.1.3 Social Services in Clinics

4.3	Consensus-based Recommendation	new 2023
EC	All inpatient or outpatient oncology care facilities shall offer social counseling from qualified social service professionals.	
	Strong Consensus	

Social services in hospitals and rehabilitation clinics are part of the psycho-oncological care in inpatient settings. The counseling in the social services provided through social work aims at promoting social participation, as well as preventing and coping with social problems that may arise from the cancer disease or lead to further health disorders [\[117\]](#), [\[118\]](#). The resources and services necessary to support coping with life are developed with patients and relatives during inpatient care. Access to outpatient psychosocial counseling services is made available. Information about oncological rehabilitation services is provided early on. Consultations regarding all

relevant areas of social security legislation take place and also encompass mediation at the interfaces between the services that need to be coordinated, as well as the active utilization of resources and the referral to additional support and counselling services offered by the treatment providers who are involved.

The needs assessment for intervention planning includes disease phase, support networks and resources, the extent of physical impairment, and rehabilitation potential. Interventions are implemented as part of an inter-professional team with medical and nursing staff, psycho-oncology services, and other therapeutic professional groups. With respect to social services in rehabilitation clinics, a main focus of the work is on issues relating to vocational reintegration [\[119\]](#).

4.2 Palliative Care Facilities

4.4	Consensus-based Recommendation	new 2023
EC	In all inpatient palliative care facilities, psycho-oncological care services should be provided by staff members who are qualified in psycho-oncology (according to the S3 Guideline for Palliative Medicine (AWMF register number: 128-001OL) and integrated into the units.	
	Consensus	

The term palliative care covers inpatient and outpatient care services for cancer patients with incurable cancer and their relatives. This includes inpatient hospices, palliative care units as well as various forms of outpatient hospice work, palliative networks and specialized outpatient palliative care (SAPV). Palliative care focuses in particular on improving the quality of life of patients and their relatives with regard to physical as well as psychosocial and spiritual aspects during the last phase of life.

For palliative care units and palliative care services, the recommendations of the "Extended S3 Guideline Palliative Care for Patients with Non-curable Cancer" (AWMF Register Number: 128-001OL) apply. There, the overlap between the actions in palliative care and other support services, such as independent psycho-oncology services, are emphasized and close cooperation and mutual support are recommended.

Psychosocial professionals in palliative care are part of the core team. In hospitals, psycho-oncologists can be part of the psycho-oncology service as well as part of the palliative team and/or palliative services.

4.3 Outpatient Psycho-oncology Care Facilities

4.5	Consensus-based Recommendation	modified 2023
EC	Cancer patients and their relatives shall have access to local, quality-assured outpatient psycho-oncological support and treatment services in all phases of the disease.	
	Strong Consensus	

4.6	Consensus-based Recommendation	new 2023
EC	In the outpatient sector, psychosocial cancer counseling centers shall be recommended as a point of contact in the case of subsyndromal psychosocial distress among cancer patients and their families.	
	Strong Consensus	

Due to the shortening of the length of inpatient stays, outpatient psycho-oncological care has an important task which can be ensured by various service providers:

- psycho-oncological support within the framework of psychosomatic primary care by general practitioners and specialists.
- practicing specialists for: psychiatry and psychotherapy, psychosomatic medicine and psychotherapy, neurology and neurological medicine as well as specialists working primarily in somatic medicine with the additional field of psychotherapy.
- practicing psychological psychotherapists
- psychosocial cancer counseling centers
- psycho-oncological outpatient clinics of hospitals / certified centers
- psycho-oncological care within the framework of outpatient rehabilitation
- psycho-oncological care within the framework of specialized oncological practices
- psycho-oncological support services in SAPV and inpatient hospices as well as in palliative outpatient clinics or day-clinic palliative medical care ("Extended S3 Guideline on Palliative Medicine for Patients with Non-curable Cancer" [AWMF Register Number: 128-001OL](#)).

General practitioners and specialists working primarily in somatic medicine offer basic **psychosomatic care** for cancer patients in the form of psychosomatic primary care. The aim is the early diagnostic clarification of the somatic, psychological and psychosocial aspects of the disease in the context of a comprehensive biopsychosocial diagnosis as well as a low-threshold psychosomatic treatment option with a time-defined scope.

Outpatient psycho-oncological care in the context of psychotherapeutic treatment of cancer patients within the health insurance scheme is mainly offered by psychological psychotherapists, followed by specialists in psychosomatic medicine and psychotherapy as well as specialists in psychiatry and psychotherapy [5]. After a

comprehensive diagnosis – also within the framework of a psychotherapeutic consultation – a psychotherapeutic treatment or a guideline psychotherapy can be offered depending upon indication. Psychopharmacological treatment can also be provided by specialists for psychosomatic medicine and psychotherapy as well as specialists in psychiatry and psychotherapy, if indicated. In addition to the aforementioned specialists, specialists working primarily in somatic medicine with the additional title „Psychotherapy“ can also be involved in the psychotherapeutic care of cancer patients.

Psychosocial cancer counseling centers serve as a contact point for psychosocial distress in connection with cancer and the resulting medical treatment [120]. The focus of counseling can be social problems, being overwhelmed by everyday life and questions about possible social benefits, as well as psychological distress and crises. The target groups are cancer patients and their family, especially partners and children, but also people close to them in their social environment. Advice is given to people of all ages and in all phases of the disease, including long-term survivors. Outreach counseling can be offered to immobile patients. In addition to continuous quality assurance, the central principles are the low-threshold nature of the counseling services, the fact that they are free of charge, the availability of services at short notice, as well as the complete absence of formal access restrictions (e.g., verification of eligibility requirements).

The services provided by cancer counseling centers are fundamentally aimed at helping patients overcome psychological and social problems and crises, filling information deficits, and strengthening patient competence and individual psychological coping skills. Early psychosocial counseling can have a preventive effect on the development of mental disorders. Other important goals are:

- the development of social/social welfare assistance and care services as well as referral to further care services, such as self-help groups, specialists, psychotherapists, palliative care facilities, or government
- support in taking advantage of medical rehabilitation measures and subsequently maintaining the rehab success,
- advice on professional reintegration and securing social participation,
- reducing psychological distress caused by the effects and long-term consequences of medical treatments,
- promoting the use of social resources and communication with the medical treatment team,
- relieving the burden on family members.

The range of services required for this includes providing information, psychosocial counseling with a psychological focus (see [Chapter 8.7](#)), psychosocial counseling with a focus on social aspects (see [Chapter 8.7](#)), psychoeducation, psycho-oncological crisis intervention, as well as couple and family counseling.

Psychotherapeutic services and medical counseling that goes beyond basic information are not part of the range of services provided by cancer counseling centers. If necessary, those seeking advice are referred to psychotherapists or specialists.

The multidisciplinary team that provides the above-mentioned services usually consists of psychologists, social workers/pedagogues, administrative staff or

assistants and other professional groups, depending on the structure of the services offered.

In hospitals as well as certified centers, **psycho-oncological outpatient clinic** offer psycho-oncological and psychotherapeutic counseling, treatment and support for patients and their families.

Furthermore, **psycho-oncological** support services are also available in some specialized **oncology practices**.

4.4 Self-help/Peer-Support Groups

4.7	Consensus-based Recommendation	checked 2023
EC	Cancer patients and their relatives shall be informed about qualified support services offered by cancer self-help/peer-support groups (discussions with people affected by the same disease, assistance in dealing with the disease, therapies and effects of therapy in everyday life) in all phases of the care process.	
	Strong Consensus	

4.8	Consensus-based Recommendation	new 2023
EC	The support services from qualified self-help representatives shall be included in psychosocial care in accordance with the certification requirements for cancer centers.	
	Strong Consensus	

4.9	Consensus-based Recommendation	new 2023
EC	Psycho-oncology professionals in all care settings should cooperate with organized self-help associations and/or local self-help/peer-support groups.	
	Strong Consensus	

Self-help organizations offer cancer patients non-professional psychosocial support. They thus have an important function in the interplay of psychosocial care services, since from the patient's point of view, psychosocial distress is not usually sufficiently addressed in discussions with medical practitioners and many patients have little knowledge about the content and effectiveness of psychosocial support. The situation is made worse by the fact that patients often downplay their distress for fear of being stigmatized or psychiatrized.

The members of the **cancer self-help/support groups** and the voluntary staff of the cancer self-help organizations, who have themselves endured the disease, can

provide confidence to others by being a conversation partner in terms of exchanging experiences and informational sessions, and thus contribute to overcoming fears and leading a self-determined life.

The **cancer self-help organizations** qualify their staff affected by cancer through seminars and provide information (including brochures), especially on everyday life with the disease, therapies, and possible side-effects of therapy.

4.5 Cross-sector Coordination of Psycho-oncology Care

4.10	Consensus-based Recommendation	checked 2023
EC	Patient-oriented information about psycho-oncological support services shall be provided at an early stage and accompany the course of the disease.	
	Strong Consensus	

4.11	Consensus-based Recommendation	checked 2023
EC	Psycho-oncological interventions should be provided according to individual need in all sectors of care and at all stages of the disease.	
	Strong Consensus	

Patient-oriented information about psycho-oncological support services at an early stage during the course of treatment can initiate individually tailored psycho-oncological care based on individual needs (see [Chapter 5](#)).

Appropriate and standardized instruments or suitable assessment procedures should be used to determine needs (see [Chapter 7](#)). Due to shorter lengths of inpatient hospital stays, the respective psycho-oncological services, in addition to their direct care functions, also have the task of providing information and referrals for further psycho-oncological services. In order to be able to ensure these tasks, a good regional as well as interregional networking of the psycho-oncological services in the inpatient as well as outpatient setting is necessary.

The continuity of psycho-oncological care as well as the optimization of the interfaces between the care sectors must be ensured by making referrals and passing on information to the patient. For this purpose, a good regional as well as interregional network of psycho-oncological services in the inpatient as well as outpatient sector must be established. On the regional level, psycho-oncological working groups for interdisciplinary exchange and further training are helpful and should therefore be established and expanded in the care regions [\[121\]](#).

5 Psychosocial Distress

5.1 Quality of Life and its Assessment

Psychosocial distress, symptoms, and functional limitations are grouped under the concept quality of life [122], [123]. The concept of health-related quality of life encompasses a wide range of aspects such as physical complaints, functional abilities, activities, family well-being, psychological well-being, treatment satisfaction, body image, sexuality, social function, and satisfaction [124]. According to current understanding, health-related quality of life is a multidimensional, subjective and dynamic construct [125] with at least three dimensions: physical functioning/symptoms, psychological and mental functioning, and social functioning.

In the assessment of quality of life, patients are asked about various symptoms, complaints or subjective limitations in functionality with the use of standardized questionnaires [126]. Among the most common instruments used in oncology are the EORTC QLQ C30 inventory [127] as well as the FACT [128]. In addition to the more symptom-oriented questionnaires, there are also methods that allow subjective weighting of relevant quality-of-life aspects, such as the SEIQOL by Waldron et al. [129]. Furthermore, there are a number of generic, i.e. independent of diagnosis, quality of life assessment methods. Probably the best known method is the SF-36 [130]. To date, there are good reviews of the quality of life instruments currently available [131], [132], [133].

In the methods of the EORTC Quality of Life Group (<http://groups.eortc.be/qol/>) or the FACT working group of D. Cella (<http://www.facit.org/>), a basic survey is usually carried out by means of a core questionnaire (EORTC QLQ C30 or FACT-G) which assesses quality of life in a differentiated and multidimensional approach. Specific problems related to different diagnosis groups, special forms of treatment or the exacerbation of certain symptoms or other partial aspects of quality of life are collected via modules. For this purpose, different categories of modules are available. Initially, diagnosis-specific modules were developed to capture the special problems of individual diagnosis groups (e.g. breast cancer, bronchial Ca, cervix, etc.). In further development, treatment-specific modules (e.g., high-dose therapy) and symptom-specific modules (e.g., anemia, fatigue, etc.) were created. Core modules (e.g. information, patient satisfaction, spirituality) include the assessment of general treatment and diagnosis areas. The survey instruments of the EORTC Quality of Life Group and the FACT Working Group can be downloaded from the websites.

Figure 1 (Figure 1) shows a graphical overview (source: [126]):

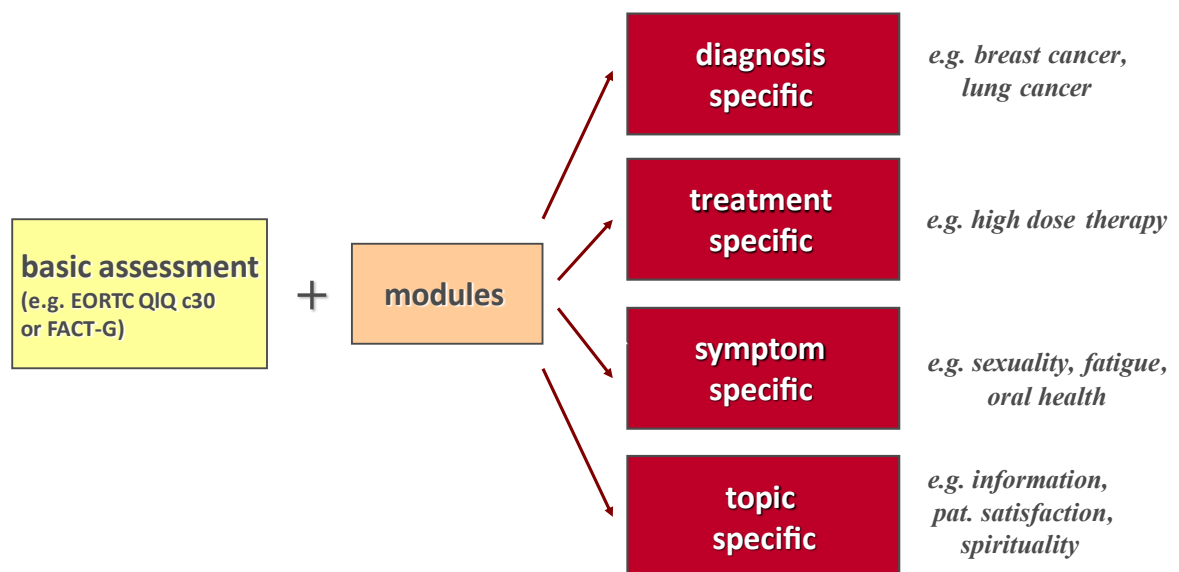


Figure 1: Quality of Life Assessment

The standardized questionnaires for assessing quality of life are suitable for cross-sectional surveys as well as for longitudinal measurements with the aim of mapping changes. The availability of reference or norm comparison values allows the interpretation of the found characteristics with regard to different disease groups or normal populations [126].

Computer-assisted methods in quality-of-life assessment open up new possibilities for use in clinical routine as well. Via computer-adapted testing based on touch screen technologies or mobile apps, the number of questions to be answered can be reduced due to an algorithm based on the difficulty of the individual questions. This allows the creation of an individual quality-of-life profile based on only a few questions which, for example, can be of great benefit in the area of palliative care [126].

5.2 Physical, Mental, Social and Spiritual/Religious Problems

5.1	Consensus-based Recommendation	modified 2023
EC	Cancer patients are confronted with physical, psychological, social, and spiritual/religious problems. These needs shall be taken into account in the psycho-oncological care.	
	Strong Consensus	

Cancer patients are confronted with a range of different physical, mental health, social, and spiritual as well as religious problems during the course of their illness and medical treatment which can affect all areas of life and reduce the quality of life [\[134\]](#), [\[135\]](#).

Physical problems

Physical problems include physical weakness, exhaustion (fatigue), lack of physical performance; Pain such as wound and scar pain; Sleep problems such as difficulty falling asleep and staying asleep, nightmares; Lack of appetite, uneasiness, nausea, vomiting, diarrhea; Weight changes such as weight gain, weight loss, and cachexia; Swallowing problems; Respiratory problems such as dyspnea, cough; Fever, sweating, dizziness; Skin changes, inflammation around the mouth, bleeding, itching, body odor that is difficult to control and visible physical changes [\[134\]](#), [\[136\]](#), [\[137\]](#), [\[138\]](#), [\[139\]](#), [\[140\]](#), [\[141\]](#), [\[142\]](#), [\[143\]](#), [\[144\]](#), [\[145\]](#), [\[146\]](#), [\[147\]](#), [\[148\]](#), [\[149\]](#), [\[150\]](#), [\[151\]](#), [\[152\]](#), [\[153\]](#), [\[154\]](#), [\[155\]](#), [\[156\]](#), [\[157\]](#), [\[158\]](#), [\[159\]](#), [\[160\]](#), [\[161\]](#), [\[162\]](#), [\[163\]](#).

Mental health problems

Mental health problems can be described as impairments of general mental wellbeing (distress); anxiety, fear, worry, brooding, fear of the progression or recurrence of the disease (fear of progression/recurrence), fear of death, phobias, existential and social fears; furthermore, depression, despondency, grief, demoralization, drive disorders, social withdrawal, guilt, self-reproach, suicidal tendencies, helplessness and hopelessness, and loss of sense of dignity. Mental health problems also include self-esteem problems, self-efficacy problems, body image problems, shame, anger and resentment, aggression, dissatisfaction with treatment and medical staff, and maladaptive attributions of causality and control [\[164\]](#), [\[165\]](#), [\[166\]](#). In addition to distress of the partner, children and relatives, distress of the medical staff can also occur [\[134\]](#), [\[151\]](#), [\[164\]](#), [\[165\]](#), [\[166\]](#), [\[167\]](#), [\[168\]](#), [\[169\]](#), [\[170\]](#), [\[171\]](#), [\[172\]](#), [\[173\]](#), [\[174\]](#), [\[175\]](#), [\[176\]](#), [\[177\]](#), [\[158\]](#), [\[178\]](#), [\[179\]](#), [\[180\]](#), [\[181\]](#), [\[182\]](#), [\[183\]](#), [\[184\]](#), [\[185\]](#), [\[186\]](#), [\[187\]](#), [\[188\]](#), [\[189\]](#), [\[190\]](#), [\[191\]](#), [\[192\]](#), [\[193\]](#).

Psychological distress, pain, and physical dysfunction are closely interrelated. Thus, psychological distress can increase pain perception and perceived limitations due to physical dysfunction, and in turn, severe pain and physical dysfunction can increase psychological distress.

Social problems

Social problems include loneliness, isolation, social exclusion and discrimination, communication barriers and conflicts in social interactions with family, relatives and friends, impaired decision-making ability, problems in the context of a trusting cooperation with medical and nursing staff (compliance) and lack of support when in need of help. Furthermore, financial burdens, problems at work and in the context of returning to work, as well as additional individual social burdens should be mentioned [134], [194], [195], [196], [197], [198], [199], [200], [201], [202], [203].

Spiritual/religious problems

Religion and spirituality can have both a protective as well as burdening nature in the context of cancer. Spiritual and religious problems include loss of faith, doubt, hopelessness and loss of meaning, as well as pronounced feelings of guilt, fears of judgement or punishment based on religious values, problems coping with illness, fears of death, and ethical conflicts in the hospital [134], [204], [205], [206].

5.3 Psycho-oncological Relevant Dysfunctions

The physical, psychological and social problems can lead to numerous dysfunctions that require psycho-oncological care or joint-care.

Physical dysfunction

Physical dysfunctions include: movement and mobility (limited mobility, limited arm range of motion); sensory impairments (sensory disturbances, polyneuropathies, impaired sense of smell and taste, balance disorders, vision changes, speech disorders), voice disorders; gastrointestinal and urologic dysfunctions (digestive disorders, bladder and bowel incontinence, micturition disorders, bowel dysfunction, swallowing disorders); sexual dysfunction (impaired libido, lack of lubrication, erectile dysfunction, pain during intercourse, premature menopause, infertility) and cognitive impairments (attention, concentration, and memory problems, fine motor skills, mental fatigue) [134], [207], [208], [209], [210], [211], [212], [213], [214], [215], [216], [217], [218], [219], [220], [221], [222], [223], [224], [225], [226], [227].

Psychological dysfunction

Psychological dysfunction includes limitations in emotional functioning and emotional role functioning; difficulties connecting with others; limitations in problem-solving skills and coping with the illness (including problems in finding meaning and purpose, in developing a combative attitude, in self-encouragement and self-affirmation, in accepting the illness, in seeking information and distraction); lack of ability to mobilize social support; problems with lifestyle modification; and limitations in the ability to enjoy [134], [228], [229], [230], [231], [232], [233], [234].

Social dysfunction

Social dysfunction manifests as impairments in the activities of daily living: limitations in independent living and self-care (washing, dressing, meal preparation); limitations in mobility (leaving home, running errands, transportation, doctor's visits); educational and occupational limitations (work productivity, performance, extent of employment, physical work demands, psychosocial work demands, problems with supervisors, stress). In addition, limitations related to child care, family and social

interaction, and taking care of dependents, as well as limitations in leisure activities and use of health care services [\[134\]](#), [\[235\]](#), [\[236\]](#), [\[237\]](#).

5.4 The Frequency of Subsyndromal Mental Distress

5.2	Consensus-based Statement	modified 2023
EC	Common subsyndromal symptoms in cancer patients include distress, anxiety, fear of progression/recurrence, and depressiveness.	
	Strong Consensus	

Subsyndromal mental distress is subthreshold distress that falls below the cut-off value of the diagnostic criteria according to ICD-10 or DSM-IV. In cancer patients, they include general mental stress (distress), anxiety, especially fear of progression/recurrence, and depressiveness. Depressiveness is understood to be a depressed mood that promotes the development of a depressive mood or a depressive episode.

A general high level of mental stress (distress) occurs with up to 59% of cancer patients [\[176\]](#), [\[177\]](#), [\[238\]](#), [\[239\]](#). Severe anxiety is found in up to 48% of cancer patients [\[240\]](#), [\[241\]](#). Thereby, the fear of recurrence and progression of the disease plays a significant role and occurs in up to 32% of cancer patients [\[242\]](#). Depressiveness and dejection occur in up to 58% of cancer patients, often together with high anxiety [\[176\]](#), [\[177\]](#), [\[238\]](#), [\[239\]](#), [\[240\]](#), [\[241\]](#), [\[242\]](#), [\[243\]](#), [\[244\]](#), [\[245\]](#), [\[246\]](#).

6 Psychiatric Comorbidity

6.1	Evidence-based Statement	checked 2023
LoE 1b	The most common mental disorders in cancer patients are affective disorders, anxiety disorders, adjustment disorders, and psychotropic substance disorders. A history of pain, a high physical symptom burden, fatigue, and the presence of an existing mental disorder heighten the risk of developing a mental disorder in cancer patients.	
	[39] , [75] , [247] , [248] , [249] , [250] , [251] , [252] , [253] , [254] , [255] , [256] , [257] , [258] , [259] , [260] , [261] , [262] , [263] , [264] , [265] , [266] , [267] , [268] , [269] , [270] , [271] , [272] , [273] , [274] , [275] , [276] , [277] , [278] , [279] , [280] , [281] , [282] , [283] , [284] , [285] , [286] , [287] , [288] , [289] , [290] , [291] , [292] , [293] , [294] , [295] , [296] , [297] , [298] , [299] , [300] , [301] , [302] , [303] , [304] , [305] , [306] , [307] , [308] , [309] , [310] , [311] , [312] , [313] , [314] , [315] , [316] , [317] , [318] , [319] , [320] , [321] , [322] , [323] , [324] , [325] , [326] , [327] , [328] , [329] , [330] , [331] , [332] , [333] , [334] , [335] , [336] , [337] , [338] , [339] , [340] , [341] , [342] , [343] , [344] , [345] , [346] , [347] , [348] , [349] , [350] , [351] , [352] , [353] , [354] , [355] , [356] , [357] , [358] , [359] , [360] , [361] , [362] , [363] , [364] , [365] , [366] , [367] , [368] , [369] , [370] , [371] , [372] , [373] , [374] , [375] , [376]	
	Strong Consensus	

6.2	Evidence-based Recommendation	checked 2023
GoR A	Mental distress as well as the presence of a mental disorder shall be clarified, especially in the case of persistent pain, severe physical symptom burden, or fatigue.	
LoE 1b	[283] , [251] , [328]	
	Consensus	

The recommendations are based on a systematic literature review with a concluding summary of the available empirical evidence. Studies were included in which the prevalence of comorbid mental disorders in the classification areas F1, F3, and F4 was recorded on the basis of structured interview procedures for the diagnosis of mental disorders according to ICD and DSM. For the topic of suicidality, studies with standardized and validated self-description instruments were also included.

Since the quality of the relevant studies judged as being very heterogeneous both in terms of sample size and in terms of the representativeness of the prevalence data collected, all relevant studies were therefore initially considered for the pooling of the prevalence data.

6.1 Risk Factors that Promote the Occurrence of Mental Disorders

Pain, high physical symptom burden, and fatigue, as well as the presence of a history of mental disorder favor the occurrence of a mental disorder in cancer patients [39], [75], [174], [240], [246], [377], [378], [379], [380], [381], [382], [383], [384], [385], [259], [386], [261], [262], [263], [387], [265], [388], [267], [268], [269], [270], [271], [272], [389], [274], [390], [276], [277], [391], [279], [392], [281], [282], [283], [284], [393], [286], [394], [288], [395], [396], [291], [292], [293], [294], [295], [296], [297], [298], [299], [300], [301], [302], [303], [397], [305], [306], [307], [398], [399], [400], [311], [401], [313], [314], [315], [402], [317], [318], [319], [320], [321], [403], [323], [404], [325], [326], [327], [328], [405], [330], [406], [332], [333], [334], [335], [407], [408], [409], [339], [340], [341], [343], [410], [344], [345], [346], [347], [348], [349], [411], [412], [352], [353], [354], [355], [356], [357], [358], [359], [360], [361], [362], [363], [364], [365], [366], [367], [368], [413], [369], [370], [371], [414], [372], [373], [374], [375], [415], [416], [376]. The risk of mental disorders tends to be increased by younger age, tumor entities with poorer prognosis in terms of survival, and advanced disease [39], [75], [174], [240], [246], [377], [378], [379], [380], [381], [382], [383], [384], [385], [259], [386], [261], [262], [263], [387], [265], [388], [267], [268], [269], [270], [271], [272], [389], [274], [390], [276], [277], [391], [279], [392], [281], [282], [283], [284], [393], [286], [394], [288], [395], [396], [291], [292], [293], [294], [295], [296], [297], [298], [299], [300], [301], [302], [303], [397], [305], [306], [307], [398], [399], [400], [311], [401], [313], [314], [315], [402], [317], [318], [319], [320], [417], [321], [403], [323], [404], [325], [326], [327], [328], [405], [330], [406], [332], [333], [334], [335], [407], [408], [409], [339], [340], [341], [343], [410], [344], [345], [346], [347], [348], [349], [411], [412], [352], [353], [354], [355], [356], [357], [358], [359], [360], [361], [362], [363], [364], [365], [366], [367], [368], [413], [369], [370], [374], [375], [415], [372], [376].

There are inconclusive findings with regard to the characteristics gender, education level, marital status and partnership, socioeconomic status, tumor stage, time since diagnosis, as well as the treatment carried out and treatment setting.

Vulnerability factors and predictors of mental disorders

Sociodemographic factors

Age

Of the 131 studies included, 60 studies examined age as a potential influencing factor with regard to psychiatric comorbidity: 26 studies showed a negative association (i.e., younger patients have a higher risk of developing a mental disorder), seven studies showed a positive association (i.e., older patients have a higher risk of developing a mental disorder), and 27 studies failed to demonstrate an association.

Gender

Of the 131 studies included, 43 studies examine gender as a potential influencing factor with regard to psychiatric comorbidity: 16 studies show that women are at higher risk for the occurrence of a mental disorder, five studies show that men are at higher risk for the occurrence of a mental disorder, and 22 studies failed to demonstrate gender as an influencing factor.

Education level

Of the 131 studies included, 26 studies reported educational level as a potential influencing factor with regard to psychiatric comorbidity: five studies showed a negative association (i.e., patients with a lower level of education have a higher risk for the occurrence of a mental disorder), 1 study showed a positive association, and 19 studies could not demonstrate an association.

Marital status and partnership

Of the 131 studies included, 29 studies examined marital status and partnership as a potential influencing factor regarding psychiatric comorbidity: nine studies showed that single and divorced individuals are at higher risk for the occurrence of a mental disorder, one study showed that individuals who are married are at higher risk for the occurrence of a mental disorder, and 19 studies failed to demonstrate an association.

Socioeconomic status

Of the 131 studies included, 21 studies examined socioeconomic status as a potential influencing factor: 10 studies showed that unemployment or low income was associated with a higher risk of developing a mental disorder, one study showed that individuals with higher income had a higher risk of comorbidity, and 10 studies failed to demonstrate an association.

Medical and disease-related factors*Type of tumor entity*

Of the 131 studies included, 29 studies provide information on the influence of tumor entity on psychological comorbidity. Increased risk was found for lung cancer (5 studies), head and neck tumors (4 studies), breast cancer (2 studies), gastrointestinal tumors (2 studies), as well as gynecologic, visceral surgical, and urologic tumors (1 study each). Thirteen studies failed to demonstrate an association.

Tumor stage and disease progression

Of the included 131 studies, 17 studies provide information on the influence of tumor stage and 10 studies provide information on the influence of disease progression/remote metastasis on psychiatric comorbidity. With respect to tumor stage, 6 studies show a positive association, one study a negative association, and 10 studies no association. With respect to disease progression, 8 studies showed a positive association, whereas 2 studies demonstrated no association.

Time since diagnosis

Of the included 131 studies, 11 studies provide information on the influence of time since diagnosis/recurrence on psychiatric comorbidity. Overall, the majority of studies (8 studies) show no association, one study shows a positive association, and two studies show a negative association.

Treatment and treatment setting.

Of the included 131 studies, 18 studies provide information on the influence of treatment or treatment setting on psychiatric comorbidity. The results show an increased risk for the presence of a mental disorder with chemotherapy (3 studies),

hormone therapy (2 studies), in the inpatient treatment setting (2 studies), and in the diagnostic phase (1 study). 7 studies failed to demonstrate an association.

Physical and psychosocial factors

Pain, physical symptom burden, and fatigue.

Of the included 131 studies, 57 studies reported pain, physical symptom burden, and fatigue as potential influencing factors regarding psychiatric comorbidity. Regarding pain, 22 studies show a positive association, while six studies demonstrate no association. Impaired physical functional status and high symptom burden were shown to be a risk factor for psychiatric comorbidity in 24 studies, whereas four studies found no associations. Fatigue was shown to be a risk factor in seven studies.

History of mental illness

Of the included 131 studies, 19 studies investigated previous mental illness as a potential influencing factor with regard to psychiatric comorbidity in the presence of cancer. While 2 studies showed no association, the majority of studies (17) showed that a history of mental illness (11 studies), and in particular depression (6 studies), led to higher mental comorbidity.

6.2 Mental Disorders According to ICD-10/DMS-IV Classification

Affective disorders (see table 7) (F30-39) occur on average in 13% (point prevalence) of cancer patients (0-49%). In Germany, the average point prevalence in cancer patients for affective disorder is 9.8%. The most common mental disorder among affective disorders is depression (F32.0-32.2) with a point prevalence of 8.2 % (0-49 %) (German studies: 5.4 %). Other affective disorders in cancer patients include Dysthymic Disorder (F34.1) with a point prevalence of 1.9% (Germany: 2.2%) as well as Bipolar Disorder and Mania (F31.0-31.9) with a point prevalence of 1.7% (0-4%).

Anxiety disorders (F40-42.9) occur on average in 11.1 % (point prevalence) of cancer patients (0-50 %). In Germany, the average point prevalence for anxiety disorders in cancer patients is 13.1 %. The most common mental disorders among anxiety disorders in cancer patients are generalized anxiety disorder (F41.1) with a point prevalence of 2.7 % (0-15 %) (German studies: 2.2 %) and specific phobias (F40.2) with a point prevalence of 3.5 % (0-14 %) (German studies: 3.8 %). Other anxiety disorders include panic disorder (F41.0) with a point prevalence of 2.3 % (0-11 %) (German studies: 2.1 %), obsessive-compulsive disorder (F42.0-42.9) with a point prevalence of 2.3% (1-5%) (German studies: 2.5%), social phobias (F40.1) with a point prevalence of 1.1% (0-7%) (German studies: 0.7%), and agoraphobia (F40.0) with a point prevalence of 1.6% (German studies: 2.3%).

An **adjustment disorder** (F43.2.) occurs on average in 12.1% (point prevalence) of cancer patients (0-40%). In Germany, the average point prevalence for an adjustment disorder in cancer patients is 8.8%. Acute stress disorder (F43.0) occurs on average in 4.8% (point prevalence) of cancer patients (0-28%). In Germany, the average point prevalence for acute stress disorder in cancer patients is 4.1%. Post-traumatic stress disorder (F43.1) occurs on average in 2.2% (point prevalence) of cancer patients (0-22%). In Germany, the average point prevalence for post-traumatic stress disorder in cancer patients is 1.9%. **Somatoform disorders** (F45.0- 45.9) occur on average in

2.7% (point prevalence) of cancer patients (0.5- 13%). In Germany, the average point prevalence for any somatoform disorder in cancer patients is 4.7%.

Also to be mentioned is the **dependence on psychotropic substances** such as alcohol, alkaloids, including nicotine, opioids or other drugs such as analgesics or sedatives, whereby the point prevalence in cancer patients can only be named for tobacco dependence and alcohol dependence. Across all studies, tobacco dependence/abuse (F17) occurs on average in 11.3% (point prevalence) of cancer patients (2-51%). In Germany, the average point prevalence for tobacco dependence/abuse in cancer patients is 6.2%. Alcohol dependence/abuse (F10) occurs on average in 4.9% (point prevalence) of cancer patients (0-40%). In Germany, the average point prevalence for alcohol dependence/abuse in cancer patients is 2.9%.

A comparison of the point prevalences of affective and anxiety disorders with the results of the German National Health Survey 1998/99, Additional Survey "Mental Disorders" shows a comparable prevalence for depression (5.6 %) in cancer patients compared to the general population [418]. Somewhat lower are the point prevalences in the general population for total affective disorders (6.3%), generalized anxiety disorder (1.2%), panic disorder (1.1%), and anxiety disorders overall (9.0%), although the comparison could be based on significantly fewer studies for these disorders. Comparison of 12-month prevalences shows comparable incidence rate for depression (8.3%), dysthymia (4.5%), bipolar disorder (0.8%), generalized anxiety disorder (1.5%), agoraphobia (2.0%), social phobia (2.0%), and obsessive-compulsive disorder (0.7%) [419]. Somewhat lower are the 12-month prevalences in the general population for total affective disorders (11.9%), panic disorder (2.3%), specific phobias (7.6%), and anxiety disorders overall (14.5%). However, it must be taken into account that the number of studies on the 12-month prevalence of mental disorders in cancer patients is very small and that they largely included small numbers of cases.

Table 7: Frequency of Mental Disorders in Cancer Patients

Mental disorder	Point prevalence (international)	Range	Point prevalence (Germany)
1. Affective disorders (F30-39)	13.0 %	0-49 %	9.8 %
a. Depression (F32.0-32.2)	8.2 %	0-49 %	5.4 %
b. Dysthymia (F34.1)	2.2 %	0-15 %	1.9 %
c. Bipolar affective disorder (F31.0-31.9)	1.7 %	0-4 %	n/a
2. Anxiety disorders (F40-42.9)	11.1 %	0-50 %	13.1 %
a. Generalized anxiety disorder (F41.1)	2.2 %	0-15 %	2.7 %
b. Panic disorder (F41.0)	2.3 %	0-9 %	2.1 %
c. Obsessive-compulsive disorder (F42.0-42.9)	2.3 %	1-5 %	2.5 %
d. Social phobias (F40.1)	1.1 %	0-7 %	0.7 %
e. Agoraphobia (F40.0)	1.6 %	0-3 %	2.3 %
3. Acute stress reaction (F43.0)	4.8 %	0-28 %	4.1 %
4. Post-traumatic stress disorder (F43.1)	2.2 %	0-22 %	1.9 %
5. Adjustment disorder (F43.2)	12.1 %	0-40 %	8.8 %
6. Somatoform disorders (F45.0-45.9)	2.7 %	0.5-13 %	4.7 %
7. Mental and behavioral disorders due to tobacco (F17)	11.3 %	2-51 %	6.2 %
8. Mental and behavioral disorders due to alcohol (F10)	4.9 %	0-40 %	2.9 %

A total of 43 studies focus on the topic of **suicidality**. The majority of the studies were conducted in patients with advanced cancer. The results show that suicidal ideation occurs in an average of 14.3% of patients (SD=13.4), median=15.2% (range 0.8-51%). The frequency of attempted suicide averaged 1.3% (SD=8.8) with a median of 1% (range 0-22.6%). An average of 15.9% expressed a desire for an early death (Desire for Hastened Death) (SD=10.7), median 15.4% (range 2-41%). The standardized suicide risk related to the frequency of suicides is mean $M=1.9$ (SD=1.0) with a median of 1.5 (range 1,2-4.2) [420], [421], [422], [423], [250], [410], [424], [425], [386], [426], [375], [374], [427], [428], [429], [430], [431], [416], [432], [433], [376], [434], [435], [436], [437], [438], [439], [440], [441], [442], [443], [444], [445], [406], [446], [447], [448], [449], [450], [415], [451], [452], [453], [454].

7 Diagnostics

7.1 Tasks and Special Features

Psycho-oncology is based on a biopsychosocial model of disease and health. This means that biological, psychological and social factors determine the development of diseases and that diseases can in turn affect biological, psychological and social factors [\[455\]](#).

In this context, the overlapping of physical symptoms of mental disorders with disease- or therapy-related symptoms is distinctive for the diagnosis of mental disorders in cancer patients, and thus makes a careful differential diagnosis necessary.

Primary tasks of diagnosis in cancer patients include the identification of psychosocial stress, mental disorders and other problems with the aim of describing existing problems and disorders as well as changes in symptoms; the classification of existing problems and disorders into diagnostic categories of a classification system (ICD-10); the provision of diagnostic information for the indication of psycho-oncological interventions and the evaluation of psycho-oncological interventions.

The diagnosis of a clinically relevant comorbid disorder requires differentiation from somatic complaints or an appropriate psychological response to cancer, as well as an appropriate consideration of biological-organic sequelae of the cancer or treatment [\[239\]](#), [\[386\]](#), [\[456\]](#), [\[457\]](#).

The diagnosis of specific problems such as unipolar depression, post-traumatic stress disorder, and trauma sequelae is explained in detail in the relevant guidelines ([Table 9](#)).

7.1.1 The Objective of Psycho-oncological Diagnostics

7.1	Consensus-based Recommendation	checked 2023
EC	The assessment of psychosocial distress and individual psycho-oncological support and treatment needs should occur as early as possible and then repeatedly during the course of the disease.	
	Strong Consensus	

The primary objective of psycho-oncological diagnostics is the early recognition of psychological, family, and social distress; psychological and psychosomatic symptoms; and the processing of the disease, especially with regard to the effects of the cancer and treatment measures. In addition to the type of stress, the psycho-oncological diagnosis also determines its severity, the time of occurrence as well as the course of the distress. It also aims to assess individual and social resources and the quality of life as well as the subjective need for treatment and the motivation for treatment.

A diagnosis of mental health disorders and the assessment of psychopathological findings are generally useful, but, in addition to the internationally recognized criteria of the ICD/DSM classification, should always be based on the stage of the disease, the prognosis and the physical health of the cancer patient, and the available local care and treatment options.

The psycho-oncological diagnosis is the basis for the recommendation of psycho-oncological support measures. It takes place in a staged process beginning with distress screening and a more in-depth clarification depending on the results of the screening (see [Chapter 7.4](#)). Psycho-oncological diagnostics should be carried out as early as possible in the course of the disease, so that existing stressors can be identified early and a worsening of the symptoms can be prevented.

7.2 Screening

7.2	Consensus-based Recommendation	modified 2023
EC	All cancer patients shall be screened for psychosocial stress.	
	Strong Consensus	

7.3	Consensus-based Recommendation	modified 2023
EC	Psycho-oncological screening should be performed as early as possible, at appropriate intervals, during the course of the disease, when clinically indicated or if a patient's disease status changes (e.g., recurrence or progression of the disease).	
	Strong Consensus	

A screening instrument (e.g., screening questionnaire) is defined as a means to identify a specific feature (e.g., psychological distress) in a large group of individuals. A screening for psychosocial distress and mental disorders indicates with a specific probability the absence or presence of distress, which should be further clarified through a clinical interview. Methods may include either self-description questionnaires or clinical screening questions.

Most screening instruments for psychosocial stress and mental disorders are self-description questionnaires that gather psychological symptoms in an easy to understand language. The scoring of such a questionnaire is based on a certain limit or threshold value (cut-off value) which defines whether the sum of the given positive answers makes the presence of a mental disorder or psychosocial distress likely or not.

In any screening, individuals may be misclassified. In the context of psycho-oncology, this means that individuals are falsely identified as having a high level of psychosocial distress even though they do not present with a problem requiring treatment upon further assessment (false positives), or, individuals are highly distressed but are not

detected by screening (false negatives). Sensitivity refers to the proportion of impacted individuals who are correctly identified by screening. High sensitivity means that only a few mentally distressed individuals are missed by the screening instrument (i.e., few false negatives). Specificity means the proportion of marginally or not at all distressed individuals who are correctly identified as marginally or not at all distressed by the screening. High specificity means that only a few healthy individuals are incorrectly classified as ill by the screening instrument (i.e., few false positives). The quality of a screening instrument is determined by the balance of sensitivity and specificity. A screening is more accurate the higher the percentage of individuals correctly classified by the screening instrument.

For the psycho-oncological diagnosis, there are a number of questionnaires available that screen to identify low-threshold patients with specific disorders or problems. Specific recommendations for suitable questionnaires are given in [Chapter 7.3.1](#)

A psycho-oncological screening questionnaire can be implemented in all care settings, i.e. inpatient as well as outpatient care. A psycho-oncological screening questionnaire can be incorporated into the medical or nursing history alongside the psychosocial history [\[458\]](#), [\[459\]](#), [\[460\]](#), [\[461\]](#).

Clinical screening questions include „How distressed have you felt in the past week?“, „How much did you feel affected by nervousness, anxiety, or tension in the past two weeks?“ or „How much did you feel affected by feeling down and/or depressiveness in the past two weeks?“.

Screening for psychosocial distress can be performed by any member of the treatment team involved in the care of cancer patients after appropriate training, depending on the situation at the site. The professional groups involved in the treatment of cancer patients should be able to recognize the type and extent of psychosocial distress and, if necessary, initiate a specific diagnostic clarification by a specialist or psychotherapist. This also applies to the assessment of suicidal tendencies or other forms of danger to self or others by the patient.

The clinical diagnostic process includes the assessment of complaints and symptoms, findings and classification diagnostics, trait diagnostics, the analysis of living conditions (including the role of caregivers) as well as the planning and discussion of intervention services, patient information and, if necessary, clarification with respect to the patients' motivation to change [\[462\]](#).

According to expert consensus, screening implemented as early as possible can prevent the chronification of psychological distress and is therefore of great importance in the diagnosis process. Empirical evidence is still lacking and should be supported by appropriate studies. It should therefore be carried out as part of the first contact with an outpatient or inpatient care facility. However, it must be taken into account that the screening should not be stressful for the patient. In rare cases, patients refuse screening due to the fear of being stigmatized.

Screening for psychosocial distress and determination of support needs should be voluntary. Information and support options based on the criteria of participatory decision-making should be discussed with the patient.

7.3 Diagnostic Procedures

7.3.1 Appropriate Screening Methods for Assessing the Need for Psycho-oncological Intervention

7.4	Evidence-based Recommendation	modified 2023
GoR A	Validated and standardized screening instruments shall be used to assess psychosocial distress. The screening instruments that shall be used are the Distress Thermometer (DT), the Hospital Anxiety and Depression Scale (HADS), the Questionnaire on Distress in Cancer Patients (FBK), the Depression Module of the Patient Health Questionnaire (PHQ-9), or the Generalized Anxiety Disorder Scale-7 (GAD-7).	
LoE 1b	[463] , [464] , [465] , [466] , [467] , [468] , [469] , [470] , [471] , [472] , [473] , [474] , [475] , [476] , [332] , [477] , [478] , [335] , [479] , [480] , [481] , [482]	
	Consensus	

7.5	Consensus-based Recommendation	new 2023
EC	In addition to the distress screening, the subjective need for psychosocial support shall also be asked.	
	Consensus	

7.6	Consensus-based Recommendation	checked 2023
EC	If the screening is positive and/or there is a subjective need for support identified, a diagnostic interview shall be offered to clarify psychosocial distress, psychiatric comorbidity, as well as the need for support and treatment.	
	Consensus	

7.7	Consensus-based Recommendation	checked 2023
EC	Further diagnostic clarification should be carried out according to individual psychological/social/somatic problems identified during the interview.	
	Strong Consensus	

In the context of psycho-oncological diagnostics, only diagnostic procedures that fulfill the psychometric quality criteria (objectivity, reliability and validity) should be implemented. Practicability, even for patients with severe cancer, as well as cost-effectiveness are further important prerequisites. In addition to the aforementioned quality criteria, there should be empirically determined limits or threshold values (cut-off values) established for screening procedures, that also ensure satisfactory sensitivity and specificity.

The following criteria were defined for the selection of a screening instrument:

It measures psychosocial distress. Based on the definition of the NCCN (National Comprehensive Cancer Network), psychosocial distress is defined as „a broad spectrum of unpleasant emotional experiences of a psychological, social, or spiritual nature that can range from normal feelings of vulnerability, sadness, and anxiety to severely limiting problems such as depressiveness, anxiety disorders, panic, social isolation, and spiritual crises.“

Psychosocial distress is assessed across all types of cancers, meaning that the instrument can be implemented for all tumor entities in adult patients.

The psychometric quality criteria of practicability, objectivity, reliability and validity, which have been demonstrated in validation studies of cancer patients in Germany, are fulfilled.

There are empirically determined threshold values (cut-off values) for the identification of patients with significant psychological distress, thus ensuring satisfactory sensitivity and specificity [\[461\]](#).

On the basis of these selection criteria, the psychometric parameters for the following screening methods were tested ([see table 8](#))

- Hospital Anxiety and Depression Scale (HADS-D) [\[72\]](#), [\[293\]](#), [\[326\]](#), [\[339\]](#), [\[483\]](#), [\[484\]](#), [\[485\]](#), [\[486\]](#), [\[487\]](#), [\[488\]](#), [\[489\]](#), [\[490\]](#), [\[491\]](#), [\[492\]](#), [\[478\]](#), [\[493\]](#), [\[494\]](#), [\[495\]](#), [\[496\]](#), [\[497\]](#), [\[465\]](#), [\[468\]](#), [\[498\]](#), [\[499\]](#), [\[500\]](#), [\[501\]](#), [\[502\]](#), [\[503\]](#), [\[504\]](#)
- Hornheider Screening Instrument (HSI) [\[480\]](#), [\[479\]](#), [\[477\]](#), [\[505\]](#), [\[506\]](#), [\[507\]](#)
- Distress Thermometer (DT) [\[177\]](#), [\[391\]](#), [\[326\]](#), [\[508\]](#), [\[509\]](#), [\[510\]](#), [\[511\]](#), [\[512\]](#), [\[513\]](#), [\[514\]](#), [\[473\]](#), [\[515\]](#), [\[516\]](#), [\[517\]](#), [\[518\]](#), [\[519\]](#), [\[520\]](#), [\[482\]](#), [\[521\]](#), [\[522\]](#), [\[523\]](#), [\[524\]](#), [\[498\]](#), [\[525\]](#), [\[526\]](#), [\[527\]](#), [\[528\]](#), [\[529\]](#), [\[499\]](#), [\[520\]](#), [\[530\]](#), [\[531\]](#), [\[532\]](#), [\[533\]](#), [\[534\]](#), [\[535\]](#), [\[471\]](#), [\[536\]](#), [\[537\]](#), [\[538\]](#), [\[539\]](#), [\[540\]](#), [\[541\]](#), [\[542\]](#), [\[543\]](#), [\[544\]](#), [\[474\]](#), [\[545\]](#), [\[546\]](#), [\[547\]](#), [\[502\]](#), [\[548\]](#), [\[549\]](#), [\[550\]](#), [\[551\]](#), [\[552\]](#), [\[553\]](#), [\[554\]](#)
- Questionnaire on Distress in Cancer Patients (FBK-23 and FBK-10) [\[170\]](#), [\[463\]](#), [\[555\]](#), [\[556\]](#), [\[557\]](#)
- Basic Psycho-Oncology Documentation (PO-Bado, PO-Bado KF and PO-Bado Breast Cancer) [\[74\]](#), [\[558\]](#), [\[464\]](#), [\[470\]](#), [\[469\]](#), [\[559\]](#), [\[560\]](#), [\[472\]](#), -
- Patient Health Questionnaire – Depression Module (PHQ-9 and PHQ-4) [\[512\]](#), [\[561\]](#), [\[562\]](#), [\[563\]](#), [\[468\]](#), [\[476\]](#), [\[564\]](#), [\[565\]](#), [\[566\]](#)
- Health Questionnaire for Patients – Generalized Anxiety Disorder Module (GAD-7) [\[567\]](#), [\[568\]](#), [\[569\]](#), [\[465\]](#), [\[570\]](#)

Based on a systematic literature review (see guideline report), the psychometric quality criteria and evidence levels for the screening questionnaires were determined. As part of the update of this guideline, the publications pertaining to German

patients (n=22) were subjected to a systematic analysis. The results of this analysis are the basis of recommendation 7.4. The corresponding evidence table can be found in the Guideline Report.

Table 8: Psychometric Criteria of the Screening Instruments

Instrument	Reliability		Validity		Sensitivity/ Specificity		Cut-off Score(s)	To be filled in by the patient	Cut-off value must be calculated	Evidence level**	
	DE*	INT†	DE*	INT	DE*	INT				DE	INT
HADS-D	+	+	+	+	+	+	yes 0-7: normal 8-10: borderline 11-21: moderate to severe	yes	yes	1b	1b
HSI‡	+	-	+	-	+	-	Yes (determined by discriminant function)	yes	yes	2b	-
DT	+	+	+	+	+	+	Yes 0-4: normal 5-10: high	yes	no	1b	1b
FBK	+	-	+	-	+	-	Yes at least 2 x 5 or at least 1 x 5 plus at least 4 x 4 or at least 5 x 4 or at least 1 x 5 plus at least 3 x 4 plus item 22 ≥ 1	yes	yes	1b	-
PO-Bado	+	-	+	-	+	-	Yes at least 1 x 4 or at least 2 x 3 or 2 additional items or at least 1 x 3 plus 1 additional item	no	yes	2b	-
PHQ	+	+	+	+	+	+	yes 0-4: low 5-9: mild expression 10-14: moderate expression 15-27: severe expression	yes	yes	1b	1b
GAD-7	+	+	+	+	+	+	yes 0-4: low 5-9: mild expression 10-14: moderate expression 15-21: severe expression	yes	yes	1b	1b

HADS-D: Hospital Anxiety and Depression Scale, HSI: Hornheider Screening Instrument, DT: Distress Thermometer, FBK: Questionnaire on Distress in Cancer Patients (FBK-23 and FBK-10), PO-Bado: Basic psycho-oncology Documentation (PO-Bado, PO-Bado KF and PO-Bado breast cancer), PHQ: Health Questionnaire for Patients – Depression Module (PHQ-4 and PHQ-9), GAD-7: Health Questionnaire for Patients – Generalized Anxiety Disorder Module, * Studies conducted in Germany, ** Determination of evidence level according to Centre for Evidence Based Medicine (CEBM) (Oxford), † International studies, ‡ Interview version available, + proven, - not proven

The best evidence is available nationally and internationally regarding cancer patients is provided by the Hospital Anxiety and Depression Scale (HADS-D), the Distress Thermometer (DT), the Depression Module of the Patient Health Questionnaire (PHQ-9), and the Generalized Anxiety Disorder (GAD-7) Module. In German-speaking regions, the Questionnaire on Distress in Cancer Patients (FBK-23 and FBK-10) continues to be well validated.

Among the other screening instruments, the PO-Bado (PO-Bado, PO-Bado KF, and PO-Bado Breast Cancer) as an independent assessment tool continues to have good evidence base in cancer patients with regard to the psychometric quality criteria. The Hornheider Screening Instrument (HSI) has good psychometric parameters, but has only been validated in patients with skin cancer.

If psychosocial distress has already been identified through a discussion with the patient, then no additional screening is required, rather, a clinical diagnosis is promptly established (or the recommendation and, if necessary, referral to the relevant psychosocial professional groups).

Psycho-oncological diagnostics

A comprehensive psycho-oncological diagnosis may include multiple approaches (self and external assessment) and important reference partners (family members, members of the health care team). Clinical interviews are part of a comprehensive psychosocial diagnosis and the most valid method for assessing a mental disorder. Common clinical interviews include the Structured Clinical Interview for DSM-5 and the Composite International Diagnostic Interview based on ICD-10 and ICD-11, respectively. Most screening instruments are not available for free and must be purchased from the publishers. The PHQ-9 and the GAD-7 are available on the web. The Distress Thermometer can be found in the article on the German version of the NCCN Distress Thermometer by Mehnert and colleagues [473]. A concise compilation of screening methods can be found in the brochure on Screening Methods in Psycho-oncology, published by the German Cancer Society [571].

In the context of the diagnosis, the potential interactions between somatic or treatment-related symptoms and the occurrence of psychosocial distress and psychological disorders should be emphasized. Thus, the management and interpretation of somatic symptoms often poses a difficult problem in the diagnosis of mental disorders in patients with severe physical illness. The diagnostic clarification of physical, cancer-related and treatment-related factors contributing to and perpetuating psychosocial stress and mental disorders is therefore of great importance. Cancer patients may experience individual distress in response to the diagnosis and treatment of cancer (e.g., uncertainty about the course of the disease, family conflicts), due to treatment-related factors (e.g., inadequate pain management), as well as due to specific medications that increase the incidence of psychological distress (e.g., corticosteroids or certain cytostatic drugs), or due to withdrawal symptoms (e.g., opiate, benzodiazepine withdrawal). In addition, psychosocial distress and psychological disorders may already exist prior to the cancer diagnosis and may worsen during the course of treatment [572].

The documentation of disease sequelae should be based on the International Classification of Functioning, Disability and Health (ICF) of the WHO [573] and focus particularly on the limitations of activity in everyday life and social participation. For specific questioning, for example, in the area of cognitive impairments and

psychomotorfunction, neuropsychological test procedures (e.g., TAP) can be recommended [\[458\]](#), [\[460\]](#), [\[574\]](#), [\[575\]](#), [\[576\]](#).

7.4 Diagnostic Process Steps

Psycho-oncological diagnosis is the essential basis for the recommendation of psycho-oncological support measures. It should be carried out as early as possible in the course of the disease, so that existing stressors can be identified early on, and a worsening of the symptoms can be prevented. It should be carried out in a stepwise process using a psycho-oncological screening that takes all patients into account and is also based on a clinical care algorithm (see [Figure 2](#)). Patients who obtain a significant value (screening cut-off value: positive) by means of a screening instrument (questionnaire or clinical assessment via screening questions) should receive more in-depth diagnostics, information, counseling and support. The need for treatment and the readiness for treatment should be further clarified in an initial interview, usually in the context of an anamnestic interview, if necessary with the aid of various diagnostic procedures. Patients with high psychosocial distress should be given access to psychosocial support services. The extent of which these services are taken advantage of should be evaluated.

Patients identified by a screening instrument with an under threshold value (screening cut-off value: under threshold) should be informed about psychosocial support services (see [Figure 2](#)). Since a screening instrument does not provide one hundred percent detection, it should be possible to identify both false positive and false negative cases according to the clinical care algorithm. In the case of false positive cases, further care is provided in the framework of information and counseling. False negative cases should be identified in the scope of personal counseling and information and then further diagnosed for subsequent treatment planning.

In addition to this initial psycho-oncological diagnosis, a re-evaluation of the diagnosis should be implemented during the course of the illness (at the end of treatment or with changes in the clinical status of the disease, such as recurrence or progression). If there is a change of care setting (inpatient, outpatient, and rehabilitation), the psycho-oncological findings should be updated. An assessment of the diagnosis at the end of a psycho-oncological intervention provides evidence of the success of the intervention [\[577\]](#), [\[574\]](#), [\[461\]](#).

8 Psycho-oncological Interventions

8.1 Concept and General Principles for the Indication of Psycho-oncological Treatment

8.1	Consensus-based Recommendation	modified 2023
EC	The indication for psycho-oncological interventions shall be made on the basis of the individual needs identified in accordance with recommendations 7.1. to 7.5, the setting, as well as the phase of the patient's illness (initial diagnosis, surgery, adjuvant therapy, recurrence-free phase, recurrence phase, palliative phase) and shall take into account the patient's wish for psycho-oncological support.	
	Strong Consensus	

8.2	Consensus-based Recommendation	modified 2023
EC	Patients with no or low distress (determined through screening and further diagnostics) shall be offered or given patient-oriented information and psychosocial counseling.	
	Strong Consensus	

8.3	Evidence-based Recommendation	modified 2023
GoR A	In addition to Recommendation 8.2, patients with subsyndromal psychological distress (determined through screening and further diagnostics) shall be offered an individual and/or group psychotherapeutic/psycho-oncological intervention.	
LoE 1a	[578] , [579] , [580] , [581] , [582] , [583] , [584] , [585] , [586] , [587] , [588] , [589] , [590] , [591] , [592] , [593] , [594] , [595] , [596] , [597] , [598] , [599] , [600] , [601] , [602] , [603] , [604] , [605] , [606] , [607] , [608] , [609] , [610] , [611] , [612] , [613] , [614] , [615] , [616] , [617] , [618] , [619] , [620] , [621] , [622] , [623] , [624]	
	Strong Consensus	

8.4	Consensus-based Recommendation	checked 2023
EC	Patients with diagnosed psychiatric disorders shall be treated according to current disorder-specific guidelines.	
	Strong Consensus	

8.5	Consensus-based Recommendation	modified 2023
EC	Patients with an adjustment disorder according to ICD-10 (determined through screening and further diagnostics) shall be offered patient-centered information and psychosocial counseling and also an individual and/or group psychotherapeutic intervention.	
	Strong Consensus	

The recommendations in this chapter refer to **psycho-oncological interventions** in the narrower sense.

The recommendations of [Chapter 8.2](#) to [Chapter 8.5](#) are based on a systematic literature search and review. A search was conducted for systematic reviews for the period 2010 - 2020, as well as a search for randomized controlled trials for the period 2015 - 2020 (Chapter 8.2-8.5). Similarly, the recommendations of [Chapter 8.8](#) are based on a systematic literature search for the period 2012 - 2020. The data on the evaluation of effect sizes are based on the classification according to Cohen (Cohen's d): d=0.2 corresponds to a small effect, d=0.5 to a medium effect, and d=0.8 to a large effect [\[625\]](#). *Short-term effects* refer to measurement immediately after completion of an intervention, *medium-term effects* refer to measurement by a follow-up survey within a period of 6 months, and *long-term effects* refer to a catamnestic measurement period of more than six months [\[626\]](#). The effect sizes described are always between-group effects (comparison of the intervention group with the control group), not pre-post effects within the intervention group. A detailed explanation of the systematic searches can be found in the Guideline Report.

Due to the insufficient evidence available, a systematic literature search was not performed for Chapters [Chapter 8.7](#) and [Chapter 8.6](#).

A **psycho-oncological intervention** in the narrower sense is defined as a non-pharmacological intervention in which psychological, psychotherapeutic, and social work methods are used alone or in combination, by professional therapists or counselors in a face-to-face interaction with cancer patients to reduce their psychological and social distress and improve their quality of life. A detailed explanation of this definition based on the PICO criteria can be found in the Guideline Report.

Furthermore, psycho-oncological interventions also include the Creative Arts Therapies.

In the course of updating the guideline, e-health based interventions [Chapter 8.4](#)) as well as specific psycho-oncological interventions for patients in the palliative situation [Chapter 8.5.3](#)) have been added.

For further forms of intervention, please refer to [Chapter 9](#) „Additional Therapies“.

As already mentioned at the beginning of the guideline, mind-body interventions for cancer patients such as yoga, qigong, and mindfulness-based methods are covered in the S3 guideline "Complementary Medicine in the Treatment of Oncological Patients" (AWMF register number: 032-055OL, <https://www.awmf.org/leitlinien/detail/II/032-055OL>).

[055OL.html](#)) and are therefore not part of this guideline. In addition, reference is also made here to the S3 guideline „Supportive Therapy for Oncological Patients“ (AWMF register number: 032-054OL, <https://www.awmf.org/leitlinien/detail/II/032-054OL.html>) and the "Extended S3 Guideline Palliative Care for Patients with a Non-curable Cancer" (AWMF register number: 128-001OL, <https://www.awmf.org/leitlinien/detail/II/128-001OL.html>).

In general:

- The indication for psycho-oncological interventions is based on individual need. The individual need is determined by psycho-oncological screening procedures such as self-description questionnaires or clinical screening questions, further diagnostic clarification and differential diagnosis, as well as the identification of the individual wishes of the patient with regard to psycho-oncological support. Further diagnostic procedures can be implemented in order to support the diagnosis (see [Chapter 7](#)).
- Psycho-oncological measures are recommended based upon the degree of distress or the type of psychological disorder identified.

In cases of no or low distress, information and psychosocial counseling are the appropriate interventions [\[578\]](#).

For subsyndromal distress, the updated evidence on psycho-oncological interventions shows that cancer patients benefit from psychoeducation, relaxation techniques, and psychotherapeutic procedures with respect to various complaints (see [Chapter 8.2](#), [Chapter 8.3](#) and [Chapter 8.5](#)). Art therapy should be offered, music and dance therapy as well as psycho-oncological e-health interventions can be offered (see [Chapter 8.4](#) and [Chapter 8.8](#)).

Patients with ICD-10 diagnoses of a mental disorder are treated according to the available guidelines (see [table 9](#)). Guidelines are available for the disorders or aspects covered in [Chapter 7](#). Here, the somatic and social factors identified during the diagnosis and their interactions should be taken into account. The following two examples illustrate the consideration of cancer-specific somatic and social factors in guideline-based treatment:

- Progression anxiety as a "typical" subsyndromal distress in people with cancer must be differentiated from an anxiety disorder according to ICD-10 in the diagnosis process.
- For the diagnosis of a somatoform disorder according to ICD-10, it should be taken into account that physical symptoms (such as fatigue, nausea, hot flashes) can often occur as a result of oncological therapy.

For the ICD-10 diagnosis of an adjustment disorder (F43.2), there is currently no separate guideline available in German. Since adjustment disorders are common in cancer patients along with affective and anxiety disorders (see [Chapter 6.2](#)), the treatment of cancer patients with an adjustment disorder according to ICD-10 is specified in the corresponding recommendations in this chapter.

- According to the definition of evidence-based medicine, the preferences of the patient should be taken into consideration in addition to the best evidence and clinical expertise when determining indications. Consideration of patient preference for psycho-oncological interventions is particularly important because (a) patient motivation is an important efficacy factor of

therapy and (b) there is little evidence to compare and test the efficacy of different psycho-oncological interventions so the choice between indicated interventions can be made on the basis of patient preference.

- The recommendation for psycho-oncological interventions should take into account the treatment setting (hospital, rehabilitation facility, outpatient setting) and the stage of disease (initial diagnosis, surgery, adjuvant therapy, recurrence-free phase, recurrence phase, palliative phase). For example, during an inpatient stay in an acute hospital, a psychoeducational program is not indicated due to the short length of stay. Here, priority will be given to an individual psychotherapeutic intervention supportive in nature or relaxation techniques.
- Based on the identified need for intervention, the diagnostic assessment, clinical evidence, patient preference, setting, and phase of illness, a clinical care algorithm can be formulated as follows:

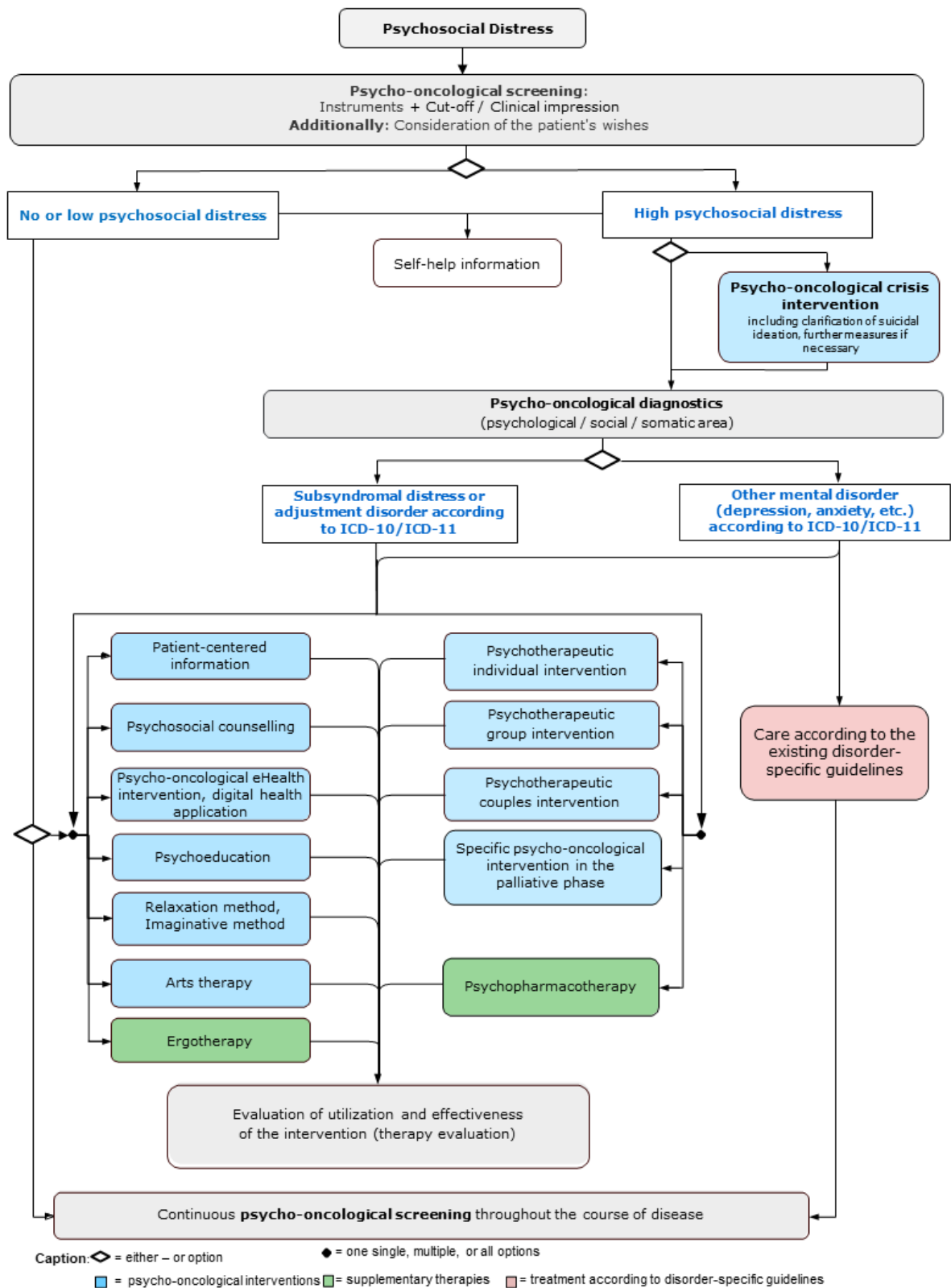


Figure 2: Clinical Care Algorithm

Table 9: Overview of German S3 Guidelines on Mental Disorders

Disorder/Guideline	AWMF number	Source (http://www.awmf.org/leitlinien/aktuelle-leitlinien.html)
Anxiety disorders	051-028	https://www.awmf.org/leitlinien/detail/II/051-028.html
Post-traumatic stress disorder	055-001	https://www.awmf.org/leitlinien/detail/II/155-001.html
Functional physical complaints	051-001	https://www.awmf.org/leitlinien/detail/II/051-001.html
Eating disorders	051-026	https://www.awmf.org/leitlinien/detail/II/051-026.html
Bipolar disorders	038-019	https://www.awmf.org/leitlinien/detail/II/038-019.html
Insomnia in adults Still being drafted at the time of this update, scheduled for completion in late 2022	063-001	https://www.awmf.org/leitlinien/detail/II/063-001.html
Unipolar depression	nvl-005	http://www.versorgungsleitlinien.de/themen/depression/

8.2 Relaxation and Imaginative Techniques

8.6	Evidence-based Recommendation	modified 2023
GoR A	Relaxation techniques shall be offered to cancer patients, regardless of their level of distress, in order to reduce anxiety, depression, mental distress, fatigue, and nausea, as well as to improve quality of life.	
LoE 1a	[578], [627], [581], [628], [629], [630], [631], [632], [633], [634], [635]	
	Strong Consensus	

8.7	Evidence-based Recommendation	modified 2023
GoR 0	Relaxation techniques can be offered to cancer patients, regardless of their level of distress, in order to reduce pain.	
LoE 1b	[630], [636], [633], [634], [637], [638]	
	Consensus	

Relaxation techniques are a collective term for various methods that actively focus on physical, mental or spiritual relaxation. The most common methods are autogenic training, progressive muscle relaxation according to Jacobson (PMR), and guided imagery. Mindfulness-based methods (e.g. Mindfulness-based stress reduction (MBSR)) also belong to the relaxation techniques, however, as mentioned in [Chapter 3.3](#), they are covered in Chapter 5 of the S3 guideline "Complementary Medicine in the Treatment of Oncological Patients" (AWMF register number: 032-055OL) and therefore not listed here. Relaxation techniques can be carried out by patients on their own after having received instruction and practice under professional guidance. This provides them with an instrument that enables them to reduce emotional tension (self-management) and strengthens their ability to regulate emotions (resource orientation). Compared to more intensive forms of psychotherapy, relaxation techniques are low-threshold and can be offered in an individual or group format. Likewise, relaxation techniques are often used as a component of other individual or group psycho-oncological interventions.

Relaxation techniques can be used in all phases of medical treatment for cancer, as well as in rehabilitation and follow-up care. They are particularly suitable for use before or during stressful diagnostic procedures, in preparation for radiotherapy or during chemotherapeutic treatments in order to reduce their side effects (e.g. nausea or anxiety).

Systematic literature review

The evaluation of the effectiveness of relaxation techniques in cancer patients and – survivors is based on five systematic reviews as well as ten RCTs. Three of the ten RCTs were already included in the systematic reviews; therefore, the results of these three studies are not reported separately in the presentation of results.

The five **systematic reviews** (three meta-analyses, two systematic reviews) included between five and 245 primary studies in the analysis. All reviews included mixed cancer populations. Primary studies included were from the US, China, Japan, UK, and the EU, among others. One meta-analysis addressed only the effectiveness of relaxation techniques in reducing anxiety [581], another exclusively fatigue [627], and one systematic review only pain reduction [635].

The sample size of the ten **RCTs** varied from 50 to 236 patients (N=1088), of which 28-100% were female. Studies were from Turkey (n=2) and Iran (n=2); the others were from Belgium, Italy, Greece, Romania, France, Thailand, and Taiwan (n=1 each). Often, the studies investigated specifically breast cancer (n=5) and breast and prostate cancer (n=2). One study specifically investigated head and neck cancer. The remaining studies (n=2) included patients with mixed cancer diagnoses. Common relaxation techniques offered were progressive muscle relaxation combined with guided imagery (n=2), progressive muscle relaxation alone (n=2), and hypnosis (n=2). Other relaxation methods offered were autogenic training (n=1) and other methods (n=3). The number of sessions ranged from one session to 12 sessions. Fatigue (n=4), pain (n=4), and anxiety (n=3) were most frequently assessed as primary endpoints. Furthermore, quality of life, depressiveness, and psychological distress (n=2 each) as well as nausea (n=1) represented primary endpoints in the RCTs.

Results

Quality of life, psychological distress, depressiveness, anxiety, fatigue, and nausea (Recommendation 8.6)

The *short-term effectiveness* of relaxation techniques on **global quality of life** was examined in a meta-analysis [578]. This was able to determine a significant short-term effect in favor of relaxation techniques ($d=0.35$). In addition, the results of three RCTs [630], [631], [632] were available, one of which was able to demonstrate a significant short-term effect in favor of relaxation techniques.

The *medium-term effectiveness* of relaxation techniques with regard to global quality of life was investigated in a meta-analysis [578]. This meta-analysis demonstrated a significant medium-term effect in favor of relaxation techniques ($d=0.78$). In addition, the results of three RCTs [630], [631], [632] were available, one of which was able to determine a significant medium-term effect in favor of relaxation techniques.

The *short-term effectiveness* of relaxation techniques with regard to **mental stress (distress)** was investigated in a meta-analysis [578]. This was able to determine a significant, short-term effect in favor of relaxation techniques ($d=-0.29$). In addition, the results of an RCT were available [633] which also demonstrated a significant short-term effect in favor of relaxation techniques.

The *medium- and long-term effectiveness* of relaxation techniques with regard to mental stress (distress) was investigated in only one meta-analysis [578]. This was

unable to demonstrate any significant medium- or long-term effects in favor of relaxation techniques.

The *short-term effectiveness* of relaxation techniques with regard to **depressiveness** was investigated in one meta-analysis [578]. This showed a significant short-term effect in favor of relaxation techniques ($d=-0.37$). In addition, the results of one RCT [629] also demonstrated a significant short-term effect in favor of relaxation techniques.

The *short-term effectiveness* of relaxation techniques with regard to **anxiety** was examined in two meta-analyses [581], [578]. Both were able to establish significant, short-term effects in favor of relaxation techniques ($d=-0.53$ in each case). In addition, the results of two RCTs [629], [634] were available, one of which was able to demonstrate a significant, short-term effect in favor of relaxation techniques.

The *medium-term effectiveness* of relaxation techniques with regard to anxiety was investigated in one meta-analysis [578]. This was able to determine a significant, medium-term effect in favor of relaxation techniques ($d=-1.12$). In addition, the results of one RCT [634] were available which could not determine a significant, medium-term effect in favor of relaxation techniques.

The *short-term effectiveness* of relaxation techniques with regard to **fatigue** was investigated in one meta-analysis [627]. This demonstrated a significant short-term effect in favor of relaxation techniques ($d=-0.77^2$). In addition, the results of four RCTs [629], [630], [631], [634] were available, two of which demonstrated significant short-term effects in favor of relaxation techniques.

No systematic reviews were available to evaluate the *medium-term effectiveness* of relaxation techniques on fatigue. Only the results of three RCTs were available [630], [631], [634], one of which demonstrated a significant, medium-term effect in favor of relaxation techniques.

The *short- and medium-term efficacy* of relaxation techniques with regard to chemotherapy-induced **nausea** was investigated in one systematic review [635], which descriptively described that significant short- and medium-term effects in favor of relaxation techniques were demonstrated in six of six RCTs included in the review. No additional RCTs were available.

² Effect significant only for patients after completion of treatment, not significant for patients receiving treatment.

Pain (Recommendation 8.7)

No systematic reviews were available to assess the *short-term effectiveness* of relaxation techniques with respect to **pain**. Only the results from six RCTs [630], [636], [633], [634], [637], [638] were available, four of which demonstrated significant short-term effects in favor of relaxation techniques. One of the six RCTs demonstrated a *greater short-term* reduction of pain in the control group (TAU) than in the relaxation group.

No systematic reviews were available to assess the *medium-term effectiveness* of relaxation techniques on pain either. Only the results of two RCTs [630], [634] were available, none of which found a significant medium-term effect in favor of relaxation techniques.

The findings on the effectiveness of relaxation techniques on pain in people with cancer can be considered heterogeneous. Pain represented the primary outcome in five of the six RCTs, and two of these five RCTs had a sufficiently large sample size according to a priori power analysis. Two of the six RCTs provided information on side effects and interactions, but these did not occur in either the control or relaxation groups. The methodological quality of all RCTs can be rated as moderate to low. The use of relaxation techniques to reduce pain is assessed by experts of the guideline group as common clinical practice. It should also be noted that evidence of efficacy exists for various forms of non-cancer pain. However, additional, methodologically high-quality studies are needed to formulate a more accurate recommendation for the use of relaxation techniques to reduce pain in people with cancer.

Supplementary evidence

In addition to the above findings per endpoint, a systematic review by Kapogiannis et al. [628] describes that significant effects in favor of relaxation techniques on at least one endpoint (including mood, anxiety, depressiveness, as well as nausea) were detectable in seven of 10 included RCTs.

Assessment of study quality

4/5 (80%) SRs had deficiencies in more than one critical assessment domain (*critical low quality*), 1/5 (20%) in one critical assessment domain (*low quality*). It should be noted that in 2/4 SRs, there was a downgrading of the quality assessment due to the lack of a list of excluded primary studies and their reasons for exclusion (critical domain 7, AMSTAR-2).

7/10 RCTs (70%) used an adequate method to generate the randomization sequence (*selection bias*), and in 7/10 RCTs (70%) the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*), and in 2/10 RCTs (20%) selective reporting of end points could be excluded through an existing study protocol (*reporting bias*). No conclusions could be drawn about the secrecy and unpredictability of group allocation of the RCTs (*selection bias*) (9/10, 90%), and in one RCT this was explicitly not possible. Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) was not possible in any of the RCTs and thus, nor was blinding of endpoint collection (*detection bias*), with the exception of one RCT.

7/10 RCTs performed a priori sample size estimation. 5/7 RCTs achieved their a priori planned sample size.

8.3 Psychoeducation

8.8	Evidence-based Recommendation	modified 2023
GoR A	Psychoeducational interventions shall be offered to cancer patients, regardless of their level of distress, in order to reduce mental distress, anxiety, and pain, as well as to improve quality of life.	
LoE 1a	[578], [582], [639], [640], [641], [642], [643], [644], [645], [646], [596], [647], [648], [649], [650], [651], [652], [653], [654], [655], [656]	
	Strong Consensus	

8.9	Evidence-based Recommendation	modified 2023
GoR B	Psychoeducational interventions should be offered to cancer patients, regardless of the level of distress, in order to reduce depressiveness and fatigue.	
LoE 1a	[588], [640], [578], [656], [596], [655], [647], [648], [649], [654], [650], [651]	
	Strong Consensus	

8.10	Evidence-based Statement	new 2023
LoE 1b	The study data on the efficacy of psychoeducational interventions for reducing nausea and sexual dysfunction does not support a recommendation for or against their use for these complaints.	
	[645], [650]	
	Strong Consensus	

Psychoeducational interventions are standardized, multimodal, interactive interventions that include a broad range of topics (Faller, 2016): Information about the illness, health-related behaviors, stress management, coping with disease, psychosocial support. „Standardized“ means the existence of a curriculum in which the learning objectives are defined and also a manual in which the learning objectives are specified and the didactic approach is defined. „Multimodal“ means the use of various, and especially interactive, activating didactic methods. This definition corresponds to the consensus definition of the Center for Patient Education. Giving information alone is not classified as patient education. Psychoeducation is offered in individual or group format.

Systematic literature review

The evaluation of the effectiveness of psychoeducational interventions in cancer patients and -survivors is based on eleven systematic reviews and 13 RCTs.

The eleven **systematic reviews** (eight meta-analyses, three systematic reviews) included between ten and 198 primary studies in the analysis. Nine of the reviews included mixed cancer populations, and in three cases [642], [643], [644], tumor-related pain also had to be present. One review examined lung cancer. The primary studies included were from the USA, Canada, Australia, China, and the EU, among others. One meta-analysis looked exclusively at the efficacy of psychoeducation in increasing quality of life [657], another looked exclusively at anxiety reduction [581], three systematic reviews looked only at pain reduction [642], [642], [643], [644], [643], and one systematic review looked at efficacy in reducing fatigue [658].

The sample size of the 13 **RCTs** varied between 40 and 2,140 patients (N=3,931), of which 15.5-100% were female. The studies were mostly from China (n=4) and Singapore (n=2). The remaining studies were from Iran, Qatar, Malaysia, Taiwan, France, Germany, and Sweden (n=1 each). Most studies specifically investigated breast cancer (n=4) or no specific cancer type (n=4). Further types of cancer specifically represented were laryngeal cancer, gynecologic cancers, bladder cancer, lung cancer, and anal and colorectal cancers (n=1 each). In most cases, psychoeducation was provided in the form of individual sessions (n=6); three studies examined a psychoeducational intervention presented in a group format. Three studies supplemented psychoeducation with other interventions, such as a training manual (n=1), self-management skills training (n=1), as well as a rehabilitation program (n=1). The number of psychoeducational intervention sessions presented ranged from one session to eight sessions. The most frequently assessed primary endpoints of the RCTs represented anxiety (n=7), depressiveness (n=6), and quality of life (n=6). Furthermore, pain (n=2), fatigue (n=2), sexual function (n=1), nausea (n=1), and psychological distress (n=1) were also collected as primary endpoints.

Results

Quality of life, psychological distress, anxiety, and pain (Recommendation 8.8)

The *short-term effectiveness* of psychoeducational interventions on **global quality of life** was examined in four meta-analyses [582], [640], [641], [578], three of which identified significant short-term effects in favor of psychoeducational interventions ($0.19 < d < 0.20$). In addition, the results of seven RCTs [656], [646], [596], [648], [649], [651], [653], [652] were available, two of which were able to demonstrate significant, short-term effects in favor of psychoeducational interventions. One of the seven RCTs provided mixed results and found a significant, short-term effect in favor of psychoeducational interventions for psychological quality of life, but not for physical quality of life.

The *medium-term effectiveness* of psychoeducational interventions on global quality of life was examined in one meta-analysis [578]. This failed to find a significant medium-term effect in favor of psychoeducational interventions. In addition, the results of two RCTs [596], [652] were available, neither of which could demonstrate a significant, medium-term effect in favor of psychoeducational interventions.

¹ Bennett 2016 report a non-standardized MD = 11.47 in global quality of life (EORTC QLQ-C30)

The *long-term effectiveness* of psychoeducational interventions regarding global quality of life was investigated in one meta-analysis [578]. This was able to demonstrate a significant long-term effect in favor of psychoeducational interventions ($d=0.18$). The result of one RCT [652] was also available, however, a significant long-term effect in favor of the psychoeducational intervention was not demonstrated.

The *short-term effectiveness* of psychoeducational interventions on **psychological distress** was examined in one meta-analysis [578]. This was able to determine a significant short-term effect in favor of psychoeducational interventions ($d=-0.18$). In addition, the result of one RCT [653] was available which found no significant short-term effect in favor of psychoeducation.

The *medium-term effectiveness* of psychoeducational interventions with regard to psychological distress was also examined in a meta-analysis [578]. This was able to demonstrate a significant medium-term effect in favor of psychoeducational interventions ($d=-0.30$). No additional RCTs were available.

The *long-term effectiveness* of psychoeducational interventions on psychological distress was examined in one meta-analysis [578]. This failed to demonstrate a significant, long-term effect in favor of psychoeducational interventions. No additional RCTs were available.

The *short-term effectiveness* of psychoeducational interventions on **anxiety** was examined in three meta-analyses [581], [640], [578], all of which were able to determine significant, short-term effects in favor of psychoeducational interventions ($-0.18 < d < -1.47$). In addition, the results of ten RCTs [645], [656], [596], [655], [647], [648], [649], [654], [651], [653] were available, five of which demonstrated significant, short-term effects in favor of psychoeducational interventions.

The *medium-term effectiveness* of psychoeducational interventions on anxiety was examined in one meta-analysis [578]. This demonstrated a significant medium-term effect in favor of psychoeducational interventions ($d=-0.24$). In addition, the result of one RCT [596] was available which also demonstrated a significant medium-term effect in favor of psychoeducation.

The *long-term effectiveness* of psychoeducational interventions on anxiety was also examined in one meta-analysis [578]. This found no significant long-term effect in favor of psychoeducational interventions. No additional RCTs were available.

The *short-term efficacy* of psychoeducational interventions on **pain** was examined in two meta-analyses [642], [643], both of which found a significant short-term effect in favor of psychoeducational interventions ($d=-0.11$ and $d=-0.27$). Furthermore, the systematic review by Oldenmenger et al. [644] describes that eight of 26 included RCTs (31%) reported significant pain differences between groups in favor of the psychoeducation group. In addition, the results of two RCTs were available from our search [646], [650], one of which demonstrated a significant short-term effect in favor of psychoeducation.

No systematic reviews were available on the *medium-term effectiveness of* psychoeducational interventions regarding pain. Only the result of one RCT [646] was available, which found a significant, medium-term effect in favor of psychoeducation.

Depressiveness and fatigue (Recommendation 8.9)

The *short-term efficacy of* psychoeducational interventions on **depressivity** was examined in three meta-analyses [588], [640], [578], one of which was able to determine a significant, short-term effect in favor of psychoeducational interventions ($d=-0.18$). In addition, the results of eight RCTs [656], [596], [655], [647], [648], [649], [654], [651] were available, four of which found significant, short-term effects in favor of psychoeducational interventions.

The *medium-term effectiveness of* psychoeducational interventions on depressivity was examined in one meta-analysis [578]. This was able to determine a significant, medium-term effect in favor of psychoeducational interventions ($d=-0.23$). In addition, the result of one RCT [596] was available which could also prove a significant, medium-term effect in favor of psychoeducational interventions.

The *long-term efficacy of* psychoeducational interventions on depressivity was examined in one meta-analysis [578]. This found no significant long-term effect in favor of psychoeducational interventions. No additional RCTs were available.

The *short-term effectiveness of* psychoeducational interventions on **fatigue** was examined in one meta-analysis [640]. This demonstrated a significant short-term effect in favor of psychoeducational interventions ($d=-0.27$). Furthermore, the systematic review by Du et al. [658] describes that five of the ten RCTs included in the review found a significant effect in favor of psychoeducation². In addition, the results of two RCTs were available from our search [649], [650] but none of these found a significant short-term effect in favor of psychoeducation.

Nausea and sexual dysfunction (Statement 8.10)

No systematic reviews were available on the *short-term effectiveness of* psychoeducational interventions regarding **nausea**. Only the result of one RCT [650] was available which demonstrated no significant short-term effect in favor of psychoeducation.

No systematic reviews were available on the *short-term effectiveness of* psychoeducational interventions regarding sexual function. Only the result of one RCT [645] was available, here significant short-term effects in favor of psychoeducation on one of five subscales of the multidimensional questionnaire were demonstrated.

The studies on the reduction of nausea as well as sexual dysfunction are not sufficiently reliable. The guideline group therefore reserves the right to refrain from making a recommendation for or against the use of psychoeducational interventions by cancer patients and these complaints. Further studies of high methodological quality are needed to formulate a recommendation.

Supporting evidence

² In 8 out of 10 RCTs included in the review from Du et al. 2015 [658], sport and exercise therapy were included in the psychoeducational interventions.

In addition to the above-mentioned findings per endpoint, a systematic review by Li et al. [659] shows that in 12 of 15 included RCTs there were significant effects in favor of psychoeducation on at least one primary endpoint (including quality of life, mental distress, pain, fatigue).

Assessment of study quality

8/11 (73%) SRs had deficiencies in more than one critical assessment domain (*critical low quality*) and 1/11 (9%) SRs in one critical assessment domain (*low quality*). 1/11 (9%) SRs had no critical but more than one non-critical deficiency (*moderate quality*), and one (9%) SR had no critical and only one non-critical deficiency (*high quality*). It should be noted that 2/10 SRs had a downgraded quality score due to the lack of a list of excluded primary studies and their reasons for exclusion (critical domain 7, AMSTAR-2).

9/13 RCTs (69%) used an adequate method to generate the randomization sequence (*selection bias*), 2/13 RCTs (15%) ensured secrecy and unpredictability of group allocation (*selection bias*), and in 6/13 RCTs (46%), the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) and thus blinding of endpoint collection (*detection bias*) were not possible in any of the RCTs. No statement could be made about the selective reporting of endpoints (*reporting bias*) due to the lack of study protocols.

10/13 RCTs performed a priori sample size estimation. 7/10 RCTs achieved their a priori planned sample size.

8.4 Psycho-oncological E-health Interventions

8.11	Evidence-based Recommendation	new 2023
GoR B	Psycho-oncological e-health interventions should be offered to cancer patients, regardless of the level of distress, in order to improve quality of life.	
LoE 1a	[660], [661], [662], [663], [664], [665], [666], [667], [668], [669], [670], [671], [672], [673], [674], [675], [676], [677]	
	Consensus	

8.12	Evidence-based Recommendation	new 2023
GoR 0	Psycho-oncological e-health interventions can be offered to cancer patients regardless of their level of distress, in order to reduce mental distress, depressiveness, anxiety, and fatigue.	
LoE 1a	[663], [662], [661], [678], [665], [664], [666], [679], [680], [668], [681], [669], [670], [671], [682], [683], [684], [672], [673], [674], [675], [685], [676], [686], [687], [688], [689], [677]	
	Strong Consensus	

8.13	Evidence-based Statement	new 2023
LoE 1b	The study data on the effectiveness of psycho-oncological e-health interventions for the reduction of pain and sexual dysfunction in cancer patients does not allow a recommendation for or against their use for these complaints.	
	[668], [669], [684], [674], [690], [691], [677]	
	Strong Consensus	

The German Federal Ministry of Health uses the term "e-health" to refer to applications and services that use the possibilities of modern information and communication technologies (ICT) to support the treatment and care of patients (<https://www.bundesgesundheitsministerium.de/service/begriffe-von-a-z/e/e-health.html>). In the context of psycho-oncological care, the use of health apps or websites, as well as telemedicine services, are of primary importance. In terms of content, the interventions are usually multimodal. In practice, educational, counseling and low-threshold psychotherapeutic services are implemented and, through the use of an ICT, can be used regardless of location. Psycho-oncological care services can thus be made available to patients who live in regions with a low density of care

and/or who are unable to take advantage of face-to-face services due to psychological or physical limitations.

In accordance with the definition of psycho-oncological interventions (in [Chapter 8.1](#)), the systematic literature review only included studies that involved personal interaction between professional therapists and cancer patients and dealt with psycho-oncological issues. For example, personal interaction could be via telephone, videoconference, or face-to-face contacts in addition to the use of websites or apps.

Digital health applications (DiGA) are also becoming increasingly important. Apps and browser-based applications tested by the Federal Institute for Drugs and Medical Devices (BfArM) for evidence-based positive care effects are now available for numerous areas of application, including oncology (<https://diga.bfarm.de/de>). It should be specifically noted once again that the pure use of health apps and websites, as well as video or audio recordings, or exclusive contact by mail, chats or forums, was excluded in the following systematic literature search.

It should be emphasized at this point that, in the viewpoint of the guideline group, psycho-oncological e-health interventions in clinical practice should not replace psycho-oncological services based on personal contact, but rather should be offered in addition to these services, especially when accessibility barriers exist.

Systematic literature review

The evaluation of the effectiveness of e-health/telehealth interventions in cancer patients and survivors is based on five systematic reviews and 28 RCTs from 30 publications³. Three of the 28 RCTs were already included in at least one of the systematic reviews, therefore, the results of these three studies are not reported separately in the results.

The five **systematic reviews** (four meta-analyses, one systematic review) included between 11 and 20 primary studies in the analysis. Cancer types studied were breast cancer (n=2) and mixed cancer populations (n=3). Primary studies included were from the US, Australia, China, Canada, UK, and the EU, among others. One meta-analysis focused exclusively on the efficacy of psycho-oncology e-health interventions on improving quality of life [660], all others reported outcomes on multiple relevant endpoints.

The sample size of the 28 **RCTs** varied between 38 and 254 patients (N=3,125), of which 0-100% were female. The studies were largely from the United States (n=15), Netherlands (n=3), and Australia (n=3); the remainder of the studies were from China (n=2), Singapore, Norway, France, Germany, and Sweden (n=1 each). The most common target group of e-health/telehealth interventions were breast cancer patients (n=10); other cancer types studied were prostate cancer (n=3) lung cancer (n=3), (colorectal) cancer (n=2), black skin cancer, cervical cancer, esophageal cancer, rectal and anal cancer, and leukemia (n=1 each). Five studies included patients with different cancer diagnoses. Intervention was frequently offered by telephone (n=16) and videoconferencing (n=5). In five studies, supplemental analog or digital materials were given. Some studies combined contact via telephone or video contacts together with face-to-face contacts (n=4). Other forms of delivery represented online modules

³ Dieng et al. 2020 [664] and Dieng et al. 2016 [665], as well as Chambers et al. 2015 [690] and Chambers et al. 2019 [691] all refer to the same sample but report results of additional points of measurement.

(n=2) and apps (n=1) combined with face-to-face contacts. Content often involved cognitive-behavioral therapy elements (n=12) or general psychosocial support (n=9, including couples counseling). Furthermore, psychoeducation (n=3), acceptance and commitment therapy (ACT; n=1), as well as imagery-based (n=1) and other (n=2) approaches were offered. The number of intervention sessions offered ranged from a single session to weekly sessions over 24 weeks or sessions with larger time intervals inbetween of up to six months. Anxiety (n=12), depressiveness (n=11), and quality of life (n=7) represented the most common primary endpoints in the RCTs. Furthermore, fatigue (n=5), sexual function/satisfaction (n=5), mental distress (n=2), and pain (n=1) were collected as primary endpoints in the RCTs.

Results

Quality of life (Recommendation 8.1.1)

The *short-term effectiveness* of psycho-oncology e-health interventions on **global quality of life** was examined in four meta-analyses [660], [661], [662], [663], three of which identified significant short-term effects in favor of psycho-oncology e-health interventions ($0.54 \leq d \leq 0.75$). In addition, the results of ten RCTs [666], [668], [669], [670], [671], [672], [673], [674], [675], [676] were available, three of which were able to establish significant, short-term effects in favor of psycho-oncological e-health interventions.

The *medium-term effectiveness* of psycho-oncological e-health interventions with respect to global quality of life has not been investigated in any systematic review. However, the results of eight RCTs [665], [664], [667], [668], [672], [673], [674], [675], [677] were available, one of which demonstrated a significant medium-term effect in favor of the psycho-oncological e-health intervention.

No systematic reviews were available to assess the *long-term effectiveness* of psycho-oncology e-health interventions on global quality of life. Only the results of two RCTs were available [665], [664], [677], one of which demonstrated a significant long-term effect in favor of the psycho-oncological e-health intervention.

Psychological distress, depressiveness, anxiety, and fatigue (Recommendation 8.1.2)

The *short-term effectiveness* of psycho-oncological e-health interventions with regard to **psychological distress** was investigated in one meta-analysis [663]. This could not determine a significant effect. In addition, the results of six RCTs [666], [669], [671], [673], [686], [689] were available, three of which were able to demonstrate a significant short-term effect in favor of psycho-oncological e-health interventions.

No systematic reviews were available to assess the *medium-term effectiveness* of psycho-oncological e-health interventions with regard to psychological distress. Only three RCTs were available [673], [686], [677], one of which was able to determine a significant medium-term effect in favor of the psycho-oncological e-health intervention.

The *long-term effectiveness* of psycho-oncological e-health interventions was not investigated in any systematic review. Only one RCT [677] was available, a significant long-term effect in favor of the psycho-oncological e-health intervention could not be determined.

The *short-term efficacy* of psycho-oncology e-health interventions with respect to **depression** was examined in two meta-analyses [662], [663]. Neither meta-analysis demonstrated significant short-term effects in favor of psycho-oncological e-health interventions. In addition, the results of 17 RCTs [666], [679], [668], [681], [670], [682], [683], [684], [672], [673], [674], [675], [685], [686], [687], [688], [689] were available, five of which were able to identify significant short-term effects in favor of psycho-oncological e-health interventions.

No systematic reviews were available to assess the *medium-term effectiveness* of psycho-oncological e-health interventions with regard to depression. However, the results of twelve RCTs [664], [665], [668], [681], [682], [683], [684], [672], [673], [674], [675], [686], [687] were available, one of which demonstrated a significant medium-term effect in favor of the psycho-oncological e-health intervention.

The *long-term efficacy* of psycho-oncological e-health interventions with regard to depression has not been investigated in any systematic review. Only the results of one RCT [665], [664] were available, but could not demonstrate a significant long-term effect.

The *short-term effectiveness* of psycho-oncological e-health interventions regarding **anxiety** was investigated in two meta-analyses [662], [663]. One of the meta-analyses demonstrated significant short-term effects in favor of psycho-oncological e-health interventions ($d=-0.16$). In addition, the results of 16 RCTs [666], [679], [681], [670], [682], [683], [684], [672], [673], [674], [675], [685], [686], [687], [688], [689] were available, four of which identified significant short-term effects in favor of psycho-oncological e-health interventions.

The *medium-term effectiveness* of psycho-oncological e-health interventions with regard to anxiety was not investigated in any systematic review. Only twelve RCTs were available [665], [664], [680], [681], [682], [683], [684], [672], [673], [674], [675], [686], [687], two of which were able to demonstrate significant medium-term effects in favor of psycho-oncological e-health interventions. One of the RCTs provided mixed results (significant effect regarding recurrence anxiety, but not regarding general anxiety).

No systematic reviews were available to assess the *long-term effectiveness* of psycho-oncology e-health interventions on anxiety. Only the results of two RCTs were available [665], [664], [680], one of which found mixed results regarding psycho-oncological e-health interventions (significant effect regarding recurrence anxiety, but not regarding general anxiety). The other RCT failed to identify a significant long-term effect.

The *short-term efficacy* of psycho-oncological e-health interventions with regard to **fatigue** was examined in two meta-analyses [661], [662], one of which demonstrated significant short-term effects in favor of psycho-oncological e-health interventions ($d=-0.30$). In addition, eight RCTs on the short-term efficacy of fatigue were available [671], [682], [683], [684], [672], [675], [676], [688], two of which found significant short-term effects in favor of psycho-oncological e-health interventions.

The *medium-term efficacy* of psycho-oncological e-health interventions on fatigue was not investigated in any systematic review. Only five RCTs were available [682], [683], [684], [672], [675], none of which found significant medium-term effects in favor of psycho-oncological e-health interventions.

Pain and sexual dysfunction (Statement 8.13)

The *short- and medium-term efficacy* of psycho-oncological e-health interventions on **pain** has only been investigated in two RCTs [682], [684], neither of which, however, was able to determine significant, short- and medium-term effects in favor of psycho-oncological e-health interventions.

The *short-term effectiveness* of psycho-oncological e-health interventions on **sexual function** was not investigated in any systematic review. Only four RCTs were available [668], [669], [674], [690], [691], [689], one of which was able to demonstrate a significant, short-term effect in favor of psycho-oncological e-health interventions.

The *medium-term effectiveness* of psycho-oncological e-health interventions regarding sexual function has not been investigated in any systematic review. Only the results of four RCTs were available [668], [674], [690], [691], [677], none of which, however, could demonstrate a significant, medium-term effect in favor of psycho-oncological e-health interventions.

There were also no systematic reviews available for assessing the *long-term effectiveness* of psycho-oncological e-health interventions with respect to sexual function. In addition, the results of the two available RCTs [690], [691], [677], showed no significant long-term effects in favor of psycho-oncological e-health interventions.

The studies on the reduction of pain and sexual dysfunction are not sufficiently reliable. In particular, the RCTs on sexual function are very heterogeneous in terms of content; only two studies have a priori power analyses with a sufficient number of cases. Furthermore, none of the studies included makes statements on side effects and interactions of the interventions investigated. The guideline group therefore refrains from making a recommendation for or against the use of psycho-oncological e-health interventions for these complaints. Additional, methodologically high-quality studies are needed to formulate a recommendation.

Supporting evidence

In addition to the above results, the systematic review by Okuyama et al. [678] descriptively describes that in eight of 20 included RCTs, significant short-term effects in favor of psycho-oncological e-health interventions on at least one surveyed psychosocial endpoint (including quality of life, depressiveness, anxiety, mental distress, recurrence anxiety) was demonstrated. Furthermore, four RCTs in the review reported outcomes at follow-up time points, and one of these demonstrated significant effects in favor of psycho-oncology e-health interventions.

Assessment of study quality

All SRs (5/5; 100%) had deficiencies in more than one critical assessment domain (*critical low quality*).

In total, 21/28 RCTs (75%) used an adequate method to generate the randomization sequence (*selection bias*), 12/28 RCTs (43%) ensured secrecy and unpredictability of group allocation (*selection bias*), in 24/28 RCTs (86%), the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*), and in 8/28 RCTs (29%), selective reporting of endpoints could be excluded by an existing study protocol (*reporting bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of

study personnel/participants (*performance bias*) was not possible in any of the RCTs. In a large number of RCTs (n=23), blinding of the endpoint survey (*detection bias*) was not possible; in five RCTs, no statement could be made in this regard.

16/28 RCTs performed a priori case number planning, of which 12 RCTs achieved their a priori planned number of cases.

8.5 Psychotherapeutic Interventions

8.5.1 Psychotherapeutic Interventions in Individual and Group Settings

8.14	Evidence-based Recommendation	modified 2023
GoR A	Psychotherapeutic interventions shall be offered to cancer patients with an adjustment disorder or subsyndromal distress in order to reduce psychological distress, depressiveness, anxiety, and nausea, as well as to improve quality of life.	
LoE 1a	[578], [579], [580], [581], [582], [583], [584], [585], [586], [587], [588], [589], [692], [693], [590], [591], [592], [594], [595], [596], [624], [597], [598], [599], [600], [601], [602], [603], [604], [605], [606], [607], [608], [609], [610], [611], [623], [612], [613], [614], [615], [616], [617], [619], [618], [620], [621], [622]	
	Strong Consensus	

8.15	Evidence-based Recommendation	modified 2023
GoR B	Psychotherapeutic interventions should be offered to cancer patients with an adjustment disorder or subsyndromal distress in order to reduce fatigue.	
LoE 1a	[627], [584], [693], [694], [593], [600], [603], [620]	
	Strong Consensus	

8.16	Evidence-based Recommendation	new 2023
GoR 0	Psychotherapeutic interventions can be offered to cancer patients with an adjustment disorder or subsyndromal distress in order to reduce pain as an adjunct to guideline-based pain management.	
LoE 1b	[584] , [585] , [693] , [592] , [600] , [599] , [603]	
	Strong Consensus	

8.17	Evidence-based Statement	new 2023
LoE 1b	The evidence on the effectiveness of psychotherapeutic interventions in order to reduce sexual dysfunction in cancer patients does not support a recommendation for or against their use for these conditions.	
	[695] , [696] , [612] , [619]	
	Strong Consensus	

8.18	Consensus-based Recommendation	new 2023
EC	The choice between psychotherapeutic interventions in individual or group settings shall be based on the preference of the cancer patient.	
	Strong Consensus	

Systematic literature review

The evaluation of the effectiveness of psychotherapeutic interventions in cancer patients and survivors is based on 16 systematic reviews as well as 21 RCTs for individual psychotherapy, and 18 RCTs for group psychotherapy. One of these 39 RCTs was already included in one of the systematic reviews, therefore, the results of this study are not reported separately in the results.

The 16 **systematic reviews** (13 meta-analyses, three systematic reviews) included between six and 245 primary studies in the analysis. Regarding the tumor entities studied, seven reviews focused exclusively on breast cancer and one each on lung and prostate cancer. The remaining reviews (n=7) examined mixed cancer populations. The primary studies included were from the US, Asia, Australia, UK, and the EU, among others. Several reviews focused on only one endpoint: three meta-analyses reported exclusively on the efficacy of psychotherapeutic interventions for reducing depression [\[579\]](#), [\[587\]](#), [\[588\]](#), one for increasing quality of life [\[582\]](#), one for reducing anxiety [\[581\]](#), and one for reducing fatigue [\[627\]](#).

The sample size of the 21 **RCTs** that examined **individual psychotherapy** varied from 30 to 1012 patients (N=3,624), of whom 14.5-100% were female. The studies were mostly from the United States (n=3), Canada (n=2), Iran (n=2), China (n=2), and Germany (n=2). The remaining studies were from the Netherlands, Italy, Denmark, Turkey, Norway, Greece, New Zealand, Qatar, South Korea, and Brazil (n=1 each). Regarding the tumor entities investigated, eight studies focused exclusively on breast cancer, two on gynecologic cancers, and one study each on leukemia, esophageal cancer, colorectal cancer, head and neck cancer, and patients undergoing hematopoietic stem cell transplantation. The remaining studies (n=6) examined patients with various cancer diagnoses without focusing on a specific cancer type. Most individual psychotherapies were multimodal interventions with different components. Elements of psychosocial counseling (n=10), skills and management training (n=6), cognitive (-behavioral) elements (n=3), and problem-solving training (n=2) were frequently implemented. The number of intervention sessions presented ranged from one session to 35 sessions. Most frequently, depressiveness (n=10), quality of life (n=9), anxiety (n=8), and psychological distress (n=5) were collected as primary outcomes. Furthermore, pain (n=3), sexual function (n=2), nausea (n=1), and fatigue (n=1) represented primary endpoints in the RCTs.

The sample size of the 18 **RCTs** that investigated **group psychotherapy** varied from 25 to 392 patients (n=2,299), of whom 47-100% were female. The studies were mostly from the USA (n=4) and Iran (n=4), as well as China (n=3), Canada (n=2), China (n=2), and Germany (n=2). The remaining studies were from the Netherlands, Spain, and Brazil (n=1 each). Regarding the tumor entities investigated, 11 studies focused exclusively on breast cancer and one study on gynecologic cancer and breast cancer. Furthermore, one study each focused exclusively on lung cancer and prostate cancer, and one study on prostate cancer and gastrointestinal tumors. The remaining studies (n=3) examined patients* with different cancer diagnoses. In the group psychotherapies, cognitive-behavioral (n=4), social-supportive (n=3), and supportive-expressive and psychodynamic therapy elements (n=3) were most frequently used. The primary endpoints most frequently assessed in the RCTs represented depressiveness (n=7), anxiety (n=7), and quality of life (n=7). In addition, sexual function/satisfaction (n=2), psychological distress (n=1), and fatigue (n=1) were collected as primary endpoints.

Results

Of the 16 included reviews, only two differentiated between individual and group psychotherapy in the presentation of results [578], [589]. Therefore, the results of the systematic reviews are also reported below for psychotherapeutic interventions as a whole, i.e., not differentiated between individual and group therapy.

The results of the additionally searched RCTs are presented separately for individual psychotherapy and group psychotherapy.

Since no studies were available which directly compare psychotherapeutic interventions in individual versus group settings, *Recommendation 8.1* was formulated in the guideline group on the basis of expert consensus. The choice between individual and group psychotherapy should be based on the patient's preference. However, since group offerings are not as common in the reality of care, the choice will essentially depend on which offerings are available locally.

Quality of life, psychological distress, depressiveness, anxiety, and nausea (Recommendation 8.14)

The *short-term effectiveness* of psychotherapeutic interventions on **global quality of life** has been examined in seven meta-analyses [580], [582], [584], [585], [586], [589], [578], all of which demonstrated a significant short-term effect in favor of psychotherapeutic interventions ($0.09 \leq d \leq 0.65$). In contrast, one systematic review [693] describes that only one of the six RCTs included in the review found a significant effect in favor of psychotherapeutic interventions. In addition, our research found ten RCTs on individual psychotherapy [593], [596], [600], [601], [603], [606], [591], [599], [605], [602] and eight RCTs on group psychotherapy [610], [614], [615], [612], [619], [618], [620], [613] which investigated short-term efficacy with regard to global quality of life. Of these, five RCTs on individual psychotherapy and one RCT on group psychotherapy were able to show a significant effect with regard to global quality of life.

The *medium-term efficacy* of psychotherapeutic interventions with respect to global quality of life was examined in three meta-analyses [584], [585], [578], two of which demonstrated a significant medium-term effect in favor of psychotherapeutic interventions ($d = 0.15$ and $d = 0.38$). In addition, our research found eight RCTs on individual psychotherapy [593], [600], [601], [606], [591], [599], [605], [602] and six RCTs on group psychotherapy [614], [615], [612], [618], [620], [613] which examined medium-term efficacy with respect to global quality of life. Three RCTs on individual psychotherapy and one RCT on group psychotherapy showed a significant effect on global quality of life.

The *long-term efficacy* of psychotherapeutic interventions regarding global quality of life was examined in two meta-analyses [585], [578] and could only be demonstrated in Faller et al. ($d=0.37$). In addition, our research found two RCTs on individual psychotherapy [593], [596] and three RCTs on group psychotherapy [614], [622], [612] that examined long-term efficacy with respect to global quality of life. None of the RCTs on individual psychotherapy and one RCT on group psychotherapy showed a significant effect on global quality of life. One RCT [614] on group psychotherapy described mixed findings (significant effects for 6 and 12 months, but not for 18 months).

The *short-term efficacy* of psychotherapeutic interventions regarding **psychological distress** was examined in four meta-analyses [580], [584], [586], [578], all of which demonstrated a significant short-term effect in favor of psychotherapeutic interventions ($-0.23 \leq d \leq -0.48$). Furthermore, three systematic reviews describe that two of two [589], one of two [692], and eight of 13 [693] RCTs included in the respective reviews found a significant, short-term effect in favor of psychotherapeutic interventions. In addition, our research found six RCTs on individual psychotherapy [592], [593], [606], [591], [604], [602] and five RCTs on group psychotherapy [607], [615], [608], [620], [613] which investigated the short-term efficacy regarding psychological distress. Two RCTs on individual psychotherapy and two RCTs on group psychotherapy showed a significant effect on psychological distress.

The *medium-term effectiveness* of psychotherapeutic interventions with regard to psychological distress was examined in two meta-analyses [584], [578], both of which demonstrated a significant medium-term effect in favor of psychotherapeutic interventions ($d=-0.18$ and $d=-0.21$). In addition, our research found six RCTs on individual psychotherapy [592], [593], [606], [591], [604], [602] and five RCTs on

group psychotherapy [607], [615], [608], [620] which investigated the medium-term efficacy regarding psychological distress. Two RCTs on individual psychotherapy and two RCTs on group psychotherapy showed a significant effect on psychological distress. One RCT [615] on group psychotherapy showed mixed findings (significant effect after three months, but not after six months).

The *long-term effectiveness* of psychotherapeutic interventions on psychological distress was examined in one meta-analysis [578], which demonstrated a significant long-term effect in favor of psychotherapeutic interventions ($d=-0.15$). In addition, one RCT on individual psychotherapy [593] was available from our search that examined long-term efficacy with respect to psychological distress. No significant effect in favor of psychotherapy could be demonstrated.

The *short-term efficacy* of psychotherapeutic interventions regarding **depressiveness** has been examined in eight meta-analyses [579], [580], [584], [585], [587], [588], [589], [578], six of which demonstrated a significant short-term effect in favor of psychotherapeutic interventions ($-0.25 \leq d \leq -1.11$). Furthermore, one systematic review [692] describes that in four of six RCTs included in the review, a significant, short-term effect in favor of psychotherapeutic interventions was found. In addition, our search found 12 RCTs on individual psychotherapy [592], [593], [594], [595], [596], [624], [597], [600], [606], [590], [591], [605] and nine RCTs on group psychotherapy [607], [611], [623], [615], [616], [621], [608], [617], [618] which investigated short-term efficacy with regard to depression. Of these, seven RCTs on individual psychotherapy and five RCTs on group psychotherapy were able to show a significant effect with regard to depressiveness.

The *medium-term efficacy* of psychotherapeutic interventions with respect to depressiveness was examined in three meta-analyses [584], [585], [578], one of which demonstrated a significant medium-term effect in favor of psychotherapeutic interventions ($d=-0.13$ (individual), $d=-0.21$ (group)). In addition, our search found nine RCTs on individual psychotherapy [592], [593], [595], [624], [600], [606], [590], [591], [605] and seven RCTs on group psychotherapy [607], [611], [623], [615], [608], [617], [618] which examined medium-term efficacy with respect to depression. Of these, four RCTs on individual psychotherapy and three RCTs on group psychotherapy were able to show a significant effect with regard to depressiveness. One RCT [615] on group psychotherapy showed mixed findings (significant effect at three months but not at six months).

The *long-term effectiveness* of psychotherapeutic interventions with respect to depressiveness was examined in three meta-analyses [584], [585], [578], one of which demonstrated a significant long-term effect in favor of psychotherapeutic interventions ($d=-0.28$). In addition, our research found two RCTs on individual psychotherapy [596], [590] and two RCTs on group psychotherapy [622], [617] that examined long-term efficacy with respect to depression. One RCT on individual psychotherapy and one RCT on group psychotherapy showed a significant effect on depression.

The *short-term effectiveness* of psychotherapeutic interventions regarding **anxiety** was examined in seven meta-analyses [580], [581], [583], [584], [585], [589], [578], six of which demonstrated a significant short-term effect in favor of psychotherapeutic interventions ($-0.21 \leq d \leq -1.1$). Furthermore, one systematic review [692] describes that in two of the three RCTs included in the review, a significant short-term effect in favor of psychotherapeutic interventions was found. In

addition, our search found nine RCTs on individual psychotherapy [592], [593], [594], [596], [600], [606], [590], [591], [598] and nine RCTs on group psychotherapy [607], [609], [611], [623], [615], [621], [617], [618], [613] that examined short-term efficacy with respect to anxiety. Three RCTs on individual psychotherapy and six RCTs on group psychotherapy showed a significant effect on anxiety. One RCT [594] on individual psychotherapy showed mixed findings (significant effect on HADS-A, but no significant effect on SAS).

The *medium-term effectiveness* of psychotherapeutic interventions on anxiety was examined in four meta-analyses [583], [584], [585], [578], two of which demonstrated a significant medium-term effect in favor of psychotherapeutic interventions ($d=-0.19$ and $d=-0.33$ (individual) and $d=-0.22$ (group), respectively). In addition, our search found six RCTs on individual psychotherapy [592], [593], [600], [606], [590], [591] and seven RCTs on group psychotherapy [607], [611], [623], [615], [617], [618], [613] which investigated the medium-term efficacy regarding anxiety. One RCT on individual psychotherapy and four RCTs on group psychotherapy showed a significant effect on anxiety. In one RCT on group psychotherapy [618] patients in the psychotherapy group experienced more anxiety than patients in the control group three months after the intervention.

The *long-term efficacy* of psychotherapeutic interventions with regard to anxiety was examined in two meta-analyses [585], [578], one of which demonstrated a significant long-term effect in favor of psychotherapeutic interventions ($d=-0.46$). In addition, our search found three RCTs on individual psychotherapy [593], [596], [590] and one RCT on group psychotherapy [617] which examined long-term efficacy with respect to anxiety. Only two RCTs on individual psychotherapy showed a significant long-term effect on anxiety.

The *short-term effectiveness* of psychotherapeutic interventions regarding **nausea** was investigated in one meta-analysis [584]. A significant short-term effect in favor of psychotherapeutic intervention was demonstrated ($d=-0.39$). In addition, our search found one RCT on individual psychotherapy [697] which investigated the short-term efficacy regarding nausea. A significant short-term effect in favor of psychotherapy was demonstrated.

Regarding the *medium-term efficacy* of psychotherapeutic interventions on nausea, only one RCT [697] on individual psychotherapy was available according to our research. A significant medium-term effect in favor of psychotherapy could be demonstrated.

According to our search, no studies on the *long-term effectiveness* of psychotherapeutic interventions regarding nausea were available.

Fatigue (Recommendation 8.15)

The *short-term efficacy* of psychotherapeutic interventions regarding **fatigue** has been examined in two meta-analyses [627], [584], one of which demonstrated a significant short-term effect in favor of psychotherapeutic interventions ($d=-0.42^{\circ}$). Furthermore, two systematic reviews describe that in one of five [693] and two of two [694] RCTs included in the review, a significant short-term effect in favor of psychotherapeutic interventions was found. In addition, our search found three RCTs on individual psychotherapy [593], [600], [603] and two RCTs on group psychotherapy [698], [620] that examined short-term efficacy with respect to fatigue.

Two RCTs on individual psychotherapy and one RCT on group psychotherapy showed a significant effect on fatigue.

The *medium-term efficacy* of psychotherapeutic interventions regarding fatigue was only investigated in one meta-analysis [584]. No significant medium-term effect in favor of psychotherapeutic intervention could be demonstrated. In addition, our search found two RCTs on individual psychotherapy [593], [600] and one RCT on group psychotherapy [620] which investigated the medium-term efficacy regarding fatigue. Only one RCT on individual psychotherapy showed a significant medium-term effect in favor of psychotherapy.

According to our search, only one RCT [593] on individual psychotherapy was available for the *long-term* efficacy of psychotherapeutic interventions with regard to fatigue. No significant effect in favor of individual psychotherapy could be demonstrated.

⁶ Effect only significant for patients after end of treatment, not significant for patients receiving treatment.

Pain (Recommendation 8.16)

The *short-term effectiveness* of psychotherapeutic interventions regarding **pain** was investigated in two meta-analyses [584], [585]. No significant short-term effect in favor of psychotherapeutic intervention was demonstrated in either of the two. However, one systematic review [693] describes that a significant short-term effect in favor of psychotherapy was demonstrated in four of the five RCTs included in the review. In addition, our search found four RCTs on individual psychotherapy [592], [600], [603], [599], which investigated short-term efficacy with regard to pain. Of these, only one RCT was able to show a significant effect with regard to pain.

The *medium-term efficacy* of psychotherapeutic interventions regarding pain was only investigated in one meta-analysis [585]. No significant medium-term effect in favor of psychotherapeutic intervention could be demonstrated. In addition, our search found three RCTs on individual psychotherapy [592], [600], [599] which investigated the medium-term effectiveness regarding pain. Only one RCT demonstrated a significant medium-term effect in favor of psychotherapy.

According to our research, no studies on the *long-term efficacy* of psychotherapeutic interventions regarding pain were available.

Sexual dysfunction (Statement 8.17)

No systematic reviews were available on the efficacy of psychotherapeutic interventions regarding **sexual function**, according to our search.

The *short-term effectiveness* of psychotherapeutic interventions regarding sexual function was examined in one RCT on individual psychotherapy [696] and two RCTs on group psychotherapy [612], [619]. Only the RCT on individual psychotherapy was able to demonstrate a significant short-term effect in favor of psychotherapy.

The *medium-term effectiveness* of psychotherapeutic interventions regarding sexual function was investigated in one RCT on individual psychotherapy [695] and one RCT on group psychotherapy [612]. Both RCTs were able to demonstrate a significant medium-term effect regarding sexual function.

The *long-term effectiveness* of psychotherapeutic interventions regarding sexual function was only examined in one RCT on group psychotherapy [612]. No significant long-term effect could be demonstrated.

The evidence base on the effectiveness of psychotherapeutic interventions to reduce sexual dysfunction in cancer patients is heterogeneous and not sufficiently robust. Sexual function was the primary outcome in all RCTs, and two of the four RCTs had a sufficiently large sample size after a priori power analysis. One RCT provided information on side effects and interactions, but these did not occur in either the control or the psychotherapy groups. The methodological quality of all RCTs is considered moderate to low. The guideline group therefore reserves the right to refrain from recommending for or against the use of psychotherapeutic interventions in cancer patients with these complaints. Further studies of high methodological quality are needed to formulate a recommendation.

Assessment of study quality

In total, 13/16 (81%) SRs had deficiencies in more than one critical assessment domain (*critical low quality*), 2/16 (13%) had deficiencies in one critical assessment domain (*low quality*), and one (6%) SR had no critical deficiencies and only one non-critical deficiency (*high quality*). It should be noted that 5/16 SRs had a downgraded quality assessment due to the lack of a list of excluded primary studies and their reasons for exclusion (*critical domain 7, AMSTAR-2*).

17/21 RCTs (81%) on individual psychotherapy used an adequate method to generate the randomization sequence (*selection bias*) and 9/21 RCTs (43%) ensured secrecy and unpredictability of group allocation (*selection bias*); in 11/21 RCTs (52%), the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*); and in 6/21 RCTs (29%), selective reporting of endpoints could be excluded by an existing study protocol (*reporting bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) and thus blinding of endpoint collection (*detection bias*) were not possible in any of the RCTs.

In total, 13/21 RCTs performed a priori sample size estimation. 6 RCTs achieved their a priori planned sample size.

13/18 RCTs (72%) on group psychotherapy used an adequate method to generate the randomization sequence (*selection bias*); 4/18 RCTs (22%) ensured secrecy and unpredictability of group allocation (*selection bias*); in 11/18 RCTs (61%) the amount of missing data was sufficiently small (<20%) or missing data were imputed accordingly (*attrition bias*). In 1/18 RCTs (6%), selective reporting of end points could be excluded by an existing study protocol (*reporting bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) and thus, with the exception of one RCT, blinding of endpoint collection (*detection bias*) was not possible in any of the RCTs.

In total, 8/18 RCTs performed a priori sample size estimation. 6 RCTs achieved their a priori planned sample size.

8.5.2 Psychotherapeutic Couple and Family Interventions

8.19	Evidence-based Recommendation	modified 2023
GoR 0	Psychotherapeutic couple and family interventions can be offered to cancer patients with an adjustment disorder or subsyndromal distress in order to reduce mental distress, depressiveness, and anxiety, as well as to enhance quality of life.	
LoE 1a	[578] , [699] , [700] , [701] , [702] , [703] , [704] , [705] , [706] , [707] , [708]	
	Strong Consensus	

8.20	Evidence-based Statement	new 2023
LoE 1a	The evidence on the effectiveness of psychotherapeutic couple and family interventions in reducing pain, fatigue, and sexual dysfunction in cancer patients does not support a recommendation for or against their use for these conditions.	
	[699] , [704]	
	Strong Consensus	

The inclusion of partners or relatives of cancer patients in the psycho-oncological treatment is a natural component of a bio-psycho-social treatment concept. This chapter focuses on specific psychotherapeutic couple and family interventions and their effectiveness in reducing mental and physical distress in people with cancer.

Systematic Literature Review

The evaluation of the effectiveness of couple and family interventions in cancer patients and survivors is based on seven systematic reviews and five RCTs. One of the five RCTs was already included in one of the systematic reviews, therefore, the results of this study are not reported separately in the results.

The seven **systematic reviews** (five meta-analyses, two systematic reviews) included between ten and 198 primary studies in the analysis. Six of the reviews examined mixed cancer populations and one paper specifically included breast cancer patients. The primary studies included were from the United States, Australia, Canada, Iran, and the EU, among other countries. One meta-analysis reported exclusively on the effectiveness of psychotherapeutic couple and family interventions for increasing quality of life [\[702\]](#). All other reviews reported multiple relevant endpoints.

The sample size of the five **RCTs** varied from 17 to 237 patients (N=572), 0-100% were female. The studies were from Denmark (n=2), the USA, Australia, and the UK (n=1 each). In terms of tumor entities examined, three studies focused exclusively on prostate cancer, one study focused on breast cancer, and one study examined patients with multiple cancer diagnoses. Four studies examined couple-based treatment and counseling approaches, and one study examined a family coping

intervention. The number of intervention sessions presented ranged from four to six sessions over a maximum period of five months. The primary endpoints collected by the RCTs were mental distress (n=3), quality of life (n=2), and depressiveness (n=1).

Results

Quality of life, mental distress, depressiveness, and anxiety (Recommendation 8.19)

The *short-term effectiveness* of psychotherapeutic couple and family interventions on **global quality of life** has been examined in four meta-analyses [699], [700], [702], [578], one of which demonstrated a significant short-term effect ($d=0.25$). In addition, Griffin and colleagues [703] described in detail in a systematic review that a significant effect in favor of couple and family interventions was not detectable in any of the six RCTs included in the review. In addition, the results of two RCTs were available from our search [705], [708], but they did not find a significant short-term effect in favor of psychotherapeutic couple and family interventions.

The *medium-term effectiveness* of psychotherapeutic couple and family interventions with regard to global quality of life was examined in three meta-analyses [699], [700], [578] and in two RCTs [705], [708]. Neither the meta-analyses nor the RCTs demonstrated significant medium-term effects in favor of psychotherapeutic couple and family interventions.

The *long-term effectiveness* of psychotherapeutic couple and family interventions with regard to global quality of life was also examined in three meta-analyses [699], [700], [578]. However, no significant long-term effect in favor of psychotherapeutic couple and family interventions could be demonstrated.

The *short-term effectiveness* of psychotherapeutic couple and family interventions on **mental distress** was examined in two meta-analyses [700], [578], one of which demonstrated a significant short-term effect in favor of psychotherapeutic couple and family interventions ($d=-0.16$). In addition, results of three RCTs [706], [707], [708] were available, but none of them could detect a significant short-term effect in favor of psychotherapeutic couple and family interventions.

Regarding the *medium-term effectiveness* of psychotherapeutic couple and family interventions with regard to mental distress, the results of two meta-analyses [700], [578] and three RCTs [706], [707], [708] were available. Neither the meta-analyses nor the RCTs demonstrated significant medium-term effects in favor of psychotherapeutic couple and family interventions.

The *long-term effectiveness* of psychotherapeutic couple and family interventions on psychological distress was examined in two meta-analyses [700], [578], none of which, however, demonstrated a significant effect in favor of psychotherapeutic couple and family interventions. No complementary RCTs were available.

The *short-term efficacy* of psychotherapeutic couple and family interventions with respect to **depressivity** was examined in four meta-analyses [699], [700], [701], [578], two of which demonstrated a significant short-term effect in favor of psychotherapeutic couple and family interventions ($d=-0.26$ and $d=-2.15$). In addition, one systematic review [703] descriptively describes that in two of nine included RCTs there was a significant effect in favor of psychotherapeutic couple and family interventions. In addition, the results of three RCTs [705], [706], [707] were available

from our search, but none of them demonstrated a significant short-term effect in favor of psychotherapeutic couple and family interventions.

The *medium-term efficacy* of psychotherapeutic couple and family interventions on depressive symptoms was examined in three meta-analyses [699], [700], [578], two of which demonstrated a significant medium-term effect in favor of psychotherapeutic couple and family interventions ($d=-0.29$ and $d=-0.37$). In addition, the results of three RCTs were available [705], [706], [707], but they could not determine a significant medium-term effect in favor of psychotherapeutic couple and family interventions.

The *long-term efficacy* of psychotherapeutic couple and family interventions with regard to depressiveness was examined in two meta-analyses [700], [578] but they were unable to demonstrate a significant long-term effect in favor of psychotherapeutic couple and family interventions.

The *short-term effectiveness* of psychotherapeutic couple and family interventions regarding **anxiety** was examined in four meta-analyses [699], [700], [701], [578] two of which demonstrated a significant short-term effect in favor of psychotherapeutic couple and family interventions ($d=-0.30$ and $d=-1.16$). In addition, the result of one RCT [705] was available, but it did not find a significant short-term effect in favor of psychotherapeutic couple and family interventions.

The *medium-term effectiveness* of psychotherapeutic couple and family interventions with regard to anxiety was examined in a meta-analysis [700]. This demonstrated a significant medium-term effect in favor of psychotherapeutic couple and family interventions ($d=-0.43$). In addition, the results of one RCT [705] were available, but did not detect a significant, medium-term effect in favor of psychotherapeutic couple and family interventions.

The *long-term effectiveness* of psychotherapeutic couple and family interventions with regard to anxiety was examined in two meta-analyses [700], [578], one of which demonstrated a significant effect in favor of psychotherapeutic couple and family interventions ($d=-0.26$). No complementary RCTs were available.

Fatigue, pain, and sexual dysfunction (Recommendation 8.20)

Both the *short- and medium-term efficacy* of psychotherapeutic couple and family interventions on **fatigue** were examined only in the meta-analysis by Hu et al. [699]. However, no significant short- or medium-term effects in favor of psychotherapeutic couple and family interventions could be demonstrated. No complementary RCTs were available according to our search.

Both *short- and medium-term efficacy* of psychotherapeutic couple and family interventions on **pain** were also examined only in the meta-analysis by Hu et al. [699]. However, no significant short- or medium-term effects in favor of psychotherapeutic couple and family interventions could be demonstrated. No complementary RCTs were available according to our search.

Regarding **sexual dysfunction**, the systematic review by Brandao et al. [704] describes in detail that in eight of ten included RCTs, significant effects on at least one relevant outcome (psychological functioning level, physical functioning level, marital quality, sexual satisfaction) in favor of couple and family interventions were

demonstrated. Four of these eight studies showed significant effects on sexual function/satisfaction in favor of the couple and family interventions.

No other systematic reviews or RCTs were available on this endpoint.

Assessment of study quality

All seven SRs (100%) had deficiencies in more than one critical assessment domain (*critical low quality*).

In total, 2/5 RCTs (40%) used an adequate method to generate the randomization sequence (*selection bias*), 3/5 RCTs (60%) ensured secrecy and unpredictability of group allocation (*selection bias*), in 2/5 RCTs (40%), the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*), and in 2/5 RCTs (40%), selective reporting of end points could be excluded by an existing study protocol (*reporting bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) and thus blinding of endpoint collection (*detection bias*) were not possible in any of the RCTs.

In total, 4/5 RCTs performed a priori case sample size estimation of which one RCT achieved their a priori planned sample size.

8.5.3 Specific Psycho-oncological Interventions in the Palliative Phase

8.21	Evidence-based Recommendation	new 2023
GoR A	Specific psycho-oncological interventions in the palliative phase shall be offered to cancer patients with an adjustment disorder or subsyndromal distress in order to reduce mental distress, depression, anxiety, and fatigue as well as to improve quality of life.	
LoE 1a	[709], [710], [585], [711], [712], [713], [714], [715], [716], [717], [718], [719], [720], [721], [722], [723], [724], [725], [726], [727]	
	Strong Consensus	

8.22	Evidence-based Statement	new 2023
LoE 1a	The study data on the efficacy of specific psycho-oncological interventions in the palliative phase for reducing pain in people with non-curable cancer does not allow a recommendation for or against their use for these complaints.	
	[585], [720]	
	Strong Consensus	

Patients with a non-curable, progressive cancer are confronted with a variety of physical, mental, social and spiritual distress factors during the course of the disease [728]. Good palliative care therefore requires addressing the needs of patients in all four dimensions. It places the quality of life of patients with non-curable cancer at the center of its work (Extended S3 Guideline Palliative Care for Patients with Non-curable Cancer. Psycho-oncological interventions are part of a multi-professional and interdisciplinary palliative care approach. In this regard, we refer to the "Extended S3 Guideline on Palliative Care for Patients with Non-curable Cancer" (AWMF Registry Number:128-001OL, <https://www.awmf.org/leitlinien/detail/II/128-001OL.html>).

Specific psycho-oncological interventions for patients in the palliative phase are usually supportive and focus to varying degrees on spiritual, psychological, physical or social aspects of cancer [729], [730]. Relaxation techniques, mindfulness-based interventions and meditation, therapeutic hypnotherapy elements, cognitive-behavioral therapy interventions, supportive-expressive interventions, and systemic family therapy approaches, as well as creative arts therapies may be used [728], [731]. In recent decades, specific interventions for working with palliative patients have also been developed and are briefly introduced below.

Meaning-Centered Psychotherapy is a form of existential psychotherapy developed by William S. Breitbart and colleagues that aims to find meaning and significance in the face of death [732], [733]. Originally conceptualized as a group therapy, Meaning-

Centered Group Psychotherapy (MCGP) provides a framework in which (oncology) palliative care patients work together to address issues of meaning, inner peace, and goal orientation in life in the context of their illness [731]. Designed for eight sessions, seven main topics are worked on in a combination of psychoeducation, group discussions and exercises: 1. concepts of meaning and sources of meaning; 2. cancer and meaning; 3. creation of meaning from life history; 4. creation of meaning from the present and future; 5. creation of meaning from attitudes (encountering the limits of life); 6. creation of meaning from creative activity and taking responsibility; 7. experience-based creation of meaning (nature, art, humor) [734], [735]. In order to meet the needs of the palliative situation for flexibility of psychotherapeutic treatments, Individual Meaning-Centered Psychotherapy (IMCP), which works on the content of MCGP in seven individual sessions [736], [722], was also developed.

Managing Cancer and Living Meaningfully (CALM) therapy, developed by Gary Rodin and colleagues, is a manualized, semi-structured, short-term psychotherapeutic intervention in an individual setting [737], [738], [739], [719], [740]. In terms of content, CALM focuses on four areas: 1. symptom management and communication with treatment providers; 2. self-change and relationship with loved ones; 3. spirituality, meaning and significance; 4. preparing for the future, maintaining hope and coming to terms with dying [740].

Based on the empirical dignity model of Harvey M. Chochinov and colleagues, Dignity Therapy aims to alleviate patients' suffering at the end of life and improve their emotional and spiritual well-being [741], [742], [728]. In this process, patients are guided to reflect on memorable life events in an interview and 1-2 therapy sessions in an individual setting. The tape-recorded interview is then transcribed, read back to the patients, and edited if necessary. Patients are then given a document to leave with family members [728], [731]. The intervention is particularly aimed at patients in the terminal phase of their disease [728].

Systematic literature review

In this chapter, all psychotherapeutic interventions were considered that were explicitly directed at patients with non-curable cancer and addressed the physical, psychological, social and spiritual stresses of the palliative situation. The interventions were delivered exclusively in face-to-face contacts.

The evaluation of the effectiveness of psychotherapeutic interventions in the palliative phase is based on eight systematic reviews and 13 RCTs. One RCT [735] is already included in systematic reviews and is not reported separately in the results.

The eight **systematic reviews** (seven meta-analyses, one systematic review) included between eight and 68 primary studies in the analysis. All reviews included mixed cancer populations, other palliative populations were also included in three cases [710], [585], [711]. In these cases, the results reported below refer to subgroup analyses. The primary studies included were from the US, China, Canada, Australia, the UK, and the EU, among others.

The sample size of the 13 **RCTs** varied from 28 to 340 patients (N=1,926), 38.1-87.5% were female. The studies were from the USA (n=4), the Netherlands (n=2), Canada (n=2), the UK (n=2), Brazil, Nigeria, and Denmark (n=1 each). The majority of included studies (n=12) included patients with various advanced or terminal cancer diagnoses. One study was conducted with leukemia patients. Common interventions

were meaning-based psychotherapy (IMCP/MCGP, CALM; n=3), elements of cognitive behavioral therapy (CBT; n=3), and psychoeducational elements (n=2). Two studies targeted couples. The number of intervention sessions ranged from a single session to 14 weekly sessions. Depressiveness (n=4) and quality of life (n=3) were most frequently collected as primary endpoints. Furthermore, fatigue, mental distress, and anxiety (n=1 each) were collected as primary endpoints.

Results

Quality of life, mental distress, depression, anxiety, and fatigue (Recommendation 8.21)

The *short-term efficacy* of specific psycho-oncological interventions in the palliative phase with respect to **global quality of life** was examined in six meta-analyses [709], [585], [711], [710], [712], [714], of which five demonstrated a significant short-term effect in favor of specific psycho-oncological interventions in the palliative phase ($0.17 \leq d \leq 0.47$). In addition, the results of seven RCTs were available [716], [719], [721], [722], [720], [726], [727], of which three found a significant short-term effect in favor of specific psycho-oncological interventions in the palliative phase.

The *medium-term efficacy* of specific psycho-oncological interventions in the palliative phase with respect to global quality of life was investigated in two meta-analyses [585], [714], one of which demonstrated a significant, medium-term effect in favor of specific psycho-oncological interventions in the palliative phase ($d=0.82$). In addition, the results of six RCTs [718], [719], [721], [722], [720], [727] were available, two of which recorded a significant medium-term effect in favor of specific psycho-oncological interventions in the palliative phase. In addition, one RCT [718] provided mixed results. No significant effect was shown at two, four, and eight weeks, but significant effect in favor of interventions in the palliative phase at 6 months was demonstrated.

The *long-term effectiveness* of specific psycho-oncological interventions in the palliative phase with regard to global quality of life was investigated in one meta-analysis [585] and in one RCT [727]. Within these studies, no significant long-term effects in favor of specific psycho-oncological interventions in the palliative phase could be demonstrated.

The *short-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to **mental distress** was investigated in four meta-analyses [709], [710], [712], [714], all of which demonstrated a significant, short-term effect in favor of specific psycho-oncological interventions in the palliative phase ($-0.32 \leq d \leq -1.02^4$). In addition, results were available from five RCTs [721], [724], [720], [725], [726], two of which recorded a significant short-term effect in favor of specific psycho-oncological interventions in the palliative phase.

The *medium-term effectiveness* of specific psycho-oncological interventions in the palliative phase with regard to mental distress was investigated in a meta-analysis [714]. However, no significant medium-term effect in favor of specific psycho-oncological interventions in the palliative phase could be demonstrated. In addition, results of four RCTs [721], [723], [724], [720] were available, one of which

⁴ In Li et al. (2020) [709] non-standardized MD=-7.3 in Patient Dignity Inventory [743].

demonstrated a significant, medium-term effect in favor of specific psycho-oncological interventions in the palliative phase.

The *short-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to **depressiveness** was investigated in five meta-analyses [709], [585], [711], [712], [714], four of which demonstrated significant, short-term effects in favor of specific psycho-oncological interventions in the palliative phase ($-0.25 \leq d \leq -1.31$). In addition, the results of six RCTs [717], [719], [722], [720], [725], [727] were available, two of which demonstrated significant short-term effects in favor of specific psycho-oncological interventions in the palliative phase.

Significant *medium-term effects* in favor of specific psycho-oncological interventions in the palliative phase were investigated in two meta-analyses [585], [714], none of which, however, demonstrated significant effects of specific psycho-oncological interventions in the palliative phase. In addition, results were available from six RCTs [717], [718], [719], [722], [720], [727], one of which demonstrated a significant effect in favor of specific psycho-oncological interventions in the palliative phase.

Long-term effects of specific psycho-oncological interventions in the palliative phase were investigated in one systematic review [585] and one RCT [727]. However, none of the studies found a significant long-term effect in favor of specific psycho-oncological interventions in the palliative phase.

The *short-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to **anxiety** was examined in five meta-analyses [709], [585], [711], [712], [714], four of which demonstrated significant short-term effects in favor of specific psycho-oncological interventions in the palliative phase ($-0.21 \leq d \leq -1.07$). In addition, results were available from five RCTs [719], [722], [724], [725], [727], two of which demonstrated significant short-term effects in favor of specific psycho-oncological interventions in the palliative phase.

The *medium-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to anxiety was examined in two meta-analyses [585], [714]. Neither could demonstrate significant effects of specific psycho-oncological interventions in the palliative phase. In addition, results from five RCTs [718], [719], [722], [724], [727] were available, two of which demonstrated significant effects of specific psycho-oncological interventions in the palliative phase.

Long-term effects of psychotherapeutic interventions in the palliative phase have been investigated in only one systematic review [585] and one RCT [727], both of which failed to identify significant effects.

The *short-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to **fatigue** was examined in two meta-analyses [710], [713], one of which demonstrated significant effects of specific psycho-oncological interventions in the palliative phase ($d=-0.30$). In addition, results from three RCTs [716], [723], [725] were available, two of which demonstrated significant short-term effects in favor of specific psycho-oncological interventions in the palliative phase.

The *medium-term effectiveness* of specific psycho-oncological interventions in the palliative phase with regard to fatigue was investigated in a meta-analysis [713]. This showed a significant effect in favor of specific psycho-oncological interventions in the palliative phase ($d=-0.66$).

The *long-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to fatigue was only investigated in one meta-analysis [713]. This could not find a significant effect of specific psycho-oncological interventions in the palliative phase. No supporting results from RCTs were available in our search.

Pain (Statement 8.22)

The *short- and medium-term efficacy* of specific psycho-oncological interventions in the palliative phase with regard to **pain** was examined in one meta-analysis [585], and one RCT [720].

The meta-analysis showed neither short nor medium-term effects of specific psycho-oncological interventions in the palliative phase, the RCT could only detect significant medium-term effects of specific psycho-oncological interventions in the palliative phase.

The study data on the effectiveness of specific psycho-oncological interventions in the palliative phase for the reduction of pain in people with non-curable cancer has to be considered as not sufficiently robust.

The meta-analysis by Bauereis et al. [585] includes only five RCTs that consider pain reduction as an outcome. The results have high unexplained heterogeneity, which reduces confidence in the effect estimator. The results on medium-term efficacy are based on only one RCT. Furthermore, the meta-analysis includes populations of cancer patients who are not in the palliative phase, thus decreasing the match to the key question of this chapter. The RCT by Rodin et al. [720] has only a small sample, and the planned sample size could not be achieved. Because of the limitations mentioned above, the guideline group refrains from recommending for or against the use of specific psycho-oncological interventions in the palliative phase to reduce pain in people with non-curable cancer. Additional methodologically high-quality studies are needed to formulate a recommendation.

Supplementary evidence

In addition to the above results, one systematic review [715] describes significant short-term effects on at least one primary endpoint (including quality of life, distress, pain) in 6/9 adequately powered RCTs of meaning-based interventions. In 5/9 RCTs with sufficient stat. Power on dignity-based interventions also showed significant short-term effects on at least one primary endpoint.

Assessment of study quality

The study quality of the SRs was assessed using the AMSTAR-2 tool, and the risk of bias of the RCTs was assessed using the Cochrane RoB tool.

In total, 5/8 (62.5%) SRs had deficiencies in more than one critical assessment domain (*critical low quality*), 2/8 (25%) had deficiencies in one critical assessment domain (*low quality*). One (12.5%) SR had no critical deficiencies and only one non-critical deficiency (*high quality*). It should be noted that in 4/8 SRs there was a downgrading of the quality assessment due to the lack of a list of excluded primary studies and their reasons for exclusion (critical domain 7, AMSTAR-2).

12/17 RCTs (70%) used an adequate method to generate the randomization sequence (*selection bias*), and 8/17 RCTs (47%) ensured secrecy and unpredictability of group

allocation (*selection bias*). In 12/17 RCTs (70%), the amount of missing data was sufficiently small (<20%) or missing data were appropriately imputed (*attrition bias*), and in 8/17 RCTs (47%), selective reporting of endpoints could be excluded by an existing study protocol (*reporting bias*). Due to the nature of the interventions used and the collection of endpoints by self-assessment, blinding of study personnel/participants (*performance bias*) and thus blinding of endpoint collection (*detection bias*) were not possible in any of the RCTs.

In total, 10/13 RCTs performed a priori sample size estimation. 3/10 RCTs achieved their a priori planned sample size.

8.6 Psycho-oncological Crisis Intervention

8.23	Consensus-based Statement	new 2023
EC	Individuals with reduced coping resources, lack of social support, multiple somatic symptoms, additional stressors unrelated to illness, and previous traumatic experiences are at increased risk for acute crisis reactions.	
	Consensus	

8.24	Consensus-based Statement	new 2023
EC	Psycho-oncological crisis intervention usually involves three phases: emotional relief, reflection on the cause of the crisis, and reintegration. If done promptly, it can prevent the development of subsequent psychological problems.	
	Consensus	

8.25	Consensus-based Recommendation	new 2023
EC	Cancer patients and their relatives who show an acute crisis reaction shall be offered, regardless of care setting, psycho-oncological crisis intervention by psycho-oncologically trained specialists in a timely manner.	
	Strong Consensus	

Controlled studies on the effectiveness of crisis intervention in the context of psycho-oncology are not yet available, as this form of intervention is difficult to standardize as emergency care. Therefore, no statements on the effectiveness of crisis intervention can be made here.

Crisis intervention plays a central role in the context of psycho-oncological practice. *It differs from psychiatric crisis intervention in that it deals with psychological decompensation or suicidality in the context of mental disorders.* Causes for crises in the oncological context can be: the existential shock and threat to the life perspective triggered by the diagnosis, loss of self-esteem due to functional impairments or amputations, massive side-effects from therapy or chronic problems resulting from therapy, the diagnosis of a recurrence or the determination of palliative stage of the disease, and many more. Secondary problems can also trigger crises such as increasing dependence, loss of control over one's own life, financial and social distress, conflicts in the family and work environment. Relatives can also experience an acute crisis, e.g. in case of extreme deterioration of the state of the disease, non-responsiveness of the patient or their own exhaustion in case of long-term illness [\[744\]](#), [\[120\]](#), [\[745\]](#), [\[746\]](#).

A crisis is a mental state of emergency, which can be defined as a loss of mental equilibrium triggered by confrontation with exceptionally threatening events or life circumstances that cannot be coped with at the moment because the individual's coping capacity is overwhelmed. Individuals with a high coping capacity are able to cope with high-level threats, whereas individuals with a low coping capacity experience a severe crisis reaction even in the face of low- or medium-level threatening situations. Relevant for the crisis experience is always the subjective significance of the triggering event, which should therefore not be downplayed by others.

In addition to minimal coping resources, a lack of social support, stress due to massive multiple physical symptoms, additional stressors unrelated to the illness and previous traumatic experiences can increase the vulnerability to crisis reactions.

An acute crisis reaction is characterized by fear, despair and the experience of powerlessness, hopelessness and excessive demands. In addition, impaired affect control and reduced cognitive functions (thinking, perceiving, decision-making) are typical symptoms. Appeals to clear thinking or reason therefore do not help. Crises are often accompanied by self-deprecating cognitions and suicidal fantasies [747].

In general, two patterns of crisis reactions can be distinguished, depending on whether **affect flooding** (excessive emotional reactions, „nervous breakdown“) or **affect blockade** (numbness, paralysis, apathy, „inner withdrawal“) occurs. The latter form, the „silent crisis“, is problematic because it is easily overlooked. The affected person then receives support too late, and possible suicidal thoughts cannot be addressed in time.

Psycho-oncological crisis intervention aims to mentally stabilize the affected person and to enable them to cope with the problematic (disease) situation on their own by supporting their coping skills and resources. The focus is entirely on the current situation. Psycho-oncological crisis intervention should take place as soon as possible due to the high level of suffering. In this manner, the chronification of the crisis reaction (protracted crisis) and the development of subsequent psychological problems can be prevented.

The procedure is based on three phases:

- 1. Emotional relief:** active listening fosters the acceptance of emotions; the therapist avoids trivializing, rationalizing, or hastily seeking solutions.
- 2. Reflection on the cause of the crisis:** After initial emotional stabilization has been achieved, the cause of the crisis can be reflected upon in its subjective meaning, and distortions of perception can be carefully corrected. Possible coping resources are brought into focus.
- 3. Reintegration:** The focus is now on regaining a sense of self-control and self-efficacy, promoting new perspectives and appreciating the coping skills that have been regained. The success of crisis intervention is demonstrated by the restoration of self-esteem and the ability to make decisions and take action. Further assistance (e.g. psychotherapy) can be planned.

Concomitant psychopharmacological medication can complement crisis intervention, but not replace it.

Suicidal fantasies are a symptom that often accompany crises of oncological patients [747] and can be understood as a plea or cry for help, or as an attempt to regain control over one's own life in fantasy. Such fantasies usually disappear when a therapeutic perspective for the cancer disease becomes apparent. In case of doubt, a psychiatric or psychosomatic specialist should be consulted to clarify acute suicidal tendencies.

8.7 Psychosocial Counseling

8.26	Consensus-based Statement	new 2023
EC	Psychosocial counseling in cancer counseling centers is an integrative intervention that can address psychological as well as social and socio-legal questions and problems.	
	Consensus	

8.27	Consensus-based Recommendation	modified 2023
EC	Psychosocial counseling with a psychological and social focus shall be offered to cancer patients and their relatives in all phases of the disease according to their needs and as early as possible.	
	Strong Consensus	

No RCTs are available for this section and, as a result, detailed information on effectiveness is not possible here. From the available observational studies, efficacy in the following areas is described for psychosocial counseling⁵:

- Reduction of psychosocial distress [748], [749], [750], [751], [752], [753]
- Reduction of occupational and financial difficulties and worries [754], [755], [756], [751]
- Improving emotional health [757], [758], reducing depression and/or anxiety [748], [749], [759], [760], [761], [762]
- Support in coping with illness [763] and improving quality of life [761], [764], [765], [766], [767], [768], [657], [769], [770]
- Improving couple/family relationships [759], [762], [771]
- Improvement of self-esteem [761]
- Reducing information deficits [748], [751], [766].

Psychosocial counseling in the context of psycho-oncology is a professional communicative process between a psycho-oncological counseling specialist and a person seeking advice. Based on a needs assessment (anamnesis, stress screening, problem exploration related to the living environment), a problem and goal definition is developed together with the person seeking advice (counseling planning) and coping strategies are identified and developed. On the basis of a client-oriented

⁵ The term „social“ here refers to topics of social work which promotes integration in social life and participation in society, as well as access to social security programs.

approach, stabilization, problem-solving, relief and the activation of personal and social resources of those seeking advice are aimed for. Psychosocial counseling primarily serves to promote coping skills in dealing with illness-related psychosocial problems and stresses, and to facilitate access to government social assistance, which also includes referral to specialized facilities and other support services. Last but not least, the referral to regional self-help activities and opening doors to care structures play an important role.

Early counseling can also prevent the development or chronification of mental disorders. The target groups are not only those affected, but also relatives and people in the social environment [769].

Psychosocial counseling is offered in the outpatient setting primarily in psychosocial cancer counseling centers [120], [772]. In the inpatient setting, psychosocial counseling is also provided in acute care hospitals or rehabilitation clinics. Psychosocial counseling is usually the task of psychologists and social workers. Psychosocial counseling with a psychological focus can also be offered by physicians with psychotherapeutic qualifications. The counseling can relate to psychological distress and crises, as well as to social problems and questions about the use of social services. Depending on individual needs and the care setting (see [Chapter 4.1.3](#) and [Chapter 4.2](#)), the focus may be more on social or psychological issues [120].

In the following, a distinction is therefore made between **psychosocial counseling with a psychological focus** and **psychosocial counseling with a social focus**. In cases where both topics are the subject of counseling, the competencies of both professional groups are to be included.

1. Psychosocial counseling with a psychological focus relates primarily to psychological stress as a result of coping with the disease and adapting to the current disease and treatment situation [120], [773]. Examples are fears (existential threat, fear of the future, fear of progression), decision-making uncertainty, self-esteem problems, shame and guilt, depressive reactions, problems in the partnership and in dealing with children, psychological and physical long-term consequences of the therapy and thematic complex farewell/mourning/loss [773], [772]. The counseling is not based on psychopathological criteria, rather is open-ended and geared to the specific concerns of the person seeking advice. The main goals are psychological stabilization, the promotion of psychological coping and action skills, support in processing complex information and demands, and the dealing with existing inner-psychic conflicts. During the counseling process, the problem or conflict situation as well as various solutions and possible obstacles are analyzed together with the person seeking counseling, an individual solution to the problem is developed, which takes into account existing coping resources, and finally the implementation is monitored at later stages. The starting point is always the activation of existing personal and/or social resources.

2. Psychosocial counseling with a social focus aims to clarify and support processes at the level of coping with everyday life and living, which can be made more difficult through the disruption of the psychosocial balance in the context of the disease and treatment [774], [775], [118]. Social integration and participation are also sought, which can be threatened in particular by barriers to staying or returning to work and by limited social and financial resources [776], [777], [778], [779]. In view of the complex problem situation, a wide range of other assistance is offered in

addition to the communicative development of alternative perspectives and action strategies [119], [780], [751], [766], [765]:

- support in coping with everyday challenges and excessive demands as well as in communication with the social environment [781]
- support in navigating the health and social services system [753], [782]
- information about social legal claims in case of illness and disability (e.g. rehabilitation, pension, reduction in earning capacity) and related assistance in applying for the respective benefits [783]
- advice on support options in the process of occupational reintegration [784]
- promoting self-determination and autonomy.

In addition, existential economic hardship, which, for example, can lead to loss of housing, problems providing for children and dependence on social benefits, represents a high potential for distress. Securing the socioeconomic basis and family care in cooperation with the responsible offices and authorities is central.

Psychosocial counseling should be offered according to need, as early as possible and in all phases [767] of the disease. The psychosocial burden and individual needs should be assessed in accordance with recommendations 7.1 – 7.3. The individual needs of those seeking advice should be determined via a systematic needs assessment and an assessment of the social care situation. If the presence of a mental disorder is suspected in the case of highly stressed persons seeking advice during psychosocial counseling, they should be referred to licensed psychotherapists or specialists for diagnostic clarification and further treatment (see [Chapter 8.5](#)).

Recommendations resulting from counseling and referrals should always take into account the patient's preference.

8.8 Creative Arts Therapies

Creative Arts Therapies (CAT) include art, music, dance and movement therapy, theater/drama therapy as well as poetry/bibliotherapy. Their methods are based on the therapeutic relationship and the interaction between patient, therapist and the creative-artistic medium or work. The goal of creative arts therapies is to regain, maintain and promote physical, mental and psychosocial health. Through the use of the tools and mediums offered by the arts, problems on social, emotional, cognitive, and physical levels can be addressed (BAG KT, 2019). Since the beginning of the 21st century, the use of artistic disciplines has played an increasingly important role in the field of prevention, in the promotion of health and in relation to the management and treatment of diseases and in rehabilitation [785]. The study "What is the Evidence on the Role of the Arts in Improving Health and Well-being? A "Scoping Review"" published in 2019 by the WHO [785] summarizes the evidence on the role of the arts in promoting health and overall well-being based on over 900 studies (200 reviews and more than 3,000 individual studies). Based on this work, the WHO recommends the use of the arts to enhance well-being as well as to promote and maintain health.

The field of oncology has also seen a steady increase in high-quality scientific research on the effectiveness of the arts therapies in recent decades. The Working Group on Creative Arts Therapies⁹ therefore conducted a systematic literature search on the efficacy of artistic therapies in adult cancer patients for the period 2012 to 2020 in the PRIMO library portal of the FU Berlin (<https://fu->

berlin.primo.exlibrisgroup.com/discovery/search?vid=49KOBV_FUB:FUB, last accessed on 31.03.2022). Further details can be found in the Guideline Report.

There were **58 level 1 studies for art, music, and dance and movement therapy** according to the Oxford Levels of Evidence grading system, March 2009 version.

The following sections first report on studies focusing on the subdisciplines of CAT (art therapy, music therapy, dance and movement therapy), each with a LoE recommendation grading. Thereafter, studies (reviews) are reported in which more than one form of CAT has been investigated.

The evidence base (Level 1) for art therapy, music therapy, and dance therapy is summarized separately by subdiscipline on the basis of the reviews as well as the primary studies. Individual primary studies are also included in various reviews of art, music, and dance therapy from the survey period 2012-2020 and are therefore reported more than once.

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8.8.1 Art Therapy

8.28	Evidence-based Recommendation	modified 2023
GoR 0	Art therapy can be offered to cancer patients in order to reduce anxiety, depression and stress.	
LoE 1a	[786] , [787] , [788] , [697] , [789] , [790] , [791] , [792] , [793] , [794] , [795]	
	Consensus	

According to the definition of the Scientific Association for Creative Arts Therapies (WFKT), art therapy is the therapeutic application of artistic tools and media (painting, sculpture, photography, performance, etc.). It promotes in particular the skills of pictorial symbolic expression, visual communication, and an active creative exploration of personal issues and problems.

Four new systematic reviews have been found for art therapy since 2012 [\[787\]](#), [\[791\]](#), [\[697\]](#), [\[795\]](#). These included were a total of eight randomized trials and ten controlled trials from 2006 to 2019. Three of the primary studies (RCTs) included in the reviews [\[793\]](#), [\[794\]](#), [\[786\]](#) are also reported individually, since they were published in the 2012-2020 search period. The studies were from the United States, Asia, and Europe. With the exception of the studies from Monti et al. (N=184) [\[793\]](#) and Joly et al. (N=320) [\[792\]](#), they are based on smaller numbers of cases (n<60). The applied art therapy methods and also the duration of the interventions are heterogeneous in the various studies. One review [\[795\]](#), for example, compared mindfulness-based art therapy (MBAT) with other mindfulness-based therapy approaches (such as

Mindfulness Based Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT) and also included individual studies from the field of palliative care [697].

A review by Wood et al. [796] has already shown that art therapy is helpful for people with cancer in various treatment settings. The art therapy approach can help to cope with treatment-related symptoms and support the process of psychological readjustment to the loss, change, and uncertainty caused by cancer. Art therapy is now often offered in group settings, and less frequently in individual therapy sessions. Supportive techniques are often used, for example, to regulate emotions, to experience relaxation through artistic expression, or, increasingly in mindfulness-based interventions.

Meta-analyses and systematic reviews

With regard to **depressiveness, anxiety, and distress** (mental illness domain), significant improvements with small to medium effects are found in various reviews [787], [791], [795]. For example, Zhang [795] found significant improvement ($p < .001$) in depression scores as well as anxiety scores ($p = .005$) in 7 RCTs ($n = 888$). Two reviews [787], [791] demonstrated significant improvements in **quality of life** ($p < .01$, $d = 0.03$ - 1.05). The review by Kim et al. [697], however, showed mixed results regarding quality of life, whereas five RCTs showed significant improvements in quality of life. **Pain** was examined by Kim et al. [697] in their review and came to different conclusions regarding an improvement in pain in the individual studies. A significant improvement of fatigue was described by Jiang et al. [791] in their review in four studies ($p = .01$). Furthermore, **coping strategies** were investigated in the review by Azmawati et al. [787], but no significant improvements could be shown.

Primary studies

An RCT by Joly et al. [792] examined an intervention group with art therapy in addition to standard care compared to a control group (treatment as usual, TAU) during radiation therapy. There were significant improvements in the areas of social well-being and cognitive fatigue. Monti et al. [793] and Jang et al. [790] were also able to demonstrate a significant improvement in quality of life after 36 months ($p = .01$). Öster et al. [794] found mixed results in the various domains investigating quality of life.

The investigations of the domain „**Mental Illness**“ showed heterogeneous results in the studies examined [786], [788], [793]. The study by Radl et al. [786] showed no significant improvements on emotional **distress** ($p = .26$) and mental well-being ($p = .12$), but did find significant improvement on **spiritual well-being** ($p = .02$). In contrast, the study by Jalambadi et al. [789] showed significant improvement on the different levels of **distress** ($p < .05$). The study by Jang et al. [790] measured significant improvement on depressiveness ($p < .001$) as well as anxiety ($p < .001$).

For improvement in **coping**, a recent RCT by Czamanski et al. [788] found significant improvements in emotion perception ($p = .027$) and emotion acceptance ($p = .039$), which was similarly demonstrated by Öster et al. [794] in the significant improvement in coping strategy of “social relationships” ($p = .04$). A significant improvement in **fatigue** is described by Joly et al. ($p = .007$) [792]. However, the result here refers only to patients with mild fatigue and not to patients with “severe fatigue” within the one-month study period. Three RCTs are also included in the reviews by Azmawati et al. [787], Jiang et al. [791] and Zhang et al. [795].

Risk of Bias Assessment

The risk of bias assessment of the 7 RCTs for art therapy was conducted by three independent raters (two non-specialist research assistants from medicine and psychology, and one specialist from music therapy; supervised by the Guideline working group CAT (KüTh)) using the RoB 2 tool [797]. In summary, a low risk of bias was found in three primary studies and a high risk of bias in four primary studies. The assessment took place with respect to five categories. The high Risk of Bias was found exclusively in Category 3 “bias due to missing outcome data”, i.e. due to missing data in the post test. The underlying drop-out of more than 20% of the patients is mostly explained clinically by the stressful oncological treatment with complex side effects and changes in life circumstances (relocations, etc.). The missing data was handled with appropriate methods in all four cases (intention-to-treat analysis, etc.). With the exception of these four cases, the methodological quality was homogeneous and high, with a low risk of bias.

Conclusion

Art therapy interventions show significant effects on the improvement of depressiveness, anxiety and distress; likewise from four studies to date for improvement of fatigue. The results of other outcome parameters examined, such as quality of life, coping strategies, pain reduction, and spiritual well-being, are heterogeneous. In addition, the duration of intervention and the type of art therapy interventions varied widely. The study data is characterized by strongly converging evidence of art therapy findings on the four outcomes mentioned above. With the exception of a drop-out rate of over 20% in four primary studies, the risk of bias assessment shows a high quality in the new primary studies (2012-2020).

8.8.2 Music Therapy

8.29	Evidence-based Recommendation	modified 2023
GoR B	Music therapy should be offered to cancer patients to reduce anxiety, depression, stress, and improve health-related quality of life.	
LoE 1a	[798], [799], [800], [801], [802], [803], [804], [805], [806], [807], [808], [809], [810], [811], [812], [813], [814], [815], [816], [817], [818], [819], [820], [821], [822], [823], [824], [825], [826], [827], [828], [829], [830]	
	Consensus	

8.30	Evidence-based Recommendation	new 2023
GoR 0	Music therapy can be offered to cancer patients to reduce pain as an adjunct to guideline-based pain management.	
LoE 1a	[826], [802], [813], [811], [812], [818], [798], [808], [804], [799], [801], [807], [814], [827], [806], [803], [810]	
	Consensus	

Music therapy (MT) is „(...) the targeted use of music within the framework of the therapeutic relationship to restore, maintain and promote mental, physical and spiritual health“ [831]. Various music therapy concepts and methods (Neurological MT by M. Thaut; Guided Imagery and Music by Helen Bonny a.o.) are grouped under this heading and can basically be assigned to the following two approaches: Functional MT - for the treatment of primarily physiological complaints and Psychotherapeutic MT - with predominantly psychological treatment goals. The latter makes use of active methods (playing an instrument, singing, songwriting, etc.) and receptive methods (listening to individualized music, musical relaxation interventions, sound journeys, etc.), in which different mechanisms of action, both of the music as well as the therapeutic relationship, can be used. MT sessions can take place in individual and/or group settings, depending on the treatment goal and approach.

Music medicine (MM) refers to the use of music as a therapeutic tool by individuals without therapeutic training and outside of a therapeutic relationship (e.g., medical staff handing out an MP3 player/playlist to patients). Studies on music medicine were not included in the systematic literature search but are reported in some of the reviews that were included.

In the period from 2012 to 06/2020, a total of **seven systematic reviews** with meta-analyses on the use of music (therapy) and its influence on psychological and physiological parameters in cancer patients were published [799], [800], [798], [801],

[802], [803], [804]. In addition, 25 new primary studies on oncological patients (excluding palliative patients) with a LoE 1 are available.

Meta-analyses and systematic reviews

The effect of music-based interventions on **reducing anxiety** is described as significant in six reviews. Bradt et al. [798] showed significant improvements in anxiety on the IGs compared to CG in 13 RCTs (N=1,028, significant improvements IGs vs. TAU; SMD = -0.71, 95% CI: -0.98; -0.43, $p < .001$) with a moderate to large effect. Zhang et al. [799] found a significant improvement on anxiety across different measurement tools (7 RCTs, N=607, SAS: M = -2.84, 95% CI: -19.51; -6.17, $p < .001$; 2 RCTs, N=515, HAMA: M=-1.85, 95% CI: -3.43; -0.27, $p < .05$; 8 RCTs, N=681, STAI: M=-12.30, 95% CI: -18.93; -5.68, $p < .001$) with small to moderate effect sizes. Li et al. [804] showed significant improvement on anxiety in the IG compared to CG on the basis of six RCTs (6 RCTs, N=447, SMD = -1.51, 95% CI: -2.27; 0.75; $p < .05$), Gao et al. [801] based on three RCTs (N=121, SMD=0.68, 95% CI: 1.35; 0.02; $p = .04$) and Wang et al. [802], in four RCTs (Anxiety: 2 RCTs, N=200, HAMA: MD= -7.04, 95% CI: -9.31; -4.78, $p < .00001$; 5 RCTs, N=268; SAS: MD=-7.40, 95% CI: -10.28; -4.52, $p < .001$; 2 RCTs, N=110, State Anxiety Inventory: MD=-12.40, 95% CI: -21.86; -2.94, $p = .01$). In their systematic review, Nightingale et al. [800] found a significant anxiety reduction in the IG compared to the CG in 85% (11/13) of the studies included: in the meta-analysis of 4 of the 13 included studies, no significant difference between the IG and the CG with regard to anxiety was found.

The effect of music-based interventions on **reducing depressive symptoms** is largely described as significant in five reviews. Wang et al. [802] were able to show a significant effect on depressivity based on the results of 14 studies from MT and MM (6 RCTs in MT, MD=-7.39, 95% CI: -8.35; -6.43, $p < .001$). Similarly, Zhang et al. [799] (7 RCTs, M=-6.23, 95% CI: -8.85; -3.36; $p < .001$) and Li et al. [804] (6 RCTs, SMD=-1.12, 95% CI: -1.87; -0.38, $p < .05$) showed significant results with regard to depressivity. In the Cochrane review by Bradt et al. [798], a short-term, moderate reduction in depressiveness through active music therapy interventions (SMD= -0.40, 95% CI: -0.74; -0.06, $p < .02$) was described. In their meta-analysis, Köhler et al. [803] found a significant improvement in mental well-being, reaching across aspects of anxiety, depressiveness, mental distress and well-being, mood, emotional functionality, relaxation, hope, and resilience in the IG (active MT) versus CGs (TAU, waiting list, and active CG: listening to music, visiting, mindfulness practice) (19 RCTs, $d = 0.35$, 95% CI: 0.19; 0.50, $p < .01$). It was found that a lower number of sessions had greater effects ($d = 0.47$) than more frequent sessions ($d = 0.18$). There were also greater effects with receptive MT ($d = 0.33$) than with active or multimodal methods ($d = 0.19$). In addition, a positive effect on depressiveness as well as mood was found. A significant improvement of physiological distress with small effect (physiol. distress: $d = -0.34$, 95% CI: -0.55; -0.13, $p < .004$) was also described. Gao et al. [801] were able to show a significant reduction in depressiveness in their review (4 RCTs, N=227, SMD: 1.08, 95% CI: 1.64; 0.53, $p < .001$). Here, no significant improvement in **social functioning** was found (3 RCTs, SMD=0.51, 95% CI: 0.17; 1.19, $p = .14$).

For **improvement in quality of life**, a significant effect was found in five reviews. The Cochrane Review by Bradt et al. [798] showed a significant increase in quality of life, also comparing MT versus MM, with moderate effects in three studies (SMD=0.42, 95% CI: 0.06; 0.78, $p = .02$). Gao et al. [801] were able to find significant improvement on health-related quality of life in five studies (SMD=0.61, 95% CI: 0.41; 0.82, $p < .001$). Köhler et al. [803] described a significant improvement with a small effect in their

review on quality of life ($d=0.48$, 95% CI: 0.11;0.85, $p=.019$), although no significant effect was found for session frequency. Similarly, Li et al. [804] (10 RCTs, SMD: 0.54; 95% CI: 0.40;0.69; $p<0.05$) and Zhang et al. [799] (2 RCTs, $M=13.32$, 95% CI: 11.01;15.62, $p<.001$) described a significant effect for the improvement on different facets of quality of life.

Four out of five reviews could demonstrate a significant reduction in **pain**. Thus, Bradt et al. [798] (SMD: -0.91; 95% CI: -1.46;-0.36; $p=.001$), Li et al. [804] (SMD: -1.12; 95% CI: -1.87;-0.38; $p<.05$), Zhang et al. [799] ($M=-0.54$; 95%CI: -0.88; -0.20; $p<.005$), and Gao et al. [801] could determine a significant effect from MT on various parameters of pain. In addition, the review by Köhler et al. [803] described a positive effect on pain.

Inconsistent results regarding the significance on **fatigue** are found in three reviews. In the review by Bradt et al. [798], small to moderate improvements in fatigue were demonstrated in six studies with small to moderate effects (SMD: -0.38; 95% CI: -0.72;-0.04; $p=.03$). Zhang et al. [799] also report significant results on fatigue (2 RCTs, $M=0.63$; 95% CI: -2.52; 3.77; $p=.70$). In the review by Gao et al. [801], no significant differences were found between intervention and control groups for fatigue (2 RCTs, SMD: 0.17, 95% CI: 0.95;0.61, $p=.67$).

Primary studies⁶

Twenty-two primary studies were included in the analysis. Individual RCTs are already included in one or more of the reviews and meta-analyses described above. Since the overlapping studies also include older primary studies prior to the designated search period, only the evidence from RCTs after 2014 will be presented separately below.

Music therapy significantly reduced **anxiety** in the majority of available studies. In the study by Palmer et al. [818] with inpatient breast cancer patients ($N=201$), the applications of listening to music pre- and perioperatively were compared live vs. recorded music compared to TAU. Anxiety was significantly reduced in both music IGs compared to TAU (MD: -26.5; $d=-0.57$; MD: -25.7; $d=-0.55$). By Romito et al. [822], anxiety was significantly improved in both the IG as well as the CG ($d=0.69$; $p=.000$). Wang et al. [802] (HAMA: $p<.001$; SAS: $p<.001$; State Anxiety Inventory: $p=.01$) as well as Yates and Silverman [829] ($p=.009$) each found significant improvement on anxiety in the IGs. Rossetti et al. [824], found a reduction in anxiety through MT (10 sessions à 35 minutes listening to music with therapist, before and during treatment) during radiation treatment in gynecologic patients (MD: 8.2; $p=.002$). Dóro et al. [810], found significant group differences with regard to anxiety (IG vs EK: $p<.001$), whereas Bradt et al. [808] failed to find a significant effect with regard to anxiety (SMD: 0.21; 95% CI: -0.09;0.51, $p=.18$). A significant reduction in **depressiveness** in the IG compared to the CG was demonstrated in the study by Alcântara-Silva et al. ($p=.011$) [805], as well as in Chen et al. [832]. Romito et al. [822] investigated the use of one session of integrative group MT ($N=31$) à two and a half hours concomitant with outpatient chemotherapy in 62 patients with breast cancer. Twenty-minute talks ($N=31$) were used as a control group. The MT group showed significant improvements for **depressiveness** ($d=0.52$; $p=.000$) and **anger** ($d=0.58$; $p=.000$). With regard to

⁶ For three of the 25 primary studies at evidence level 1, the full text is only available in Chinese, so they could not be described in more detail and no risk of bias assessment was performed. Their results are included in the review by Wang et al. (2018) [802].

negative affect (SMD: -2.86; $p=.003$) and **positive affect** (SMD: 2.15; $p=.001$), the IG achieved greater improvements than the CG in the studies by Fredenburg and Silverman [811], [812].

With regard to **hope** and **helplessness**, two studies showed improvements. According to research by Chen et al. [822], the use of music-imagery in eight sessions à 60 minutes led to a reduction in helplessness and hopelessness, as well as cognitive improvement in 52 patients with breast cancer compared TAU. A study by Verstegen et al. [827] compared MT with therapeutic dialogue versus TAU in 10 patients with blood and bone marrow transplantation. The two sessions lasted between 30 and 60 minutes. The parameter **hope** was significantly improved here in the IG as well (post-test: $p=.035$). The parameter **stress** improved significantly in the study by Romito et al. (IG: $d=0.62$; $p=.036$) [822]. Rossetti et al. [824] showed a reduction of distress through MT (IG: $p=.0064$). Regarding symptom-related physical stress, Fredenburg and Silverman [811], [812] found no significant difference between the intervention and waitlist groups. Regarding **quality of life**, a study by Bieligmeyer et al. [807] showed significantly lower scores after MT intervention (single session à 10 minutes of vibroacoustic-combination of auditory and sensory sound experiences) compared to the CG (quiet time) ($d=0.37$; $p<.001$). A study by Alcântara-Silva et al. [805] showed a greater improvement in quality of life when listening to music together with a therapist before and after radiation therapy for gynecological oncology patients ($N=164$; 10 sessions of 35 minutes each) compared with TAU ($p=.005$). In a prospective palliative study by Warth et al. [828], 2 sessions of MT (30 min each at least 2 days apart) vs. MBSR were compared. With regard to quality of life, the authors found no significant group differences between intervention and control groups for the total quality of life scale in the pre-post comparison ($F[1;81]=2.23$, $p=.14$, $MD= 3.26$ [95%, CI: -5.99/ 12.5], $\eta^2=.03$, $SMD=.14$ $NNT=7$). Ratcliff et al. (2014) [820] compared two different MT formats (ISO principle-based vs unstructured music (UM); 4 sessions each à 50 minutes) vs. TAU in patients after stem cell transplantation and found significant group differences in quality of life improvement comparing baseline to follow-up ($p=.001$) in favor of ISO principle-based MT (MT > UM > TAU). The investigation of **pain** showed improvements in the IG, but no significant effect in the group comparison [807], [808], [810], [814], [827]. Bates et al. [806] examined the effect of two MT sessions à 30 minutes for a total of seven days on patients with multiple melanomas or lymphomas during their first stem cell therapy. Compared to the CG (TAU), there was no significant group difference regarding pain at any time ($p=.73$). The use of **analgesics** was not significantly different between IG and CG ($p=.73$), but it significantly increased in both groups at follow-up measurement ($p=.001$). Tuinmann et al. [826] investigated the effect of playing music, singing and listening to music in 66 lymphoma patients over eight sessions à 20 minutes versus TAU. They were able to demonstrate that the need for **analgesics** and the subjective **pain perception** were lower in the EG than in the CG (SMD: 10; 95% CI: 1.2;18.9; $p=.027$). Wang et al. [802] investigated the effect of perioperative music relaxation and postoperative music listening in five sessions à 60 minutes in 60 patients with lung cancer. The control conditions were TAU. The effect shown for the EG was a greater reduction in the need for analgesics. In 200 patients with advanced-stage cancer, Gutgsell et al. [813] found greater reduction in pain after a 20-minute session of music relaxation than in the wait-list CG ($MD: -1.39$; 95% CI: -1.95;0.83; $p<.001$). In two studies on blood and bone marrow patients [812], [811], Fredenburg and Silverman examined the effect of music therapy (various techniques) in one session à 30-45 minutes. Regarding pain, a greater decrease was demonstrated in the IG (SMD: -2.86; $p=.009$). Letwin and Silverman [814], examined

15 patients with different oncological diagnoses (oncology/hematology department) before and after two sessions of music listening à 30-45 minutes. Compared to the waiting-list CG, no significant differences in **pain** ($p=.891$) and **resilience** ($p=.079$) were demonstrated. In a study by Palmer et al. [818], no reduction in the need for anesthetics was seen with MT compared to the CG (LM vs. CG: MD: -3.3; 95% CI: -19.0; 12.4; $d=-0.09$; RM vs. CG: MD: -8.6; 95% CI: -20.8; 3.5; $d=-0.24$). Warth et al. [828] also found no significant group difference in pain perception between IG vs. the CG ($F[1;81]=.40$, $p=.53$, MD= -.18 [95%, CI: 0.74/ 0.39], $\eta^2=.01$, SMD=-.15 NNT=8.40). In contrast, Ratcliff et al. [820] described significant group differences in terms of improvement in cancer-related symptoms (such as pain, nausea, etc.) in the comparison between baseline to follow-up ($p=0.01$) in favor of ISO principle-based MT. No improvement in **fatigue** was found by Fredenburg and Silverman ($p>.05$) [811]. However, Alcântara-Silva et al. [805] observed a significant reduction in fatigue in the IG compared to the CG ($p=.01$). In the study by Warth et al. [828], the authors demonstrated significant improvements in fatigue in favor of the IG vs. the CG ($F[1;81]=4.74$, $p=.03$). The study results on the outcome **mood** are heterogeneous. The study by Bieligmeyer et al. [807] showed significant effects for current mood ($d=0.43$; $p<.001$) as well as for mood and well-being ($p=0.47$; $p<.01$), whereas no improvements were found in the CG. Especially the subscales of the BMQ used for **inner balance** ($d=0.73$; $p<.001$), **vitality** ($d=0.51$; $p<.001$) and **alertness** ($d=0.37$; $p<.001$) achieved significant improvements for the IG. Further significance in favor of the IGs was shown for the parameter **satisfaction** ($d=0.43$; $p<.001$). Palmer et al. [818] could not observe any improvement in satisfaction as a result of the live music intervention. In a study by Dóro et al. [810], stem cell therapy patients ($N=100$) were examined. Here, singing and musical Improvisation took place in eight sessions à 30 minutes. The CG received TAU. Mood improved in the IG more than in the CG ($p<.001$). Bradt et al. [808] offered music therapy employing different therapeutic techniques versus music listening as an active CG to inpatients and outpatients with different cancer diagnoses ($N=31$). Two sessions à 20-45 minutes did not lead to any significant group differences with regard to **mood** (MT: $p<.0001$ MM: $p>.0001$). Bates et al. [806] also found no significant group differences in the measurement of mood. Ratcliff et al. [820] showed significant improvement in mood after stem cell transplantation over four sessions of MT for both MT groups ($p<.0001$), with no significant difference detectable between the different MT interventions. Warth et al. [828] also described a significant improvement in the mood of palliative patients in the IG vs CG ($F[1;81]=6.41$, $p=.01$, MD= .98 [95%, CI: 0.28/ 1.68], $\eta^2=.61$, SMD=.61 NNT=5.25). Improved **spiritual well-being** in the IG compared to the CG was found by Cook and Silverman [809] (subscales: Hope: MD: 3.856; $p=.011$; Peace: MD: 2.194; $p=.018$; Meaning: MD: 0.416; $p=.677$). They described the use of listening to music versus talking for 34 hematologic oncology patients (leukemia and other diagnoses). In three sessions à 15-30 minutes, the IG was compared with a waiting list CG. Lin et al. [816] were able to show an improvement in **relaxation** with MT compared to TAU. Yates and Silverman [829] implemented one session of music listening à 20-30 minutes in 26 inpatients with colon, rectal, or uterine cancer. Compared to the waiting list group, increased relaxation was achieved in the experimental conditions ($p=.009$). Warth et al. [828] were also able to demonstrate a significant improvement in relaxation in favor of the IG vs. CG ($F[1;81]=13.7$, $p<.01$, MD=1.19 [CI: 0.50; 1.88], $\eta^2=.75$, SMD=.75, NNT=2.80) in a pre-post comparison after two 30-minute sessions of MT in palliative patients. Bradt et al. [808] did not find significant group differences with regard to anxiety (MT: $p=.0002$; MM: $p<.0001$).

For postoperative **recovery time**, Palmer et al. [818] showed significant results for live music compared to the use of recorded music ($p=.018$), but not compared to the TAU group. For 86 cancer patients (with various diagnoses) in outpatient treatment, Burns et al. [833] found improved **responsiveness** and post-traumatic growth (benefit finding/increased resilience) in a single session (45-50 min) with guided visualization with music compared to decreasing scores in the CG. When examining physiological outcomes, the study by Bates et al. [806] showed no significant effect in regard to **nausea**. In the follow-up survey, the CG performed significantly better ($p=.035$). Moradian et al. [817], used active listening with the Nevasic audio program (pre-recorded audio program) during chemotherapy to reduce treatment-related nausea and **vomiting** in breast cancer patients ($N=99$). Listening to music in one group and TAU in another group were used as CGs. No group-specific differences were found with regard to nausea and vomiting. In the IG, the use of antiemetics significantly decreased compared to both CGs ($p=.003$). Warth et al. [828] found in their study in the palliative setting a significantly greater increase in the high-frequency component of **heart rate variability** in favor of the IG vs. CG ($F(1;81)=8.13$, $p=.01$, $MD=.44$ [95%, CI: 0.12/.77], $\eta^2=.09$, $SMD=.59$ $NNT=3.50$). When **blood volume and -amplitude** were examined, only a trend toward vasodilation in favor of the IG vs. CG ($F(1;81)=3.33$, $p=.07$, $MD=.11$ [95%, CI: -.03/.24], $\eta^2=.04$, $SMD=.35$, $NNT=42$) was demonstrated.

Risk of Bias Assessment

The Risk of Bias assessment of the 22 RCTs in MT was performed analogously to art therapy and, in summary, found a low Risk of Bias in 15 studies, "some concerns" in four studies, and a high Risk of Bias in three studies. The assessment took place with regard to the five categories of the RoB 2: The high Risk of Bias occurred exclusively in Category 3, "bias due to missing outcome data", due to missing data in the post-test. From a clinical point of view, a high dropout rate (of more than 20% for the classification as high risk) can mostly be explained by the stressful oncological treatment with complex side effects or changed life circumstances. Missing data were handled with adequate methods (intention-to-treat analysis, etc.). Missing or insufficient information in the publications led to the assessment of *some concerns* for one study in the Category 4, "bias in the measurement of the outcome", and in three studies in Category 5, "bias in the selection of the reported results". Except for these cases, the homogeneity of methodological quality was high with a low risk of bias in 15 studies.

Conclusion

The overall findings of music therapy in oncology are positive. There is increasing methodological improvement in conducting clinical trials. Within the creative arts therapies, MT represents the majority of studies on evidence level 1. Across all treatment stages, stable, positive effects on the **enhancement of health-related quality of life, the reduction of anxiety and depression, and the reduction of pain** can be found for different diagnostic groups and treatment methods. The study findings for fatigue reduction, mood improvement and relaxation, are mixed. Here, further studies are needed to investigate possible positive effects from MT. Other outcomes with hope, satisfaction, positive affect, and spiritual well-being improved with MT; feelings of helplessness and anger could be reduced. With regard to the **physiological parameters**, the study data is heterogeneous so far. Overall, further studies with high methodological quality are needed in order to determine the

process-related influences and mechanisms and contextual factors underlying the improvements.

8.8.3 Dance and Movement Therapy

8.31	Evidence-based Recommendation	modified 2023
GoR 0	Dance and movement therapy can be offered to cancer patients to reduce pain, stress and anxiety, and to enhance quality of life.	
LoE 1b	[834] , [835] , [836] , [837] , [838] , [839] , [840] , [841]	
	Strong Consensus	

Dance and movement therapy (DMT) is a practice at the interface of movement, art, and psychotherapy and its interventions are directed towards these three core areas of psychosocial treatment. In contrast to other forms of movement therapy, dance therapy focuses on the creative artistic elements as well as the improvisational elements of movement and the psychotherapeutic aspect. Dance therapy works with active methods such as, the Chace Technique (group process in movement), authentic movement, body image work, stick fighting, and dance and movement elements from different cultures.

Five new reviews ([\[835\]](#), [\[834\]](#), [\[836\]](#), [\[838\]](#), [\[841\]](#)) are available for dance and movement therapy for the period 2012 to 2020. The Cochrane review by Bradt et al. (N=207) [\[834\]](#) includes the primary studies by Dibbell-Hope [\[842\]](#), Sandel et al. [\[843\]](#), and Ho and Fong [\[844\]](#), a conference abstract of the later published study by Ho et al. [\[839\]](#). The other reviews ([\[835\]](#), [\[836\]](#), [\[838\]](#)) are summarized by Koch and Bräuninger in a review [\[841\]](#) which included 13 studies, of which six were RCTs with a total of 282 participants. Of these, two studies are at evidence level 1 ([\[837\]](#), [\[839\]](#), [\[840\]](#)). Other studies have evidence levels 2-4 and are not discussed here.

Meta-analyses and systematic reviews

Results on **anxiety reduction** are mixed. On the one hand, Boing et al. [\[835\]](#) reported a reduction in fear of recurrence ($p=.02$). On the other hand, dance and movement therapy interventions did not significantly reduce anxiety ($p=.18$) in two of the RCTs [\[842\]](#), [\[844\]](#) included in the Cochrane review by Bradt et al. [\[834\]](#).

Mixed results were found in the reviews with regard to **depressiveness**.

On the one hand, in their systematic review, Boing et al. [\[835\]](#) found significant results demonstrating a decrease in depressiveness ($p=.01$) in one RCT [\[845\]](#). On the other hand, two RCTs [\[842\]](#), [\[844\]](#) from the review by Bradt et al. [\[834\]](#) found no significant reduction in depressiveness ($p=.89$).

Regarding the outcome measure **stress**, only one RCT [\[840\]](#) showed a significant reduction in stress through dance and exercise therapy with a medium effect ($d=0.33$, $p=.039$). This study was included in the systematic reviews by Koch and Bräuninger

[841], and Boing et al. [835]. Two RCTs [842], [844] from the review by Bradt et al. [834] were unable to demonstrate any significant improvement ($p=.24$).

For **quality of life**, Boing et al. [835] summarized the outcomes in regard to mental health ($p=.01$), environment ($p=.029$), body image ($p<.01$), and overall quality of life ($p<.01$). They also report an improvement in the physical aspects of quality of life ($p<.001$). The systematic review by Koch and Bräuninger [841] found an increase in quality of life in one RCT [843], while two other RCTs did not demonstrate a significant improvement in quality of life [839], [837]. It should be noted that two RCTs [842], [843] from the Cochrane Review by Bradt et al. [834] also found no improvements with regard to **body image** ($p=.58$), whereby body image was assessed by different measurement tools in the studies.

With regard to patients' **experience of pain**, one RCT [839], which was included in the systematic review by Koch and Bräuninger [841] as well as Boing et al. [835], showed a significant reduction in pain intensity ($d=.36$; $p=.035$) and pain interference ($d=.35$; $p=.048$).

Regarding **fatigue**, two RCTs [842], [844] in the Cochrane review by Bradt et al. [834] did not show significant improvements ($p=.44$). The reviews by Boing et al. [835], Goodill et al. [838], and Koch and Bräuninger [841] also report the results of the aforementioned RCTs. Other positive findings are reported by Boing et al. [835] for **social functioning** ($p=.04$), **mental health** ($p=.04$), **emotional role** ($p=.07$), **well-being**, and **mood** ($p<.05$). Koch and Bräuninger [841] report the results of an RCT [845], which demonstrated a significant improvement regarding **life satisfaction** ($d=2.69$; $p<.001$).

In addition, the influence of dance therapy interventions on various **physiological variables** was investigated. In the review by Boing et al. [835], one RCT each reported an improvement in functional capacity ($p=.03$), physical activity ($p=.01$), strength ($p<.05$), grip strength and arm volume ($p=.028$), as well as physical function ($p=.001$).

Primary studies

The studies described (RCTs) are already included in the reviews by Boing et al. [835] and Koch et al. [841], but are presented again in detail here. **Fear of Recurrence** was significantly reduced ($p=.02$) in the intervention group from Crane-Okada et al. [837], whereas the intervention by Ho et al. [839] showed no effect on participant's anxiety. Regarding perceived **stress**, Ho et al. demonstrated a significant reduction in their study ($d=0.33$; $p=.039$) [839]. In a secondary analysis of the data on the question of moderator effects of the interventions on stress parameters, Ho et al. [840] found no significant effect of the intervention on cortisol levels over the course of the day after three weeks ($B=-0.55$; 95% CI: $-1.2; 0.08$). There was also no significant effect on the **quality of life** of the intervention groups after a Mindful Movement Program or after six concomitant sessions of DMT [837], [839]. No significant improvements were found on the severity ($d=0.01$; $p=.98$) and interference ($d=0.14$; $p=.43$) on **fatigue**, **sleep disturbance** ($d=0.20$; $p=.24$) and depressiveness ($d=0.53$; $p=.11$) [839]. Significant improvements were seen in the aforementioned studies in terms of **severity** ($d=0.36$; $p=.035$) and impairment due to **pain** ($d=0.35$; $p=.048$) [839] as well as **mindfulness** of the IG (post-test: $p=.026$) in the study by Crane-Okada et al. [837].

Risk of Bias Assessment

The risk of bias assessment of the 2 RCTs for dance and movement therapy was conducted analogously to the process for art and music therapy by three independent raters and showed a consistently low risk of bias (low RoB) across four assessment categories, whereby in Dimension 2, possible bias can be suspected due to the lack of blinding as well as an unequal implementation of the intervention in the study by Crane-Okada et al. [837] (see GL-Report).

Conclusion

The current studies and reviews on dance and movement therapy show an improved, but heterogenous picture with regard to most of the target criteria investigated. Only in a few studies demonstrated a significant reduction of **pain** and the **effects of pain** and **perceived stress**. In addition, in the context of psycho-oncological rehabilitation, there was an increase in **life satisfaction**, a decrease in the **fear of recurrence**, and an improvement in **mindfulness** after dance and movement therapy. The findings on quality of life, depression, fatigue, and upper body mobility were mixed. No effects could be demonstrated for improvement in sleep and body image, although in the latter case, difficulties in the measurability of the construct and a high heterogeneity of the outcome measures should be taken into account.

One should take into account that it is necessary to look not only at the effects but also at the **mechanisms** of action in order to gain a deeper understanding of the results (for initial findings see: De Witte et al. [846]).

8.8.4 Overarching Systematic Reviews

From 2012 to 2020, six high-quality, overarching reviews of various creative arts therapies (CAT) were published, which include 42 studies, 39 of which were RCTs from art, music, and dance therapies (N=3,726) [847], [848], [849], [850], [851], [852].

Converging empirical evidence

Findings on anxiety reduction through creative arts therapies (CAT) are largely positive. Hertrampf et al. [849] reported a significant reduction in anxiety through CAT in five RCTs (N=478; post-test: $0.12 < d < 0.67$; FU: $d < 0.38$) as well as MM, in five RCTs (N=600; post-test: $0.2 < d < 0.7$). The most recent review by Tang et al. [852] included nine RCTs (N=747) and found a significant reduction in anxiety through CAT in four RCTs (N=337, SMD=-0.48; 95% CI: -0.75;-0.21; $p=.0005$). A significant reduction in anxiety through CAT was also demonstrated in three RCTs from Archer et al. [847] and in four RCTs from Boehm et al. [848]. Rabadán et al. [850] included 11 studies (N=680) with CAT in patients with breast cancer and found no effect of DMT on anxiety, but a significant reduction in anxiety with MT.

Significant results were also recorded for the reduction of depressiveness. A significant reduction in depressiveness with CAT resulted in five RCTs (N=304) (post-test: $0.14 < d < 0.52$) and for MM in two RCTs (N=290) (post-test: $0.4 < d < 0.43$) [849]. Tang et al. [852] (SMD=-6.59; 95% CI: -7.70; -5.47; $p<.00001$) and Archer et al. [847] also reported positive results in terms of a reduction in depressiveness in two RCTs (N=180) and three RCTs (N=213), respectively. Boehm et al. [848] demonstrated an improvement in depressivity in the IG in five RCTs (N=241), but this was not significant (M: -0.30; 95% CI: -0.60;0.00; $p=.05$). Only one study in the review by

Rabadán et al. [850] failed to show any effects of DMT on depressive symptoms ($p=.53$) [839].

A reduction in stress was shown not only for CAT in four RCTs ($N=262$) from the review by Hertrampf et al. [849] (post-test: $0.07 < d < 0.33$; FU: $0.1 < d < 0.38$) and in one RCT from Archer et al., but also through DM as well as in a study by Ho et al. ($p=.39$; $d=0.33$) [839].

With regard to an increase in quality of life, Hertrampf et al. (post-test: $0.12 < d < 0.56$; FU: $0.26 < d < 0.31$) [849] and Archer et al. [847] each found improvements in quality of life through CAT in four RCTs ($N=260$) and five RCTs, respectively. However, no effect on sleep or quality of life was found by Rabadán et al. [850] after dance and movement therapy. The results from Boehm et al. [848], showed no significant group differences in four RCTs ($M=0.15$; 95% CI: $-0.09; 0.40$; $p=.22$) as well.

Positive results are consistently reported for pain reduction. In the review by Hertrampf et al. [849], a moderate to large effect could be observed regarding the reduction of pain on the post-test in four RCTs ($N=430$) from MM (post-test: $0.54 < d < 1.31$). In addition, one of the studies included in the review by Rabadán et al. [850] showed that dance therapy significantly reduced both the severity ($p=.035$; $d=0.36$) and interference of pain ($p=.048$; $d=0.35$) [839].

Non-converging evidence

The findings of the studies on the reduction of fatigue show heterogeneous results. While Tang et al. [852] found a significant improvement in fatigue in one RCT ($N=60$; SMD: -1.90 ; 95% CI: $-2.93; -0.87$, $p=.0003$), Ho et al. [839] found no effect of DMT on fatigue (severity: $p=0.98$; $d=0.01$; interference: $p=.43$; $d=0.14$). Finally, two RCTs ($N=170$) from CAT on fatigue found no to a moderate effect at post-test (immediately after treatment in Dibbel-Hope [842]; no measurement in Ho et al. [839]), and a small to large effect at follow-up after 3 weeks. Follow-up effects were partly larger than post-test effects (post-test: $0.42 < d$; FU: $0.05 < d < 0.87$) [849]. In another study included in the review by Rabadán et al. [850], fatigue was examined from different aspects. Art therapy significantly reduced fatigue ($p=0.007$; for patients with mild fatigue), it provided an increase in social well-being ($p=.02$; for patients with severe general fatigue who had received chemotherapy), it led to an increase in quality of life ($p=.034$), emotional well-being ($p=.017$), social well-being ($p=.025$), and motivation ($p=.03$; in patients with initially low motivation), and significantly reduced fatigue after six months for patients with severe fatigue [792].

The results on the improvement of body image are heterogeneous, which can be largely attributed to the heterogeneity and problematic nature of the outcome measures on body image. The specific review on the outcome body image by Lewis-Smith et al. [851] included three CAT studies up to 2017 ($N=110$). The authors found no significant improvements in body image through AT and DMT. The review by Hertrampf et al. [849] included two RCTs ($N=79$) from CAT on body image improvement, both of which showed no effect or a small effect ($0.01 < d < 0.23$). In one RCT from each of the reviews by Rabadán et al. [850] and Archer et al. [847], found improvements in body image.

With regard to strengthening coping strategies (strategies for dealing with illness), no to small effects were reported ($0.1 < d < 0.32$) in two RCTs ($N=61$) from CAT included in the review by Hertrampf et al. [849]. A review of art therapy also showed no effects

on coping strategies [794]. In contrast, the review by Archer et al. [847] found significant improvements in coping strategies in one RCT.

Furthermore, two RCTs (N=79) showed small to medium effects ($0.04 < d < 0.23$) [849] of CAT on mental health.

Conclusion

The number and quality of systematic reviews on CAT has increased significantly in recent years. Nevertheless, in many reviews, no meta-analysis could be performed due to the heterogeneity of the primary studies. The heterogeneity can be explained through the use of a wide range of methods, interventions, and measurement instruments. Only Boehm et al. [848] and Tang et al. [852] calculated overlapping effect sizes. Boehm et al. [848] was able to show a significant reduction in anxiety (four RCTs; $M = -1.10$; 95% CI: $-1.4; -0.88$; $p < .01$), whereas Tang et al. [852], in the more recent study, in addition to also demonstrating a significant reduction in anxiety (four RCTs; $SMD = -0.48$; 95% CI: $-0.75; -0.21$; $p = .0005$), was also able to show a significant reduction in depression (two RCTs; $SMD = -6.59$; 95% CI: $-7.70; -5.47$; $p < .00001$) and a significant improvement in fatigue (one RCT) ($SMD = -1.90$; 95% CI: $-2.93; -0.87$; $p = .0003$) through CAT. Thus, the consistently demonstrated reduction in anxiety is the most consistent finding for CAT, with long-term effects also emerging. These findings on the three main outcomes of the overlapping studies are reflected in the individual recommendations and strengthen the evidence base, especially with regard to depression and anxiety reduction.

9 Additional Therapies

9.1 Psychopharmacotherapy

9.1	Consensus-based Recommendation	modified 2023
EC	The treatment of cancer patients with psychopharmaceuticals should be embedded in an overall psycho-oncological treatment concept.	
	Strong Consensus	

9.2	Consensus-based Recommendation	modified 2023
EC	Somatic, psychological, and social factors as well as the effects of the oncological disease and therapy should be taken into account before and during psychopharmacological treatment.	
	Strong Consensus	

9.3	Consensus-based Recommendation	modified 2023
EC	Psychopharmacotherapy for patients with ICD-10 diagnoses of a mental disorder shall be provided according to available guidelines (unipolar depression (AWMF registry number: nvl-005); trauma sequelae disorders (AWMF registry numbers: 051-027 and 155-001); anxiety disorders (AWMF registry number: 051-028); sleep disorders (AWMF registry number: 063-003)).	
	Strong Consensus	

An effective treatment of depression, anxiety disorders and other psychological disorders in cancer patients requires close cooperation between the treating physicians, psycho-oncologists, and nurses, both in terms of diagnosis as well as an optimal treatment of somatic causes, possible triggers, and symptoms. All these factors should be taken into account when choosing the appropriate psychopharmacological therapy. In addition, the preferences of the patient with regard to psychotherapeutic and psychopharmacological treatment are to be taken into account when making treatment recommendations [\[853\]](#).

The treatment of cancer patients with psychopharmaceuticals should therefore always be embedded in an overall oncological treatment concept. Before any psychopharmacological or psychotherapeutic treatment, the medical causes or triggers should be taken into account and included in the treatment concept (see [Chapter 7](#)). These include, first and foremost, the diagnosis and treatment of tumor-related causes: symptom control (e.g., pain), [CNS](#) affections (e.g., tumors), endocrine or electrolyte disturbances, withdrawal symptoms, or medication side effects (see

Table 10). An optimal symptom control of pain, dyspnea, nausea, or fatigue should be undertaken, as well as any necessary correction of electrolyte imbalances. The influence of potentially depressant medications (e.g., steroids, interferon, or tyrosine kinase inhibitors) should be assessed and, if appropriate, the corresponding medication should be discontinued if oncologically safe. The modification of potentially anxiety-inducing medications, which include corticosteroids, metoclopramide, or benzodiazepines, should also be considered in advance. Furthermore, withdrawal states from opiates, benzodiazepines or alcohol can play a role and should be diagnostically clarified, just as states of confusion (delirium) should also be taken into account.

Table 10: Contextual Factors Influencing Mental Health that Should be Considered Before and During Psychopharmacological Treatment

Optimized symptom control of tumor and tumor therapy sequelae: • Pain, nausea, dyspnea, fatigue, etc.
Diagnosis and treatment of brain-organic tumor sequelae: • Local: CNS metastases, CNS tumors, seizure risk, meningeosis • Systemic: endocrine disorders e.g. paracrine or ovarian insufficiency due to oncological therapy, electrolyte disturbances, hypercalcemia • Multifactorial: cognitive disorders / delirium, withdrawal symptoms after opiates, benzodiazepines, alcohol, etc.
Psychotropic drug side effects: • Depression: steroids, interferons, tyrosine kinase inhibitors, aromatase inhibitors, GnRH analogs • Anxiety: corticosteroids, metoclopramide, benzodiazepines

The following sections focus on the most commonly cited indications for psychopharmacological treatment in cancer patients for the syndrome and diagnosis groups:

- Depressive symptoms and depression
- Anxiety and anxiety disorders
- Sleep disorders

9.1.1 Depressive Symptoms and Depression

9.4	Consensus-based Recommendation	modified 2023
EC	Psychopharmacological treatment of subsyndromal disorders or as a preventative measure for depressive disorders should be given only in individual cases after strict indication, as insufficient evidence is available.	
	Strong Consensus	

Guidelines with a high level of evidence are available for the treatment of depressive disorders that fulfill the diagnostic criteria according to ICD-10 (also valid for DSM-IV, DSM-5 and ICD-11). Especially for unipolar depression, the „NVL Unipolar Depression“ provides a reference that also addresses somatic comorbidities (see Recommendation 9.2). For depressive episodes associated with bipolar disorder, in addition to the evidence from the general "S3-Guideline: Diagnostic and Therapy of Bipolar Disorders" (AWMF-Registernummer: 038-019), the general principles of psychopharmacological treatment with cancer should be followed (recommendations and background text from this [Chapter 9.1](#)).

On the question of the efficacy of psychopharmacological interventions in cancer patients with depression, other depressive disorders, or depressive symptoms without a formal diagnosis, a recent Cochrane Review by Ostuzzi et al. [\[854\]](#), [\[855\]](#) on antidepressants in cancer patients is available. The authors conclude that the quality of the available evidence for this group of patients is very low, but that there is no indication for an unfavorable safety profile of antidepressants. Based on similar studies, but also with longer study duration, the meta-analysis [\[856\]](#) found a weakly significant effect and a low quality of the studies as well, so that overall one can speak of an inhomogeneous study situation with a lack of high-quality RCTs regarding cancer. Another review by Grassi et al. (2018) [\[857\]](#) concludes that the use of antidepressants is recommended in cancer patients with major depressive disorder. Here, side effects and interactions with the cancer therapy as well as patient preferences should be considered. Cancer patients without significant depressive disorder in terms of major depression, e.g., with advanced cancer or with other, non-depressive symptoms (e.g., fatigue during chemotherapy) do not recognizably benefit from antidepressant therapy. The current scientific knowledge does not allow an evidence-based recommendation on the combined or additive effectiveness of antidepressant treatment in addition to or complementary to psychotherapy in cancer patients. With reference to the „NVL Depression“, however, a combination treatment with pharmacotherapy and psychotherapy is explicitly recommended for acute severe depressive episodes; for the treatment of acute moderate depressive episodes, psychotherapeutic treatment or pharmacotherapy is recommended.

For patients with depressive disorders without somatic comorbidity, the relationship between the initial severity of depression and the effectiveness of antidepressant or psychotherapeutic therapy is well established [\[858\]](#), [\[859\]](#), [\[860\]](#). Therefore, these patients should be treated according to the recommendations of the „NVL Depression“.

9.1.2 Fears and Anxiety Disorders

9.5	Consensus-based Recommendation	modified 2023
EC	The treatment of situational anxiety in cancer patients should be interdisciplinary and multimodal.	
	Consensus	

9.6	Consensus-based Recommendation	modified 2023
EC	As a psychopharmacological treatment of situational anxiety in cancer patients, anxiolytic medications can be offered over a short duration if carefully indicated.	
	Consensus	

Effective treatment of anxiety and anxiety disorders in cancer patients requires close cooperation with the treating physicians and nurses, both from a diagnostic point of view and for the optimal treatment of somatic etiologies, triggers and symptoms, and for the determination of an individually appropriate psychopharmacological therapy. The treatment is carried out according to the current guidelines for anxiety and trauma sequelae disorders, or organic mental disorders. Antidepressants with anxiolytic effects (e.g., paroxetine, venlafaxine, mirtazapine) can be used for longer-term treatment, as well as for concomitant sleep disorders (see [Chapter 9.1.3](#)) [\[861\]](#), [\[862\]](#), [\[863\]](#). In routine clinical practice, benzodiazepines with a rapid onset of action (e.g., alprazolam, lorazepam) can be used short-term for anxiety occurring in temporary and situational contexts. In the case of non-curable cancer, reference should also be made to the current "Extended S3 Guideline on Palliative Care for Patients with Non-curable Cancer" (AWMF Register Number: 128-001OL) which recommends the use of benzodiazepines under certain conditions and objectives. Because of the potential for dependency, care must be taken to ensure that the indications are well defined and that the duration of use is limited. Antipsychotics (haloperidol, possibly risperidone, olanzapine, or quetiapine) may also be used to treat delirium, pronounced nausea, and paradoxical reaction to benzodiazepines [\[861\]](#), [\[862\]](#), [\[864\]](#).

9.1.3 Sleep Disorders

9.7	Consensus-based Recommendation	new 2023
EC	In cancer patients, sleep disorders frequently occur as a result of psychological distress (e.g., fear of illness/recurrence) and side effects of treatment (e.g., after steroids, polyneuropathy), as well as the cancer disease itself (e.g., sleep apnea from head and neck tumors). These shall be documented regularly and treated with a multimodal approach.	
	Strong Consensus	

9.8	Consensus-based Recommendation	new 2023
EC	The indication for psychopharmacological treatment of sleep disorders in cancer patients should be reviewed and carried out under consideration of the current guideline recommendations (S3 guidelines "Sleep-related Respiratory Disorders" (AWMF register number: 063-001) and "Insomnia in Adults" (AWMF register number: 063-003)).	
	Strong Consensus	

For general recommendations on sleep disorders, please refer to the corresponding S3 guideline (AWMF register number: 063-003). In this chapter, only special features of sleep disorders in cancer patients are detailed.

The cause of sleep disorders in cancer patients is multifactorial. Predisposing factors (e.g., female gender, older age, positive self- or family history) and perpetuating factors (e.g., excessive daytime sleeping) for sleep disorders exist regardless of the cancer disease and treatment [865]. However, there are a number of precipitating factors that are specific to cancer patients. These include antitumor treatments that affect the levels of inflammatory cytokines or disrupt circadian rhythms (e.g., corticosteroids), adverse side effects of antitumor treatments (e.g., hot flashes with anti-hormonal therapy), hospitalization, psychological distress, and somatic symptoms such as pain, nausea, dyspnea, and hot flashes [866], [865], [867], [868], [869].

25% to 80% of oncology patients suffer from disturbed sleep, with particularly high prevalences reported for the initial treatment period and the palliative stage [866], [870], [871], [872], [873], [874]. The most common forms of disturbed sleep in cancer patients are difficulty falling asleep and staying asleep [872]. A limiting observation regarding these epidemiological data is that the methodology has been criticized for poor operationalization of sleep disturbances – most studies do not differentiate between sleep disturbance as a symptom and sleep disturbance as a diagnostic category [870], [875]. The two large studies that diagnosed insomnia according to the diagnostic manuals found prevalences between 21% and 43% [871], [874]. With regard to the entity, there is evidence that sleep is most frequently disturbed in carcinomas of the respiratory tract (head and neck, lung) and the

reproductive organs (breast, gynecological, prostate) [874], [871], [873], [866]. The latter are thought to be linked to hot flashes related to anti-hormone therapy [876], [877].

Sleep disturbances in cancer patients are closely associated with fatigue [878] as well as the quality of life [879]. They are mediators (the same as depressive symptoms) for the correlation between distress and quality of life [880] as well as between recurrent cancer and days of absence from work [877].

Despite this high clinical relevance, sleep disorders are underdiagnosed in cancer patients [869], [865]. In the outpatient setting, it has been found that sleep was addressed in conversation with health professionals in less than 1/5 of oncology patients with disturbed sleep [872] and in 2/3 of patients with significantly disturbed sleep [881]. A qualitative study confirmed the strong reluctance of cancer patients to discuss disturbed sleep with their oncologists. Patients believed that the doctor was not responsible for this symptom or would not be interested in it, and they did not want to „whine“ or disturb [882]. Pro-active, repeated screening of cancer patients for sleep disorders is therefore recommended [865].

If screening is positive, it is important to consider obstructive sleep apnea syndrome (OSAS) as a cause, as OSAS is associated with the development and progression of cancer [883]. In particular, a high prevalence of OSAS has been reported in patients following initial treatment of a head and neck tumors. Here, a meta-analysis of nine studies found a pooled prevalence of 71% (95% CI [48%; 86%], defined as apnea-hypopnea index ≥ 5 , [884]. See also the "S3 Guideline Non-restorative Sleep/Sleep Disorder", Chapter „Sleep-related Breathing Disorders in Adults" (AWMF register number: 063-001) [885]. In several case reports, central sleep apnea syndrome (CSAS) occurred with and following brainstem tumors [886], [887], [888]. It is debated whether treatment with opioids can also lead to CSAS. The relevant data are sparse and inconsistent. For example, a meta-analysis of studies examining non-oncologic pain patients receiving opioids found increased prevalences of CSAS (33%, 95% CI [3 – 72] vs. 3%, 95% CI [1 – 6]) and an increased Central Apnea Index (CAI) compared to pain patients not receiving opioids [889]. These studies are limited, however, by the low methodological quality of the meta-analysis and the small number of included studies (e.g. the prevalence of CSAS in pain patients without opioid medication is based on only one study).

If somatic symptoms such as pain, nausea, dyspnea or hot flashes can be identified as (co-)causes of the sleep disorder based on the medical history, it is recommended to optimize the treatment of these symptoms first. Recommendations for this can be found in the "S3-Guideline Supportive Therapy for Oncological Patients " (AWMF-Registerummer: 032/054OL) and regarding hot flushes in the guidelines "S3-Leitlinie Prostate Cancer" (AWMF-Registerummer: 043/022OL) and "Interdisciplinary S3-Guideline for the Early Detection, Diagnosis, Therapy and Follow-up of Breast Carcinoma" (AWMF-Registerummer: 032/045OL).

While the efficacy of Cognitive Behavioral Therapy (CBT) for insomnia has also been shown in cancer patients [868], [890], there is little empirical research on the tolerability and efficacy of psychotropic drugs for sleep disorders in cancer patients [865], [891]. This is of particular concern since a relevant percentage of cancer patients take sleep medication. In a study of 124 breast cancer patients undergoing chemotherapy, 32.3% were prescribed a sleep medication, most commonly lorazepam and zolpidem [892]. In another study of 219 breast cancer patients undergoing

chemotherapy, 12 – 23% reported taking a prescribed or over-the-counter sleep medication (depending on the agent and cycle of chemotherapy [893]).

A double-blind RCT with 53 breast cancer patients with sleep disturbances due to nocturnal hot flashes investigated 10 mg zolpidem vs. placebo for five weeks as an augmentation to pre-existing SSRI/SNRI medication, or 75 mg venlafaxine [894]. More patients in the augmentation group responded to treatment (40% vs. 14%, $p=.035$, defined as significant improvement on the Pittsburgh Sleep Quality Index and/or a reduction in wake time after sleep onset of ≥ 15 min as measured with an actigraph). Adverse side effects were reported by 60% in the augmentation group and 53.5% in the placebo group and were mild in severity, for example, nausea, fatigue, and dry mouth. Reliability of the findings is limited because a per-protocol analysis was performed and the placebo group in particular had a high dropout rate (43% vs. 12%).

A small RCT with 45 hematology patients with mucositis requiring opioids found self-reported improvement of duration, depth, and quality of sleep and reduced nocturnal awakenings when taking 2 – 3 mg eszopiclone (all $p < .05$) compared with the placebo over two days [895]. There were three participants per group who did not receive the second dose due to daytime sleepiness or confusion. No other adverse effects were reported

A double-blind RCT with 95 breast cancer patients after completion of active treatment found improved sleep while taking 3 mg melatonin compared with placebo (mean Pittsburgh Sleep Quality Index score -1.9 vs. -0.1) [896].

A double-blind phase III RCT with 227 cancer patients (mostly with breast cancer) on active antitumor treatment found good tolerability of 450 mg Valeriana officinalis (valerian) for eight weeks, but no difference in sleep quality [897].

An RCT with 96 cancer patients of different entities in remission over 47 days found no efficacy of 50 mg Armodafinil 2 x daily on the Insomnia Severity Index (ISI), neither as a monotherapy nor in combination with CBT ($p=.174$) [898].

9.1.4 Special Risks Regarding Side Effects and Interactions of Psychotropic Drugs in Cancer Patients

9.9	Consensus-based Recommendation	new 2023
EC	In the psychopharmacological treatment of cancer patients, an amplification of the side effects of underlying somatic disease and pharmacokinetic interactions with cancer treatment should be considered. In particular, seizure susceptibility can be enhanced, and the inhibition or induction of liver enzymes may affect the efficacy of anti-tumor substances.	
	Strong Consensus	

Consideration of side effects and interactions

Following the review by Grassi et al. [857], some of the side effects and interactions of antidepressant medications should be considered when determining the treatment indication for cancer patients (see Table 10). The indication should always be determined in close consultation with the patient's treating oncologist/general practitioner and, if necessary, with the consultation of a specialist in psychiatry and psychotherapy. For example, anticholinergic side effects (dry mouth, constipation) are particularly relevant in patients receiving pain therapy with opioids. Some antidepressants have a relevant effect on the conduction of impulses in the heart (QT time), the electrolyte balance (hyponatremia) or in the form of organ toxicities (e.g., hepatotoxicity), so that regular controls or risk-benefit considerations are necessary for this purpose. Especially against the background of demographic changes and multimorbidity, these aspects are becoming increasingly important in the treatment of mental illnesses in patients with somatic illness. Detailed information on this can be found in standard medical texts [899] and specific reviews [900].

Tamoxifen in breast cancer

A special treatment situation arises in breast cancer patients taking tamoxifen, as the potential for an increase in mortality has been observed here. The group of SSRIs shows considerable differences in terms of interactions with the cytochrome P 450 system. Potent CYP2D6 inhibitors prevent the transformation of tamoxifen (TAM) to the biologically active endoxifen, thereby reducing antitumor efficacy. In addition to in vitro studies, clinical relevance was observed in a retrospective study based on increased cancer-related mortality in breast cancer patients taking TAM and paroxetine, whereas no effect of citalopram, sertraline, fluvoxamine and venlafaxine on cancer-related mortality was observed [901]. Breast cancer patients taking tamoxifen should therefore not receive SSRIs or other drugs with strong or moderate inhibitory activity [901], [902], [903], [904]. Psychotropic drugs with moderate to strong CYP2D6 inhibitory activity include the antidepressants paroxetine, fluoxetine, bupropion and duloxetine, as well as the antipsychotics thioridazine, perphenazine and pimozide [902].

Table 11: Overview of Significant and Important Interactions:

P450 Inhibition or Induction:
Isoenzyme CYP2D6 is inhibited by several psychotropic drugs, particularly antidepressants. The decreased activation of tamoxifen was associated with increased mortality in breast cancer patients receiving antidepressants with moderate or high inhibitory activity [901].
Anticholinergic side effects may affect opioid tolerance [899].
Impaired cardiac conduction may require close monitoring – especially with electrolyte shifts in the scope of the cancer illness and treatment.
Pharmacodynamic interactions with cytostatics are not known, but antidepressants and antipsychotics may enhance the risk of seizures (and if there is another underlying disease as well).

9.1.5 Psychopharmacotherapy for Individuals at Increased Risk for Epileptic Seizures due to Malignant CNS Tumors or Cerebral Metastases

9.10	Consensus-based Recommendation	new 2023
EC	Before psychopharmacological treatment of patients with malignant CNS tumors or cerebral metastases, the following constellations should be considered: (1) potential psychological side effects of a concomitant anticonvulsant therapy and (2) potential interaction of the psychopharmaca with existing anticonvulsant therapy. The risk of seizures is particularly increased with tricyclic antidepressants and maprotiline; bupropion is contraindicated.	
	Strong Consensus	

Patients with malignant CNS tumors or cerebral metastases have a significantly increased risk for epileptic seizures. The risk depends on the location and histology of the tumor: especially tumors located in the parietal, temporal or frontal lobes of the cerebral cortex increase the risk. CNS tumors generally lead to a higher risk of seizures than metastases (see Table 10). Depending on the primary tumor, however, metastases may also be associated with a high risk of seizures, e.g., up to 67% risk of seizures in cerebral metastasized malignant melanoma [905].

Before starting psychopharmacological treatment, the following points should be considered: (1) possible causal significance of a concomitant anticonvulsant therapy for the psychiatric symptoms, (2) possible interaction of psychopharmaceuticals with concomitant anticonvulsant therapy, and (3) risk of triggering epileptic seizures from the psychopharma.cal.

Treatment with antidepressants

The overall risk of triggering epileptic seizures through treatment with antidepressants is low. Tricyclic antidepressants (mainly clomipramine and imipramine) and maprotiline are associated with an increased risk of triggering epileptic seizures. Bupropion increases the risk of epileptic seizures in a dose-dependent manner; there is a contraindication in patients with CNS tumors [Ratiopharm, 2019 SmPC: Bupropion], [Glaxo SmithKline, 2020 SmPC: Elontril]. SSRIs and other newer antidepressants may have more of an anticonvulsant effect at therapeutic doses [906], [907].

Treatment with antipsychotics

The effect of treatment with antipsychotics on seizure risk in patients with brain tumors has not been systematically studied. In a review of FDA phase II and III pivotal trials (non-oncology patients), clozapine (SIR 9.5; 95% CI 7.27 – 12.2), olanzapine (SIR 2.5; 95% CI 1.58 – 3.74), and quetiapine (SIR 2.05; 95% CI 1.21 – 2.03) were associated with an increased risk of epileptic seizures [908].

9.1.6 Risk of Bleeding Associated with Antidepressants

9.11	Consensus-based Recommendation	new 2023
EC	Patients with a high risk of bleeding should preferably receive antidepressants with low serotonin transporter affinity (e.g., bupropion, mirtazapine, trazodone, trimipramine) for the pharmacological treatment of depression.	
	Strong Consensus	

Bleeding is a common complication, particularly in advanced cancers. Antidepressants may influence the risk of bleeding through several mechanisms. To date, no studies have examined the risk of tumor associated bleeding with antidepressant therapy or the influence of antidepressants on the bleeding risk specifically in cancer patients. Therefore, extrapolation from studies of the general population is necessary. The best studied risk is with serotonin reuptake inhibitors, especially SSRIs.

Serotonin reuptake inhibitors

Serotonin reuptake inhibitors impair hemostasis primarily by inhibiting the reuptake of serotonin in platelets, thereby interfering with platelet aggregation as well as vasoconstriction in response to vessel wall injury. Other mechanisms will be discussed [909].

In a meta-analysis of 11 case-control and 11 cohort studies, Laporte et al. [910] found an increased risk (OR 1.41; 95% CI 1.27-1.57) of clinically relevant bleeding with SSRI use. The risk was highest for gastrointestinal bleeding (OR 1.55; 95% CI 1.32-1.81) and lower for intracerebral hemorrhage (OR 1.16; 95% CI 1.01-1.33).

In a meta-analysis of 8 cohort studies, Singh et al. [911] examined the risk of postoperative bleeding when taking serotonergic antidepressants. They found no significantly increased risk of reoperation due to bleeding complications (OR 1.48;

95% CI 0.84-2.62), but an increased risk of bleeding requiring transfusion (OR 1.19; 95% CI 1.09-1.30).

The risk of bleeding depends on a number of additional factors. Regarding the use of SSRIs, it has been shown that the risk of gastrointestinal bleeding is higher when SSRIs and NSAIDs are combined than when only one of the drug classes is used, and, that in the treatment with SSRIs alone as well as SSRIs + NSAIDs combined, the risk could be reduced below the significant threshold level with the additional administration of PPIs [912].

Other antidepressants

In a meta-analysis from Na et al. [913], patients taking mirtazapine had a higher risk of gastrointestinal bleeding compared with patients not taking antidepressants (OR=1.17; CI = 1.01 – 1.38). In the same study, no significant difference in bleeding risk was found between mirtazapine and SSRIs or between bupropion and SSRIs.

In contrast, van Walraven et al. [914] and Wang et al. [915] found an association between the affinity of antidepressants for the serotonin transporter and the risk of gastrointestinal bleeding.

In summary, an increased overall risk of bleeding during treatment with serotonergic antidepressants is well established. Patients with other risk factors for bleeding should preferably be treated with antidepressants that have a low affinity for the serotonin transporter (e.g., bupropion, mirtazapine, trazodone, trimipramine). In particular, the individual risk for gastrointestinal bleeding should be considered and prophylactic administration of PPIs should be considered.

9.2 Occupational Therapy

9.12	Consensus-based Recommendation	modified 2023
EC	Occupational therapy can be offered to cancer patients with limitations in the activities of daily living in order to improve quality of life.	
	Strong Consensus	

The central task of occupational therapy is to maintain, stabilize, or restore a person's (client's) ability to function as a prerequisite for participation in the various areas of life.

Occupational therapy measures therefore always focus on activities that are important for the individual and which they need to manage everyday life (activities).

The most important methods in occupational therapy are specific activities (e.g. ADL training, creative/design measures, [senso-]motoric or cognitive training, work-related measures); environmental modification/compensation/adaptation (provision of therapeutic aids, adaptation of the home, the workplace); and counseling/education/training (e.g. time, energy, stress management, instructing relatives, behavioral interventions).

Here, the intersection with psychoeducational, neuro-psychological and body-based therapies, such as physiotherapy, also becomes visible [916]. However, the main domain of occupational therapy is activation, both nationally and internationally [916]. Occupational therapy can be implemented in oncology in all disease phases and settings, including palliative care units [917]. It follows a client-centered, resource-oriented approach, and a bio-psycho-social understanding of health (International Classification of Functioning, Disability and Health, ICF).

Based on a systematic search conducted in the course of the first version of the S3 Guideline Psycho-oncology, four randomized controlled trials ([918], [919], [920], [921]), up to and including 2011 with a total of 95 participants (majority with breast cancer), reported initial positive effects of occupational therapy, e.g. on the management of concomitant symptoms (range of motion, fatigue), mood, and health-related quality of life.

For the current guideline, five additional RCTs ([922], [923], [924], [925], [926]) between 2011 and 2020 with a total of 543 participants were identified along with The Occupational Therapy AOTA Guideline [917] for the Rehabilitation of Adult Cancer Patients, which is based on two systematic reviews [927], [928].

Evidence exists for longer, i.e., multi-week, multimodal occupational therapy group programs that link multiple components (e.g., client-centered ADL training, shared leisure activities, education, relaxation training, teaching energy-management strategies, exercise, and creative arts activities).

Such a program improved overall quality of life in patients with breast cancer, including the role function, emotional functioning, fatigue, and sleep (all subscales of the EORTC QOQ-C30), as well as breast symptomatology and the side effects of therapy. Involvement in meaningful activities also improved significantly [925].

Patients with metastatic prostate cancer receiving ongoing hormone therapy also had better quality of life after such a program and showed significant improvements in carrying out activities important to them and being satisfied with them (in the Canadian Occupational Performance Measure/COPM). Concomitant symptoms of therapy (relating to sexual activity, incontinence) were also significantly reduced [923].

Several RCTs investigated occupational therapy group programs to reduce fatigue as a primary endpoint:

Here, a multi-week program for breast cancer patients proved to be effective, significantly reduced fatigue, and promoted a healthy lifestyle. It included education; the planning/teaching/evaluation of energy-management strategies; activity/break management, daily structuring, and homework (monitoring symptoms, prioritizing activities) [924].

One study examined at what point fatigue management/education produced the best results in people receiving radiation therapy for various cancers. The group program consisted of: a one-time education session, a manual, a goal-setting sheet, and a diary to document one's progress, as well as two follow-up calls. The control group also received: a one-time individual educational intervention about the radiation therapy process and their individual diagnosis, a flyer on fatigue, and standard written information about radiation therapy. The study found no improvements or differences in fatigue between groups or between time points. However, participants

who received the intervention prior to radiation participated significantly more in moderate and vigorous physical activities (participation) during the radiation phase, whereas participation decreased in participants who did not receive the program prior to radiation [922].

In acute care, occupational therapy interventions, e.g. after surgery, can also be provided on a visiting basis at the patient's bedside. The focus at this time is, for example, practicing self-care skills (activities of daily living/ADL, such as dressing and personal hygiene); adapting the patient's (immediate) environment; planning any necessary modifications in the home environment; developing/practicing strategies to compensate for limited bodily functions and/or skills (e.g., through the use of assistive devices). Here, for example, strategies for problem-solving can be developed which improve the patient's participation in daily life and have a stabilizing effect on their mental state [919].

One RCT [926] investigated a short occupational therapy program (strategy teaching/training) in the home environment for people with different oncological diagnoses in advanced stages compared to standard care. This did not result in significant improvements in ADL performance, quality of life, or autonomy and participation compared to standard outpatient care (home or palliative care, or outpatient rehab including occupational therapy if needed). The majority of participants received only one home visit (77 of 113) and one phone call (62 of 113) as part of the intervention.

The American Occupational Therapy Association (AOTA) Guideline reports strong evidence for improvement in function and participation through multidisciplinary rehabilitation programs (including occupational therapy) [928]. This is valid regardless of the entity and stage of the cancer or the age of the patient.

Moderate evidence also exists for the use of cognitive interventions within integrated rehabilitation programs to improve attention, cognitive performance, and quality of life [917], [928].

For reducing symptoms (such as shortness of breath, fatigue, or pain) associated with cancer or its treatment, the AOTA Guideline reports moderate to strong evidence that exercise programs, cognitive-behavioral therapy, and techniques that train patients to use their resources are effective intervention components [917].

In addition, there is strong evidence that psychosocial strategies, including cognitive-behavioral therapy and educational interventions (e.g., problem solving, knowledge about the disease, and side effects), can reduce anxiety >3 months and depression 1-3 months after treatment [928].

Moderate evidence exists for the effectiveness of a variety of psychosocial interventions (including mindfulness-based interventions, brief life review with terminally ill patients, stress management program, or expressive writing in breast cancer survivors) on improving quality of life, well-being, psychosocial adjustment, and reducing anxiety and depression [917]; [928].

Limited evidence exists for occupational therapy interventions that focus on social participation and vocational reintegration regarding quality of life and the return to work after breast cancer [917]; [928]. Measures for reintegration and returning to work (e.g., job coaching, workplace counseling) are an important concern for cancer survivors (see [929]; [235]; [930]; [928]).

Problems following adjuvant oncological therapy, such as neuropathies in the hands and feet or limited range of motion (e.g., in breast cancer), can be treated with sensorimotor-perceptual approaches [\[931\]](#).

In addition to regaining the greatest possible independence in activities of daily living, the reentry into working life – when possible – (e.g., through brain performance training, counseling on dealing with fatigue, vocational preparation measures) and the resumption of desired social roles are also initiated.

Particularly important, especially in post-acute care, is how a person can optimally cope with existing difficulties and possible long-term limitations, e.g., due to neuropathies/CIPN, fatigue, or neuropsychological deficits; how they can continue to perform desired activities in a way that provides meaning and satisfaction; whether and how contextual factors can be adapted (e.g., living space, workplace, involvement of relatives); and what skills and abilities can be relearned in order to lead a life as self-determined as possible with maximum quality of life and social participation in all areas of their life.

In the palliative situation, methods and aids can be offered to maintain the highest possible level of quality of life, self-determination and (spiritual) well-being, especially with regard to depression and anxiety reduction.

10 Specifics of Individual Diagnosis Groups and Their Treatment

10.1	Consensus-based Recommendation	checked 2023
EC	All patients with specific impairments shall be diagnosed according to recommendations 7.1. to 7.6. with regard to the specific psychosocial stress.	
	Consensus	

At this point, reference should be made to specific physical impairments and the resulting mental burdens of individual tumor diagnoses resulting from the tumor condition or the respective tumor-specific treatment. Depending on their specific characteristics, these can have an impact on the mental state and/or social situation of patients. These include, in particular, treatment-related sexual dysfunction, stress due to the permanent creation of a stoma, impairment due to high-dose chemotherapy followed by stem cell transplantation, removal of the larynx, as well as treatment-related impairment of patients with gastrointestinal tumors, patients with non-small-cell bronchial carcinoma after lung resection, and patients with brain tumors. Special treatment situations may also arise in young adult cancer patients, so-called 'Adolescents and Young Adults' (AYAs), geriatric cancer patients, and people living with a cancer diagnosis (Cancer Survivors). In the context of all these specific burdens, there could arise psycho-oncological treatment needs, which are briefly discussed below.

10.1 Sexual Disorders

10.2	Consensus-based Recommendation	checked 2023
EC	Patients with sexual disorders should be offered sexual counseling in addition to the recommendations in Chapter 8 .	
	Strong Consensus	

Sexual dysfunction falls under the specific impairments that can occur in connection with various cancers. They basically have an influence on the patient's self-esteem, body image, and perceived sexual attractiveness, and thus also their quality of life. In particular, the sexual functions, such as appetite, lubrication, dyspareunia, erection or orgasm can be impaired, accompanied by negative effects on the relationship of the couple.

10.1.1 Sexual Dysfunction Associated with Breast Cancer and Gynecological Tumors

As a result of treatment, disorders of sexual function and body image and, consequently, self-esteem may occur. In addition, loss of fertility can result from the treatment of gynecological tumors. It should be taken into account that the

gynecological treatment situation differs from many other medical interventions in that a particularly self-related, emotional area is touched [932], [933].

The recommendations of the following guidelines apply to the treatment of patients with gynecologic tumors:

S3 Guidelines:

"Early Detection, Diagnosis, Therapy and Follow-up of Breast Carcinoma" (AWMF register number: 032 - 045OL, <https://www.awmf.org/leitlinien/detail/II/032-045OL.html>)

"Diagnosis, Therapy and Follow-up of the Patient with Cervical Carcinoma" (AWMF register number: 032 - 033OL, <https://www.awmf.org/leitlinien/detail/II/032-033OL.html>)

"Endometrial Carcinoma" (AWMF registry number 032 - 034OL, <https://www.awmf.org/leitlinien/detail/II/032-034OL.html>)

"Diagnosis, Therapy, and Follow-up of Malignant Ovarian Tumors" (AWMF registry number: 032 - 035OL, <https://www.awmf.org/leitlinien/detail/II/032-035OL.html>)

S2k Guidelines:

"Uterine Sarcomas" (AWMF Registry Number: 015 - 074, <https://register.awmf.org/de/leitlinien/detail/015-074>)

"Vulvar Carcinoma and its Precursors, Diagnosis and Therapy" (AWMF register number: 015 - 059OL, <https://register.awmf.org/de/leitlinien/detail/015-059OL>)

In patients with **breastcarcinoma**, negative effects on body image after surgical breast cancer treatment are common [934]. Especially during the first year after the diagnosis, patients experience worry and uncertainty due to physical changes [935]. The extent to which patients experience different levels of body image distress after mastectomy, BET and reconstruction is not uniformly described in the literature [936], [937], [938], [939], [940], [941], [942].

Patients also show lower satisfaction with their sexuality. Radiation therapy treatment may also affect body image in association with radiation fibrosis, increased skin pigmentation, or dilation of blood vessels. As a result of adjuvant chemotherapy and depending on the agents administered, patients feel impaired by sexual dysfunction such as decreased appetite, lack of vaginal lubrication, or dyspareunia. Antiestrogen use can lead to typical menopausal symptoms, with vaginal dryness, in particular, causing pain during sexual intercourse [943].

In the case of **cervical carcinoma**, patients' sexuality is particularly affected if extensive surgery had to be performed and adhesions in the surgical area or shortening of the vagina have occurred. In addition, surgery-related nerve injury can interfere with lubrication. Radiation therapy treatment can cause radiation fibrosis or fistula formation and make vaginal tissue more susceptible to infection. All of these treatments, as well as pain, can make sexual intercourse very difficult [944], [945].

In patients with **endometrial carcinoma**, depending on the stage of the tumor, a surgical procedure is performed in which the uterus, ovaries and fallopian tubes are removed and, if necessary, followed by radiation and/or chemotherapeutic treatment,

depending on the initial situation. These interventions can massively affect the patients' sexual activity (see above).

The treatment of **ovarian carcinoma**, which usually involves bilateral ovariectomy, can result in atrophy and inadequate dilatation of the vulva as well as inadequate lubrication due to the estrogen deficiency that occurs. In addition, adhesions may occur in the surgical area and, as a result, pain may occur during sexual intercourse. Removal of the ovaries results in menopause in patients who had menstrual periods before the operation and is accompanied by typical menopausal symptoms [946].

In patients with **vulvar carcinoma**, radical vulvectomy usually leads to massive impairment of normal sexual intercourse and dyspareunia [947].

10.1.2 Sexual Dysfunction Associated with Urologic Tumors in Men

Numerous effects on sexuality can be expected from existing treatment methods in the uro-oncology. This also applies to surgical measures, especially when neuronal structures that are essential for sexual sensation and sexual responsiveness (e.g., in the context of radical prostatic vesiculectomy or cystectomy) are compromised or removed. Changes in body image associated with surgical procedures (e.g., semicastration, complete or partial penectomy) should also be considered as causes. Radiation and chemotherapeutic agents also have a negative effect on sexual function and fertility [948]. Finally, various hormone therapies (especially LHRH analogues) should be mentioned which may cause sexual dysfunction.

For the treatment of patients with urologic tumor diseases, the recommendations of the following S3 guidelines apply:

- „Prostate Cancer“ (AWMF Registry Number: 043 – 022OL, <https://www.awmf.org/leitlinien/detail/II/043-022OL.html>),
- „Early Detection, Diagnosis, Therapy and Follow-up of Bladder Carcinoma“ (AWMF register number: 032 – 038OL, <https://www.awmf.org/leitlinien/detail/II/032-038OL.html>),
- „Diagnostics, Therapy and Follow-up of Germ Cell Tumors of the Testis“ (AWMF Registry Number: 043 – 049OL, <https://www.awmf.org/leitlinien/detail/II/043-049OL.html>) and Guideline
- „Diagnosis, Therapy and Follow-up of Penile Carcinoma“ (AWMF registry number: 043 – 042OL, <https://www.awmf.org/leitlinien/detail/II/043-042OL.html>).

Treatment of **prostate cancer** may directly affect sexual functioning. If a prostatic vesiculectomy is performed for a localized tumor, this may be associated with loss of erectile function. Accordingly, patients are often concerned about the sexual consequences of the disease and its therapy [949], although the fears regarding sexual impairment are often greater than those regarding the actual dysfunction [950].

Tal et al. [950] described in their meta-analysis the proportion of patients who regained erectile function after radical prostatectomy. A total of 22 high-quality studies (n = 4,983) were identified. The rate of patients who regained normal erectile function postoperatively was found to be 58%. The surgical procedure (open vs. laparoscopic) had no influence. Age showed a protective character. Even with nerve-sparing procedures, surgery carries a risk of sexual dysfunction that is difficult to assess. However, the ability to orgasm is not necessarily lost. Radiation therapy treatment may cause vascular damage to the blood vessels in the corpus cavernosum,

resulting in erectile dysfunction, pain during ejaculation, or inflammatory changes. As a result of surgery as well as hormone treatment in advanced stages, there is a decrease or even complete disappearance of sexual desire [951], [952], [953], [954].

It stands to reason that **bladder cancer** has an impact on sexual satisfaction and functioning. Botteman et al. [955] note the lack of studies on this topic and state that impairment in sexual quality of life is common in both superficial and invasive bladder cancer. If a cystectomy has been performed for bladder cancer, sexual dysfunction is a significant problem. Depending on the radical nature of the surgery, men experience erectile dysfunction and even impotence. [956], [957], [958].

Two older reviews of sexual function after **testicular tumor** specifically address the question of what disorders are common after testicular cancer. Jonker-Pool et al. [959] indicate that ejaculatory dysfunction (44%) is particularly common. A decrease in sexual activity, orgasmic disturbances, dissatisfaction with sexuality, and a reduction in sexual appetite are shown by 19 to 24% in retrospective studies and 9 to 18% in prospective studies. A systematic review by Nazareth et al. [960] also reports that the odds ratio for impaired ejaculatory ability is 28.6% at two years postintervention. The rate for orgasmic dysfunction is reported to be 4.6 and the rate for erectile dysfunction is 2.5. A large proportion of patients with testicular carcinoma already have spermatogenesis disorder at the time of diagnosis. If chemotherapy is required, approximately one-quarter of patients remain azoospermic. If patients were fertile at diagnosis, only half regain normal spermiogenesis after two years. If damage to the sympathetic border cord occurs due to removal of the retroperitoneal lymph nodes, this can lead to loss of antegrade ejaculation [953].

Surgical therapy is usually chosen for the treatment of **penile carcinoma**. Depending on the extent of the disease, surgery ranges from removal of the tumor to complete penile amputation. Penile carcinoma has a massive impact on sexual functioning and satisfaction. In a study by Romero et al. [961], it was shown that as many as 55.6% of patients maintained erectile function and sexual intercourse took place. 2/3 of patients reported sexual desire equivalent to that before surgery. In contrast, only one-third of patients had sexual intercourse with a frequency and satisfaction similar to that before surgery. The reason for impaired sexuality was often shame because of postoperative penile length and the absence of the glans penis. In a review by Maddineni et al. [962], a frequency of impaired sexual function is described in about 2/3 of those affected [963].

10.1.3 Sexual Disorders associated with Malignant Lymphomas and Leukemias

Patients suffering from malignant lymphoma who receive intensive chemotherapy, possibly in combination with radiation therapy, must expect damage to their sexual organs. Chemotherapy affects the function of the ovaries in women and the testicles in men. The extent of impairment and the length of recovery depend on the total dose of agents administered, as well as the age and general physical condition of the patient's body.

Chemotherapeutic treatment of **acute lymphoblastic leukemia** (ALL) or **acute myeloid leukemia** (AML) shows impairment of sexual function in men. For example, germinal cell aplasia with azoospermia occurs after induction chemotherapy, although this usually resolves in the 2nd year of maintenance therapy. High-dose chemotherapy combined with total body irradiation usually has irreversible

consequences on fertility. Irreversible germinal cell aplasia occurs. In women, ovarian insufficiency occurs in many cases.

10.1.4 Sexual Dysfunction associated with an Ileostomy, Colostomy, or Urostomy

The creation of an **ileostomy, colostomy or urostomy** usually means a radical change in the patient's life. In connection with this, many stoma carriers experience a strong negative perception of their body image. As a result, the affected patients are challenged to come to terms with their changed body image. This is all the more difficult the more massive the disfigurement is perceived to be and the more impairing the functional limitations (e.g. in the sexual sphere) are. It is precisely this outwardly visible body change caused by a stoma that often makes acceptance difficult and leads to adjustment disorders and even persistent depression. For some of those affected, feelings of shame and disgust, as well as fear of dirt and odor, or the fear of uncontrollable noise development become a great psychological burden, which in turn has a serious inhibiting effect on the need for intimacy. In this respect, stoma patients often feel that their sexual life is negatively burdened by the stoma [964], [965]. The patient's self-esteem can be significantly reduced by a stoma, so that physical, sporting and social activities, as well as taking up a job, are experienced as difficult and stressful and lead to mental impairments.

10.2 Impairments after High-dose Chemotherapy Followed by Allogeneic Stem Cell Transplantation

High-dose chemotherapy followed by allogeneic **stem cell transplantation**, together with „conditioning“ and subsequent transfusion of the stem cells, can trigger a specific, serious immunological complication, the so-called GvH reaction (Graft versus Host Disease, GvHD for short). Transplantation-associated problems manifest as severe infections and changes in the mucous membranes of the gastrointestinal tract and liver, as well as visible changes in the skin. These external changes can lead to feelings of shame and impaired self-esteem and promote withdrawal behavior and social isolation. In addition to the effects of transplantation, such as pronounced fatigue, the loss of libido and sexual dysfunction, and, for younger patients, the often unfulfillable desire to have children, place an enormous mental burden [966], [967], [968].

10.3 Impairments After Removal of the Larynx in Laryngeal Carcinoma

If the **larynx** is removed as a result of laryngeal **carcinoma**, the mental distress caused by such an operation is associated with drastic consequences for the rest of life. In addition to a limited sense of smell and taste, the permanent loss of the voice is in the foreground, and with it, the loss of the ability to communicate and thus the associated social functioning. This can lead to a severe impairment of self-esteem and social isolation. With appropriate aids, patients can learn to communicate again. Nevertheless, for many patients, a permanent impairment of quality of life remains [969].

The follow-up appointments are also often associated with anxiety and stress for the patients and their relatives, as these appointments lend particular weight to the

disease that has been experienced and give rise to uncertainty as to whether they will remain tumor-free.

The psychosocial problems described here also apply, with slight differences, to patients with other head and neck tumors, such as pharynx or oral cavity, who are also an important target group for psycho-oncological support.

10.4 Specific Burdens Resulting from the Treatment of Patients with Gastrointestinal Tumors

Patients with **esophageal cancer** who have undergone surgery or conservative radiochemotherapy quite often suffer from dysphagia and weight loss. Reflux due to the lack of cardia function is also common. It is also possible that the nerves of the vocal cords may be damaged, thus resulting in impaired voice production.

Pronounced reflux symptoms can also cause major problems for **gastric cancer patients** who have undergone subtotal resection or gastrectomy whereby the cardia has been removed.

The side-effects of surgery in patients with **colon carcinoma** are often diarrhea and voiding dysfunction, or even incontinence as well as meteorism. After adjuvant chemotherapeutic treatment, severe neurological sequelae often develop which may cause long-term stress to the patient and lead to occupational disability [970].

Patients with a **rectal cancer** can also experience a multitude of highly stressful side effects as a result of a multimodal treatment, some of which permanently restrict their quality of life. These also include considerable problems with defecation, which leads to great uncertainty among patients and in many cases prevents them from going about their daily lives outside their own homes and participating in a social life.

Patients with **pancreatic cancer** who have undergone surgery often have a disturbance of the exocrine and endocrine functions of the pancreatic remnant. This leads to digestive disorders such as diarrhea, fatty stools, and meteorism, as well as various degrees of diabetes mellitus.

A large part of the treatment-related sequelae that patients with **gastrointestinal tumors** suffer from can have an enormous impact on their quality of life. In particular, the experienced loss of control over excretory functions is accompanied by pronounced feelings of shame and insecurity. This can have a considerable impact on sexuality and relationships, as well as on social and professional activities. In light of this, depressive and anxiety-related disorders among patients with gastrointestinal tumors can be explained. A prospective study by Krauß and colleagues at the University Hospital for Surgery in Leipzig shows that 19% of patients fulfilled the criteria of one or more mental disorders according to ICD10, of which 10% had an immediate relevance for psycho-oncological treatment [970].

For the general treatment of patients with gastrointestinal tumors, the recommendations of the following S3 guidelines apply:

„Diagnosis and Therapy of Squamous Cell Carcinoma and Adenocarcinoma of the Esophagus“ (AWMF Registry Number: 021 – 023OL, <https://www.awmf.org/leitlinien/detail/II/021-023OL.html>),

- „Gastric Carcinoma – Diagnosis and Therapy of Adenocarcinomas of the Stomach and Esophagogastric Junction“ (AWMF registry number: 032 – 009OL, <https://www.awmf.org/leitlinien/detail/II/032-009OL.html>),
- „Colorectal Carcinoma“ (AWMF registry number: 021 – 007OL, <https://www.awmf.org/leitlinien/detail/II/021-007OL.html>),
- „Diagnosis and Therapy of Hepatocellular Carcinoma and Biliary Carcinoma“ (AWMF Registry Number: 032 – 053OL, <https://register.awmf.org/de/leitlinien/detail/032-053OL>).

10.5 Specific Burdens of Patients with Bronchial Carcinoma after Lung Resection

In addition to surgical pain and decreased physical activity tolerance, the cardiac load also increases for these patients together with increasing lung parenchymal loss and associated decreased oxygen uptake. Increasing degrees of exercise-induced dyspnea, exacerbated by exercise or fatigue-induced tachycardic arrhythmias, are often associated with disturbances in self-concept and body image, sexuality, and overall major limitations in social interactions. Experiencing these highly stressful physical limitations often triggers marked anxiety and depression, necessitating psycho-oncological co-treatment [971], [972].

The follow-up appointments are also often associated with anxiety and stress for the patients and their relatives, as these appointments lend particular weight to the disease that has been experienced and give rise to uncertainty as to whether they will remain tumor-free.

10.6 Specific Burdens on Patients with Brain Tumors

Brain tumor patients and their relatives suffer not only from the burdens of cancer, such as a limited prognosis and the stressful therapies, but also from the fact that the self, one's own identity, is affected. Therefore, the neurological and neuropsychological limitations have a different quality than physical symptoms. In addition to motor function, sensory function, or speech; memory, attention or personality can also be affected and have a significant negative impact on everyday life and the quality of life. Regardless of the tumor grade, fatigue, lack of drive, memory difficulties, sleep disturbances and stress are among the most serious problems during the course of the disease [973].

Acutely, there are always crisis events in the course of the disease. Goebel reports that 23% of the patients had an acute stress reaction according to DSM-IV criteria at the beginning of therapy and another 4% had subsyndromal values. 57% of patients reported that discovering the tumor or receiving the diagnosis was the most stressful event [974]. A prospective screening study of 472 patients undergoing brain tumor surgery showed depressive symptoms in 7% and anxiety symptoms in 12% during the inpatient postoperative course, with a threshold score of ≥ 11 on the HAD scale. However, subjective distress was 63% on the Distress Thermometer (≥ 5) regardless of the size of the diagnosed brain tumor [975]. In the outpatient setting, progression anxiety has a high rate of about 40%. Regardless of sociodemographic data and tumor characteristics, the greatest worries are those about one's family and fear of medical treatment. Additionally, patients with high progression anxiety scores were more anxious and depressed and reported a poorer quality of life [976].

Over the long-term, the pooled prevalence of psychosocial distress was 38.2% in a meta-analysis by Liu [977]. The pooled prevalence for depression of brain tumor patients was 21.7% and remained unchanged over the long-term course [978].

Not only the patients suffer from the aforementioned problems and symptoms, but also the social environment as well. A review by Applebaum shows that relatives of brain tumor patients are already particularly burdened at an early stage of the disease. Existential issues are: identity, isolation, responsibility and guilt, fear of death, meaning of the disease and spirituality [979].

Established screening instruments can also be applied to brain tumor patients, although only the Distress Thermometer has been validated for brain tumor patients [467]. The problem list has recently been adapted to the special distress factors of neuro-oncological patients and, among other items, has been supplemented by the subject „Epilepsy“ as well as by the rubric „Neuropsychological Problems“ [980]. Within the framework of a multicentric study, the stress thermometer adapted for neuro-oncological patients will be validated in the German-speaking region in the near future.

The effectiveness of general psycho-oncological interventions is well documented. However, there are hardly any specific offerings for brain tumor patients. In the review by Pan-Weisz, only two RCT's (home-based psychosocial intervention and individualized acupuncture with standardized rehabilitation, respectively) showed an improvement in health-related quality of life. Overall, the development and evaluation of specific interventions has clearly remained behind those of more common cancers, but first small studies encourage that, for example, physical activity [981], [982], [983] of brain tumor patients is safely feasible and beneficial.

10.7 Specific Burdens on Young Adult Cancer Patients (AYAs)

The specific burdens on AYAs relate in particular to fertility and family planning issues [984]. They may also have to deal with loss of autonomy, changes in relationships, and interruptions in education. In some cases, this may be coupled with financial losses and economic problems [985], [986]. When addressing fertility issues, questions of sexuality or sexual dysfunction, sexual identity, body image, and contraception must also be considered.

In particular, therapy must be coordinated on a multidisciplinary basis [987]. In young breast cancer patients, it must be considered that the rate of genetic related cancers is higher than in older women and also requires special counseling and planning with regard to family planning aspects. More often (than in older women > 40 years), tumors are also diagnosed at more advanced tumor stages [987]. Promoting social integration of AYAs after a cancer illness is important to prevent social isolation and to maintain or restore the patient's quality of life. If the opportunities to participate in social life remain largely unrestricted, this has a positive effect on psychological well-being. Psychosocial interventions to improve participation opportunities should be offered to particularly vulnerable patients and should be age-specific [988], [989].

It should be noted that long-term AYA survivors can also develop long-term depression and anxiety (see [Chapter 10.9](#)), which means that the cancer diagnosis can also have a decisive impact on their future.

The Internet and social media are an important source of information for this group of patients [990].

10.8 Specific Burdens on Older Cancer Patients

More than half of all cancer patients are older than 65 years [991]. However, as this group of patients is underrepresented in studies [992], there is little concrete data on their needs during cancer treatment [993]. Although coping with cancer is often better in older people than at a younger age (see above) [994], the parallel occurrence of age-related co-morbidities can pose an independent stress factor. Consequently, this may lead to increased distress, depression and anxiety [995]. The effects of aging in combination with cancer may cause an increased vulnerability to anxiety and depression [996]. Increased suicidality should be taken into account in older cancer patients, as older cancer patients have the highest rate of completed suicide [997], [747]. At the same time, depression decreases the adherence to therapy and thus the prognosis the patient as well. However, it is often difficult to correctly diagnose depression in elderly patients and to adequately treat it consecutively, the episodes are often more severe and recurrences occur more frequently [998]. The symptomatology may vary in older people („depression without sadness“) [999].

A geriatric assessment can help to identify specific features [1000].

10.9 Specific Burdens on People Living with a Cancer Diagnosis (Cancer Survivors)

10.3	Consensus-based Statement	new 2023
EC	Long-term cancer survivors may continue to suffer from ongoing emotional, physical and functional problems, and unmet needs that significantly impact the quality of life many years after treatment and diagnosis of their disease.	
	Strong Consensus	

10.4	Consensus-based Recommendation	new 2023
EC	The emotional, physical, functional, and social problems of long-term cancer survivors should be identified in the various care settings in order to determine a need for counseling and treatment and to offer the appropriate provision of care.	
	Consensus	

10.5	Consensus-based Recommendation	new 2023
EC	The interventions outlined in Chapter 8 shall also be offered to long-term cancer survivors in long-term follow-up care.	
	Strong Consensus	

The working group „Long-term survival after cancer“ (WG LONKO) in the National Cancer Plan bases its definition of „Survivor“ on that of the National Coalition for Cancer Survivorship (NCCS), according to which every patient with a cancer diagnosis is a cancer survivor. However, a classification into different phases makes more sense: pre/post-treatment, acute, intermediate and long-term survivorship. Survivor status includes cancer-free survival, sustained remission, and living with (chronic) cancer. The close social network of the patients is referred to as „secondary survivors“.

Most long-term cancer survivors cope very well with their life after the disease and therapy, but a substantial proportion suffers from persistent cancer-associated anxiety, post-traumatic stress, as well as anxiety disorders or depression that impair the (health-related) quality of life [\[1001\]](#), [\[1002\]](#).

Long-term survivors suffer from emotional (anxiety, depression, sexual or body image disorders), physical (fatigue, cognitive impairment, neurotoxicity), and functional problems (limited mobility), of which 38% reported problems in all domains. Only 7% reported having no problems. 63% of respondents reported unmet needs in all three areas, and 79% received no help for these [\[1003\]](#). Long-term

survivors are at increased risk for persistent severe psychological distress, anxiety, and depression even 5 and 10 years after therapy ([1004], [1005], [1006], [1007]).

Psychological stress and anxiety may even increase over the years following the initial diagnosis [1008], [1009] or their intensity does not diminish with time ([1010]). Anxiety and distress affect all survivor groups (young adults, employed, childhood cancer survivors, adult long-term survivors) and all entities, but the quality of study data varies considerably [1002]. In the CCCS (Childhood Cancer Survivor Study), 11% of survivors showed anxiety or depressive symptoms compared to only 5% of healthy siblings [1011]. The corresponding Danish study, which examined longitudinal outcomes, found that just under 9% of adult CCS had persistent depression and just under 5% had anxiety ([1012]). Among hematologic AYAs, for example, 28% met criteria for depression, 23% for anxiety disorder, and 13% for PTSD [1013]. Other studies arrive at inconsistent results due to differences in populations, methods, and measurement tools.

Among older survivors (> 40 years), 18-20% have anxiety symptoms [1014], [1015], [1016]. Posttraumatic stress symptoms are common, whereas manifest disorder is rare. However, a meta-analysis showed that PTSD is more common among survivors than healthy controls [1017]. Up to 80% of former patients suffer from recurrence anxiety [1018], especially at follow-up appointments [1019]. According to a meta-analysis [1020], 16% of survivors in a non-palliative situation suffer from manifest depression.

Cancer-related cognitive impairments such as impaired short-term memory, executive function, attention or processing speed are also common symptoms reported by cancer survivors and negatively affect their quality of life (in terms of returning to work, social relationships, self-satisfaction). Most of the data here come from studies with breast cancer patients after chemotherapy [1021]. Cognitive complaints are reported in more than 50% of cases, but these can only be objectified in 15-25% of cases [1022]. There is also evidence that modern hormonal therapies, immune, or targeted therapies have an impact on cognitive abilities [1023], [1022]. It remains unclear whether the deficits result from the disease itself, therapy, and/or psychological factors. Factors such as age, genetic polymorphisms, and psychosocial components appear to predispose to a higher risk of cognitive dysfunction [1022].

Fatigue is the most common and distressing symptom complex described by cancer patients during the course of their disease, from diagnosis to the end of life. During active tumor treatment (chemotherapy and/or radiotherapy), 80-90% of patients report fatigue; at the time of diagnosis about 40% [1024]. However, hormone therapies, targeted therapies, or immunotherapies are also discussed as a cause of fatigue, especially if they are administered as combination therapy [1025]. One third of patients report persistent fatigue even several years after the end of therapy [1026].

11 Patient-centered Communication

11.1	Consensus-based Statement	modified 2023
EC	Patient-centered communication refers to an approach in communicating that perceives the patient in their current physical, emotional and social situation, takes into account their personal values, needs and preferences, and promotes their self-competence, ability to act and make decisions.	
	Strong Consensus	

11.2	Consensus-based Recommendation	modified 2023
EC	All professional groups working in oncology shall communicate with cancer patients and their relatives in a patient-centered manner, i.e. oriented towards the individual concerns, needs, values and preferences of patients and relatives with regard to information, education and participation in decision-making.	
	Strong Consensus	

11.3	Consensus-based Recommendation	modified 2023
EC	The communicative preferences of cancer patients and their relatives shall be assessed regularly during the course of the disease, especially in critical phases (diagnosis, progression/recurrence).	
	Consensus	

11.1 Basic Principles and Use of Patient-centered Communication

11.4	Consensus-based Recommendation	modified 2023
EC	Patient-centered communication shall be guided by the following basic principles: • Creating an appropriate, undisturbed environment for conversation • Sufficient time • Establishing a sustainable, supportive relationship with the patient and family members • Conducting the conversation on the basis of active listening • Exploration of the patient's subjective level of information • Direct and empathetic addressing of emotionally stressful topics • Conveying important information in a comprehensible language that is as simple as possible • Honest communication of risk and prognosis, leaving room for realistic hope • Using strategies to ensure patient understanding and retention of information • Encouragement to ask questions • Encouragement to express feelings • Expressing emotional support • Reassurance that the patient has understood the relevant information in the intended way • Involving relatives or caregivers depending on the patient's wishes. • Offering further psychological and social services	
	Consensus	

11.5	Consensus-based Recommendation	new 2023
EC	To promote patient-centered communication, empirically proven tools such as lists of questions, information brochures, fact boxes, or decision aids can be used during a consultation.	
	Consensus	

11.6	Consensus-based Statement	new 2023
EC	In the context of the digitalization of the health care system, digital media are being used more frequently for communication between practitioners and patients. Interaction via digital media has some special features. These include, for example, the tendency to use short, concise sentence fragments and the frequent use of abbreviations. These peculiarities can limit the quality of patient-centered communication. Patient-centered communication via digital media thus requires a reflective attitude and approach.	
	Strong Consensus	

11.7	Consensus-based Recommendation	new 2023
EC	Breaking bad news shall not take place on the phone or via digital media, rather through in a personal contact.	
	Strong Consensus	

11.8	Consensus-based Recommendation	new 2023
EC	In special justified situations or at the explicit request of the patient, telemedicine media can be used to convey bad news.	
	Strong Consensus	

The implementation of patient-centered communication is a central task of all professional groups working in oncology. In view of the described functions of patient-centered communication, it is obvious that this is relevant in all phases of patient care, from diagnosis to follow-up care. The basic core competencies of patient-centered communication are [\[1027\]](#); [\[1028\]](#), [\[1029\]](#):

- Before the interview: viewing available medical information; creating goals for the interview; anticipating the needs and reactions of the patient and family members
- Exploration of the patient's level of knowledge; collaborative topic setting; building trust and confidence in the practitioner's skills; establishing a partnership approach
- Communicate current information based on the patient's concerns and preferences for information.
- Check patient's understanding; document important issues that were discussed
- Provide opportunities for follow-up questions; repeat and summarize important information

- Respond empathically to the patient's verbal and nonverbal emotional expressions; express respect and sympathy; convey hope; use language that is universally understood

Gilligan et al. [1030] identify the following as important clinically relevant situations: discussing treatment goals and prognosis; discussing treatment options, including participation in clinical trials; discussing end-of-life care; incorporating family members in care; dealing with barriers to communication (e.g., foreign language patients, use of interpreters, patients with minimal health literacy); discussing the cost of treatment; and providing needs-based care to underserved, marginalized groups (minorities).

Current developments in personalized oncology/precision oncology also create clinically relevant situations that present a great challenge in terms of communication. Patients consenting to molecular diagnostics and possibly receiving novel immunotherapy have a high need for information, often a limited understanding of the goal of the diagnostics, unrealistic expectations of therapy, and a sense of uncertainty [1031], [1032], [1033], [1034], [1035]. Establishing informed consent, participatory decision-making, consideration of patient autonomy, and communicating a prognosis fraught with uncertainty represent typical tasks of physician communication in this situation. In addition, the patient's reactions to the results of the diagnosis and the resulting options must be addressed in the conversation [1036], [1037]. According to Kaphingst et al. [1038], there are still significant research gaps on the effects of communication between practitioner and patient.

Various recommendations for a structured approach (heuristic models) are available to help practitioners structure the patient consultation and overcome communicative challenges. They are based on empirical findings, clinical experience and expert consensus. The best-known model is SPIKES, which was developed for the communication of bad news [1039]. Other examples of such heuristic models are: REMAP, for talking about treatment goals [1040]; the 3-step Model for addressing emotional distress of patients [1041]; or AEGIS, which can be used for communicating prognosis [1042]. In addition to such heuristic models, numerous works provide concrete formulation suggestions for statements made by practitioners in relation to specific communicative challenges [1030], [1029], [1036], [1039], [1040], [1043], [1042], [1044], [1045].

In the face of ongoing globalization and continuous migration, practitioners will encounter increasing numbers of patients who have language barriers or low health literacy. Especially in such situations, it is necessary to use simple, clear language that is free of technical terms that are difficult to understand [1046].

In the conversation between practitioner and patient, various tools can be used to support patient-centered communication. If patients use a list of keywords or questions in the conversation, they typically ask more questions and retain more information from the consultation than if no list is used. However, the use of a cue list has no effect on patients' mental well-being or satisfaction [1047], [1048], [1049], [1050]. Similar results are shown when patients receive an audio recording of the conversation with the practitioner [1049]. Positive effects in terms of patient knowledge and satisfaction are also shown for patient brochures that are handed out as part of the practitioner-patient consultation. Furthermore, there are indications that handing out information brochures can have a positive effect on therapy adherence [1051].

Conveying risks presents a particular challenge in terms of communication. Comprehension of risk is influenced by health literacy and numeracy [1052], [1053]. Furthermore, the way risks are presented has an influence on the understanding of risks and on subsequent decisions (framing effect) [1052], [1054], [1055], as well as on the emotional reaction of the recipient [1056]. The communication of risks should be presented numerically rather than textual [1057]; [1055] and supported by graphical aids such as tables and bar charts [1053], [1055], [1054], [1058], [1059], [1060], which helps to improve comprehension – even by those practitioners who have difficulty understanding them [1061]. Probabilities should be expressed as natural frequencies [1059], [1060], for which fact boxes are suitable tabular aids [1057], [1062]. However, the assessment of future risks is also subject to subjective concepts of risks and probabilities as well as affective influences [350], [1063], [1056], which need to be taken into account when making decisions [1064] and require an individualized approach to risk communication and decision making.

Regarding the effect of decision aids for patients with a wide range of diseases, a Cochrane review found that decision aids for screening, treatment, or prevention increase the level of knowledge and accuracy of risk assessment, reduce decision conflicts, increase awareness of one's own values, lead to a higher congruence between personal values and the decision made, and also lead to higher patient satisfaction [1065]. A subgroup analysis for patients with cancer yielded almost identical results [1066]. This confirms the results of a previous meta-analysis, which showed positive effects with regard to knowledge and decision conflict [1067]. Regarding specific diagnostic groups, a review of breast cancer patients showed that decision aids for screening or treatment had a positive effect on reducing decision conflict, but no effect on knowledge and satisfaction [1068]. Reviews that examined decision aids exclusively for treatment decisions (not screening) found positive effect for decision conflict, knowledge level, informedness, perceived involvement in decision, and satisfaction [1069], [1070], [1071]. Comparably, positive effects of decision support were found for the question of genetic testing for patients with breast cancer. Here a positive effect could be determined regarding knowledge level and satisfaction [1072]. Reviews of decision aids for therapy decisions in patients with prostate carcinoma [1073], [1074], [1075], colorectal carcinoma, and lung carcinoma [1076] show overall contradictory results regarding knowledge level, decision conflict, satisfaction and treatment decision. The influence of decision aids on the psychological well-being of patients is estimated as being rather low [1067]; [1070]; [1077]; [1072]. Overall, it should be noted that there is considerable heterogeneity in the quality of the decision aids used [1073], [1074], [1078], [1079], [1080], [1081], [1082].

As a result of increasing digitalization in the healthcare sector, communication between healthcare professionals and patients is increasingly taking place via digital media. The digital exchange of messages via protected patient portals is appealing to both practitioners and patients. This form of communication is seen as being convenient, and patients also see it as a way of requesting information, communicating changes in health status at short notice, and thus receiving support quickly [1083], [1084]. In digital communication via a patient portal, health care providers primarily express themselves in a factual manner; the content is often lacking in affective, supporting and participatory communication [1085], [1086]. However, patients also want patient-centered communication in digital channels. If this is not the case, it is registered and negatively evaluated by patients, which can

have an impact on the perceived quality of care [1083].

The transmission of "bad news" (breaking bad news) is a particularly challenging situation. Action protocols for this situation (e.g., SPIKES) stipulate that the conveyance take place face-to-face in a quiet, undisturbed setting. In one study, 85% of patients surveyed said that this was important to them [1087]. Cancer patients prefer to have bad news delivered in person rather than over the phone [1088]. However, a survey of U.S. breast cancer patients found that nearly 60% learned of their diagnosis during a telephone conversation. Some patients had explicitly expressed the wish to be contacted by telephone. The results also showed that telephone communication has increasingly become the norm and that the proportion of patients who received a diagnosis communicated by telephone has increased over the years [1089]. Detailed results on the psychosocial effects of communicating bad news over the telephone are scarce. In a randomized-controlled trial, Bodtger et al. [1090] examined the psychosocial effects of diagnosis messaging over the telephone versus messaging in a face-to-face consultation. The results yielded no difference in psychosocial adjustment between the two groups after transmission of the diagnosis. However, if the telephone call took place at the end of a longer diagnostic clarification process, care was taken to ensure that, whenever possible, a physician already known to the patient made the telephone call. The telephone conversation followed the principles of the SPIKES protocol.

Exceptional situations can lead to a situation in which even the conveyance of bad news has to, for a certain period of time, take place via telephone or video call. The Covid-19 pandemic is such a situation, whereby contact restrictions meant that even patient consultations did not always take place in person [1091], [1092]. In an Australian study, 85% of the physicians surveyed said they had used the telephone or video to talk to patients during the pandemic; 22% said that telecommunication was an appropriate manner to convey bad news. Potentially problematic aspects of delivering bad news via video include connection instability and operating difficulties, lack of clarity about what specific social situation the patient is in, limited assessability of nonverbal cues, and limited ability to create a comfortable atmosphere and show emotional support [1091]. Some of these problematic aspects can be minimized, e.g. by informing patients beforehand about what constitutes an appropriate setting for this conversation and including relatives in the video conference. Practitioners should, among other things, choose an appropriate setting with a simple background, interact intentionally with the camera, explicitly name emotional aspects, as nonverbal signals are more difficult to judge, speak more slowly than in a face-to-face contact and, in case of connection problems, do not speculate about content but ask for what was said to be repeated again [1093]. First studies report training courses for delivering bad news through digital media [1094], [1095], [1096]. In the study by Rivet et al. [1095], over half of the participants expressed positive views regarding the future delivery of bad news via telemedicine channels. There is a great need for research on the psychosocial effects of the conveyance of bad news via telemedicine channels.

11.1.1 Communicative Preferences of Cancer Patients

Patient-centered communication should be based on the needs and values of patients. To this end, it is relevant to know the communication preferences of the patient. Important dimensions of communication preferences are patient participation and patient orientation, effective and open communication, emotionally supportive communication [1097], as well as comprehensive information, clarity/directness in conversation and documentation of subjective information needs [1098], [1099].

Specific communicative behaviors rated as particularly important are "determining the therapeutic measures in a joint conversation", "communicate how the treatment of the disease will proceed", "project calm in the conversation" [1097] as well as "give full attention", "schedule enough time for the conversation", "explain in detail all treatment options", and in a "personal contact" [1098], [1100].

Similar preferences are found in relation to the conveyance of bad news. Patients want the information to be communicated clearly and honestly, to be informed about all treatment options and to have clarity about the progression of the condition, for the practitioner to speak calmly, to offer emotional support and to inspire hope, and to allow the patient to ask questions and express feelings [1101], [1102]. However, there is certainly a broad spectrum in terms of the desire for completeness and detail of information about symptoms and prognosis, so it is necessary to elicit individual patient preferences [1101], [1103]. If communication preferences are not taken into account, this is accompanied by an increase in mental distress [1099].

Over the last 30 years, it has been observed that more and more patients want to be actively involved in medical decisions [1104], although the preference for a passive role that leaves the decision-making authority to those treating them certainly still occurs [1105], [1106]. A study from Germany showed that in each case, approximately one third of cancer patients preferred participatory, patient-led or practitioner-led decision making [1107]. Between 20% and 70% of patients report a discordance between desired and experienced participation in medical decisions, i.e. they are less actively involved than they would like to be [1108], [1109], [1110].

11.2 Definition of Patient-centered Communication

Patient-centered medicine, which is oriented towards the needs, values, and preferences of patients, is nowadays considered a characteristic of high-quality medical care. The Integrative Model of Patient-Centeredness by Scholl et al. [1111] defines three domains, each with several dimensions, to describe patient-centered care. The three domains are: basic principles, such as basic characteristics of the practitioner; actions and measures, such as patient participation in care; and facilitating factors, such as communication between practitioner and patient. From the point of view of experts from the health care system, communication between practitioners and patients is one of the five most important characteristics of patient-centeredness, along with the other characteristics of the patient as an individual, patient participation in care processes, patient information, and empowerment [1112].

Patient-centered communication refers to a communicative approach that takes into account the patient's physical, emotional and social situation, their personal values, needs and preferences; and promotes their self-competence and ability to act [1113], [1114]. Adapted to the special needs of people with cancer, Epstein and Street [1113] define goals and tasks of patient-centered communication based on six interrelated functions:

- Fostering a helpful, "healing" relationship between practitioner and patient.
- Exchange of information
- Responding to emotions
- Dealing with uncertainty
- Making decisions
- Promoting self-management

The functions listed, which are oriented to concrete communicative goals and needs for cancer patients, imply a basic communicative competence or mindset that is not limited to defined rules or conversation techniques, so-called, „skills“, [1113], [1115].

11.3 Effectiveness of Patient-centered Communication

11.9	Consensus-based Statement	new 2023
EC	Patient-centered communication has a positive effect on patient retention and informedness. It is associated with higher patient satisfaction and better therapy adherence. In addition, there is a correlation between good patient-centered communication and improved mental well-being, higher self-efficacy, lower decision conflict, and better quality of life for patients.	
	Strong Consensus	

According to Epstein and Street [1113], the effectiveness of patient-centered communication can be described by means of proximal, intermediate, and distal outcomes. Possible proximal outcomes include an appropriate understanding of the patient with regard to the information received or the establishment of trust and respect. Intermediate outcomes include patient satisfaction and patient adherence. Distal outcomes include, for example, improved quality of life, reduced health care costs, or improved survival. The various outcomes differ in terms of the available and established evidence. Patient-centered communication can have a direct effect on health-related outcomes, but indirect effects mediated by variables such as treatment adherence are more likely [1116].

Reviews examined different outcome domains across disorders and settings conclude that the implementation of patient-centered communication is associated with higher patient satisfaction, better retention and recall of information, and positive effects on mental health complaints and physiological outcome measures [1117], [1118], [1119], [1120], [1121], [1122]. Similarly, reviews in oncology have concluded that empathy and open, honest, and hopeful communication are associated with higher patient satisfaction and better psychological well-being [1123]. More recent evidence on selected outcomes and on two specific communicative tasks (participatory decision making and prognosis communication) is presented below.

11.3.1 Retention of Information

Studies with cancer patients and observed physician behavior [1124], [1125] as well as experimental, vignette-based studies with healthy individuals ("analog patients") [1126], [1127], [1128], [1129] suggest that emotion-related communication on the part of the practitioner is associated with better retention performance on the part of (analog) patients. This included building trust, communicating empathically, observing pauses, and validating emotional expressions. Experimental studies with analog patients show contradictory results for a conversational approach that primarily aims at structuring information [1130], [1131].

11.3.2 Patient Satisfaction

Studies on observed behavior in doctor-patient conversations show that higher levels of emotion-related communicative behaviors (e.g., encouragement, empathy, expression of concern, optimism, expression of hope) as well as higher levels of instrumental behaviors (e.g., exploration, counseling) are related to patient satisfaction after the consultation [1114], [1132]. Emotion-related behaviors show a stronger relationship with patient's satisfaction than instrumental behavior [1114]. Similarly, patients who rate the practitioner's communication as being more patient-centered report higher patient satisfaction [1133], [1121], [1134], [1135]. Patients who rate the communicative skills of the practitioners as excellent subjectively perceive their care as very good [1136].

11.3.3 Patient Adherence

Patient-centered communication is associated with higher patient adherence [1137], [1138]. According to a meta-analysis, practitioners with good communication skills achieve 19% higher patient adherence compared to practitioners whose communication skills were rated low [1138]. In the field of oncology, results indicate that patient-centered communication is associated with higher adherence to adjuvant endocrine therapy for breast cancer [1139].

11.3.4 Mental Well-being, Psychological Factors, and Quality of Life

Attentive, empathic, responsive communicative behavior by practitioners – both objectively observed and subjectively perceived by the patient – is associated with a decrease in distress and hopelessness following the conversation between doctor and patient [1132], [1135]. Similarly, an experimental study showed that strong patient-centered behavior when communicating a diagnosis was associated with less anxiety on the part of patients [1140]. Furthermore, associations were found between the high quality of patient-centered communication perceived by patients and better mental and physical health [1141], higher self-efficacy [1113], [1033], [1048], [1142] lower decision conflict [1135] and higher quality of life [1143], [1144].

11.3.5 Effects of Participatory Decision Making

Authors of systematic reviews on participatory decision making from the entire field of medicine conclude that there is clear evidence for a positive effect especially in relation to affective-cognitive outcomes. Thus, participatory decision making is primarily associated with patient satisfaction, understanding, and trust in the practitioner [1145], [1146], [1147]. This correlation is primarily evident when the quality of participatory decision-making is assessed from the perspective of the patient. The association is empirically less certain when observers assessed the quality of participatory decision making, and there was no association in studies in which the participating practitioners assessed the quality of participatory decision making [1147]. Positive effects on behavioral outcomes, e.g., adherence, and health-related outcomes, e.g., symptom reduction and quality of life, have been less consistently observed [1145], [1146], [1147]. In oncology, systematic reviews show weak evidence of a positive effect of participatory decision making on anxiety, depression, quality of life, and utilization of the health care system [1148], [1149]. Participatory decision making about screening and treatment options in patients with prostate cancer is associated with higher levels of knowledge and feelings of informedness, but no evidence is available for an effect on treatment adherence or health status [1150], [1151]. A systematic review in patients with glioma does not

allow a firm conclusion on the effect of participatory decision making [1152]. Regardless of the effect of participatory decision making, studies show that the majority of patients want to be involved in decisions. When decisions are strongly dominated by the caregiver, patients are less likely to report having received excellent care, regardless of their preferred level of participation [1153].

11.3.6 Effects of Communicating the Prognosis

Patients with cancer want open and honest communication about their disease situation. This also includes the question of prognosis. Appropriate information is necessary so that patients can make an informed, carefully weighed decision about treatment. However, treatment providers are often reluctant to make a prognostic statement. This is related to the difficulty of making a concrete, correct prediction in the face of a complex medical situation, but also the fear of harming the relationship between the practitioner and the patient as well as the patient's mental state [1154]. However, the results of a systematic review show that information about prognosis was associated with a better understanding of the patient's prognosis and a more correct subjective estimation of survival time. Communication of prognosis leads to a physiological distress response. A negative effect of the information about the prognosis on the mental state is rather not shown, on the contrary, positive effect results are more convincing. There is also no evidence for a negative effect of the prognosis information on the relationship between the practitioner and the patient. Furthermore, there is evidence for a relationship between prognosis communication and the discussion of treatment preferences in the terminal phase of the disease [1154]. Regarding the specific form of prognosis communication, the authors conclude from the present results that the combination of unambiguous and affective communication explaining multiple scenarios of survival (see Mori et al. [1155]), combined with collaborative behavior that recognizes the practitioner as the subject matter expert, is particularly favorable. This promotes retention, the patient's mental well-being, and the relationship between the practitioner and the patient [1154]. The conveyance of the prognosis is typically a stressful situation for patients. Stress has effects on memory and behavior, among other things. Patients who show a high degree of psychological impairment in the situation show poorer retention performance for transmitted information and they participate less in the practitioner-patient conversation [1156]. Therefore, it is useful to be empathetic when communicating the prognosis and to check at the end of the conversation whether the patient has correctly understood and retained the most important facts. In the case of mentally distressed patients, it is advisable to address the emotional situation first and to arrange another appointment for communicating the prognosis [1156], [1157].

11.4 Improving Communicative Competences

11.10	Consensus-based Statement	new 2023
EC	In order to achieve a high standard in patient-centered communication, the continuous improvement of communication skills of all professionals working in oncology should be strived for.	
	Strong Consensus	

11.11	Consensus-based Statement	modified 2023
EC	Communication skills training that meets essential quality standards improves patient-centered communicative behaviors of oncology practitioners.	
	Strong Consensus	

11.12	Consensus-based Recommendation	modified 2023
EC	Physicians and other professionals working in oncology should participate in a quality-assured communication skills training to improve their communication skills.	
	Strong Consensus	

Given the importance of patient-centered communication within the framework of patient-centered care, there are worldwide efforts to train communicative skills in order to achieve a high standard of patient-centered communication. Today, practicing communication skills is a given standard in medical school [1158], [1159]. Furthermore, there are international efforts to establish communication training as routine in institutions or certain areas of the medical care system [1160]. In Switzerland, it is mandatory for physicians to take part in communication training during their specialized training to become an ‘Oncologist’ [1161]. There are consensus recommendations available that define formal and content-related quality standards [1030]; [1161], [1162]. The standards include, among other things, that communication skills be practiced actively through role-play and that participants receive feedback on their communicative behavior. More and more, there is an emphasis that the focus should not be placed on the mere technical practice of skills. Additionally, the practice of communicative skills should also be used to promote self-reflection, to train awareness of situational characteristics of practitioner-patient communication, and to achieve individual training goals [1030]; [864], [1163], [1161].

Health care professionals who participated in communication training typically express high satisfaction with the training [1164], [1165], [1164]. Studies found no significant differences in satisfaction with communication training between treatment providers who participated in the training on a voluntary basis and treatment

providers for whom participation was a mandatory part of their continuing education. The realization of defined quality communication training standards and institutional implementation encounter numerous barriers, primarily structural and resource related. Accordingly, there is a wide variance in the formal and content aspects of communication trainings [1160], [1166]. Many of the described communication trainings for treatment providers deviate in numerous aspects from the quality standards that were defined in a consensus meeting in 2008 [1166]. This high variance makes it difficult to generate strong empirical evidence for the effectiveness of communication training. Nevertheless, there are numerous studies with positive results on the effectiveness of communication training.

11.4.1 Effectiveness of Communication Trainings

Results of a systematic review and a Cochrane review, both supplemented by meta-analytical evaluations, show that practitioners who have undergone communication training use more patient-centered communicative behavior in conversations with real patients or standardized patients than practitioners who have not participated in such training. The effects are small to moderate [1167], [1168]. Specifically, Moore et al. [1168] found a positive effect of communication training on three of seven behaviors considered. According to these findings, communication training resulted in practitioners being more likely to exhibit empathic behaviors and less likely to "simply" communicate facts without paying attention to the patient's emotional response or offering support. Furthermore, practitioners used open-ended questions more often after training than practitioners who had not participated in training. The analyses also provided evidence that these positive effects persisted in the medium term (i.e., several months after training was completed) [1168]. According to Moore et al. [1168], the analyses showed no benefit of communication training with respect to the behaviors of summarizing, inquiring about concerns, conveying appropriate information, and negotiating/agreement-making. The analysis by Barth and Lannen [1169] also revealed a pattern of results that, while not statistically significant throughout, was consistently observed. They found that communication trainings that lasted less than 24 hours produced smaller effects than trainings that lasted more than 24 hours. Considering the quality of the studies, the overall evidence is of low to moderate quality [1170], [1168].

Both studies found no convincing evidence for an effect from communication training on patient-sided outcomes [1167], [1168]. However, Haskard, Zolnieriek and DiMatteo [1138] report that physicians who had participated in a communication training achieved 12% higher treatment adherence from their patients than did physicians who had not participated in such training.

Other systematic reviews conclude that communication trainings improve the communication skills of practitioners, but it is unclear what time frame, format, and content are best for this [1171]. Selman et al. [1172] found that communication training resulted in practitioners expressing more empathy and talking about emotions. This was a medium effect, but it only applied to interactions with standardized patients, not to conversations between training participants and real patients. This work also found no effect of communication training on patient-related outcomes [1172].

Furthermore, systematic reviews suggest that communication trainings lead to an increase in the self-assessed quality of communication skills and to higher self-

efficacy. However, the authors also note that the quality of evidence is low [1173], [1174], [1175].

Furthermore, systematic reviews are available on the effects of communication trainings with non-physician practitioners. Consistent with other work, Kerr et al. [1176] found a positive effect of communication training on nurses' communicative behavior; the authors rated the quality of evidence as moderate. A systematic review on communication training with team members in radiation oncology (including physicians, nurses, medical physicists, medical technical radiology assistants) showed positive effects regarding some communication skills, especially empathic communication and the use of emotion words, but also inconsistent results regarding other communicative behaviors, e.g., the use of open-ended questions. Regarding patient-reported outcomes, inconsistent results were also evident [1177].

Current RCTs support the main conclusions of the aforementioned systematic reviews. Bylund et al. [1165] report an increase in the scope of patient-centered conversation techniques used by participants in communication training. Furthermore, positive effects were shown for the specific conversational techniques of structuring topics, checking for understanding, and organizing the delivery of information. This gain in communicative skills occurred primarily in the group of practitioners who initially demonstrated low values in their communicative behavior. Moreover, these positive effects were only evident in conversations with standardized patients. The transfer of the gain in competencies into the clinical setting could not be demonstrated; in conversations with real patients there was no difference in patient-centered communication between trained and non-trained practitioners. In contrast, Epstein et al. [1178] found that communication training with physicians (combined with an intervention for patients with advanced cancer) resulted in higher levels of patient-centered communication with real patients. However, there were no effects on secondary outcomes such as the quality of the patient-physician relationship, quality of life, or consensus on the prognosis. A positive effect of training was also reported by Henselmans et al. [1179]. It was shown here that oncologists who had participated in skills training were more likely to implement participatory decision-making in their conversations with patients with advanced cancer than oncologists who had not participated in the training.

In view of the findings presented here, research efforts are particularly indicated to investigate how the success of a communication training can be transferred to clinical practice and what the minimum scope of communication training should be in order to achieve clinically significant effects.

12 Quality Assurance

Regardless of the care setting, all areas of psycho-oncological services should be subject to a system of quality assurance which is subdivided into structural, process, and outcome quality and outlined below with regard to the specifics for the field of psycho-oncology work. For clinics, psycho-oncological services are to be integrated into the respective system of quality assurance based on legally regulated requirements for quality assurance. In other areas of care, the explanations provide guidance for the establishment of quality assurance for psycho-oncological services [1180], [1181].

12.1 Structural Quality

12.1.1 Personnel Qualification

12.1	Consensus-based Recommendation	modified 2023
EC	All professional groups working in psycho-oncology should complete a curriculum-based psycho-oncological advanced training or continuing education with relevant content recognized by the German Cancer Society.	
	Consensus	

Currently, the designation „Psycho-oncology“ is not yet regulated by law. In accordance with the principle of interdisciplinarity, various professional groups can be active in psycho-oncology. First and foremost, these include psychologists, physicians, social workers/social pedagogues and other health and social science professions.

Depending on the field of activity within psycho-oncology, the service providers must be qualified to perform the required tasks with regard to psycho-oncological diagnosis, counseling, and treatment in a quality-assured manner in accordance with current scientific knowledge.

Those working in psycho-oncology should be able to recognize specific psychosocial and psychological burdens in patients and, if a comorbid mental illness is suspected, to initiate specific assessment and treatment in consultation with an appropriate medical specialist/psychotherapist.

The basic qualification required for specific psycho-oncological work should be a degree in medicine, psychology or other subjects such as social work or education. In addition to the basic qualification, there should be specific psycho-oncological advanced training and continuing education certified by the German Cancer Society.

The respective advanced training and continuing education requirements depend on the basic qualification and the type of psycho-oncological activities. For specific psycho-oncological activities such as the diagnosis and psychotherapeutic treatment of comorbid mental illnesses, a medical qualification (physician or psychology with psychotherapy) is required.

The advanced training and continuing education requirements for psychological/psycho-oncological activities in palliative care facilities are regulated in the S3 Guideline on Palliative Care (AWMF register number: 128-001OL) as well as in the "General Recommendations for the Establishment of Positions in Psychology in Hospice and Palliative Care" from the DGP, Psychology Section.

Targeted training measures to promote communicative competence are a prerequisite for teaching basic communication skills to physicians and nurses working in oncology. These should be offered as part of the advanced training and continuing education. In addition, the competencies for conducting conversations with cancer patients and their relatives should be continuously improved and further developed [1182], [3].

For creative arts therapists working in psycho-oncology (music, dance, art therapists, etc.), a corresponding bachelor's or master's degree or in-service training that meets the quality standards of the respective trade and professional associations of the Bundesarbeitsgemeinschaft Künstlerischer Therapien (BAG-KT) is a prerequisite.

12.1.2 Personnel Requirements

12.2	Consensus-based Recommendation	new 2023
EC	In certified centers as well as in non-certified clinics, one full-time psycho-oncological staff member shall be provided for every 300 cases per year for all oncological diagnoses with the exception of prostate cancer or melanoma patients.	
	Consensus	

12.3	Consensus-based Recommendation	new 2023
EC	In certified centers as well as in non-certified clinics, one full-time psycho-oncological staff member should be provided for every 500 cases per year for prostate cancer as well as melanoma patients.	
	Consensus	

12.4	Consensus-based Recommendation	new 2023
EC	In certified centers as well as in non-certified clinics, if the number of cases is less than that stated in Recommendations 12.2 and 12.3, the positions should be prorated.	
	Consensus	

Depending on the care setting (hospital, rehabilitation clinic, outpatient facility), a sufficient number of psycho-oncology specialists based on cases must be provided to cover the psychosocial needs of the patients in the respective care facility [1183].

For palliative care facilities, there is no empirically based information on the required number of positions. Based on clinical experience, the General Recommendations of the Psychology Section of the German Society for Palliative Medicine recommend 0.05 psychology staff per bed for palliative stations and at least 0.5 psychology staff per bed for palliative medical services (inpatient or outpatient) [1184]. In order to promote accessibility, cooperation, and therapeutic constancy, it is recommended that the corresponding staff members be integrated into a psycho-oncological team.

According to the S3 Guideline Palliative Medicine (AWMF Register Number: 128-001OL), depending on the respective hospital setting, it is possible to expand the palliative services by including creative arts therapists (e.g. art therapists, music therapists).

12.1.3 Spatial Requirements

12.5	Consensus-based Recommendation	new 2023
EC	In terms of equipment, suitable space shall be provided to allow for undisturbed and confidential psycho-oncological counseling and treatment.	
	Strong Consensus	

Suitable accommodations shall be provided for psycho-oncological care services that enable undisturbed and confidential counseling and treatment, as well as fulfill general conditions that are appropriate in terms of the patient's privacy [1185]. Barrier-free access and good accessibility should be ensured [113], [1186]. For bedridden patients in multi-bed rooms, appropriate arrangements must be created so that the above-mentioned interventions can be carried out. Appropriate and well-equipped group rooms should be made available for group activities.

12.1.4 Treatment Concept

As a sign of quality standards, every facility must provide a detailed, written concept for the provision of psycho-oncological services. This should contain central statements about the contents, goals, and working practices of the psycho-oncological service providers. The concept should be based on the latest scientific findings in psycho-oncology and be updated on a regular basis. The integration of psycho-oncology into the mission statement of the respective institution is desirable.

12.1.5 Structural Characteristics of the Services

12.6	Consensus-based Statement	modified 2023
EC	Specific requirements with regard to structural quality for quality-assured psycho-oncological care are: • conceptual integration of psycho-oncology into the care concept of the respective institution and its mission statement • in hospitals: organization of psycho-oncology specialists in their own specialized departments or consultant liaison services. • specific qualification through curriculum-based psycho-oncological advanced training or continuing education • adequate spatial arrangements Recommendation and implementation of interventions according to the needs identified through screening and diagnostics.	
	Consensus	

The psycho-oncological services in the respective facilities should be tailored to the specific distress situations and needs of the cancer patients and reflect the current state of scientific knowledge. The services must be clearly recognizable for patients with appropriate opening and consultation times (by telephone and in-person) as well as the named contact persons. For psychiatric emergencies, a corresponding emergency plan must be laid down in writing in all facilities. Information about the services offered should be provided through appropriate media such as flyers, websites, etc. In this context, care should be taken to ensure that the information is conveyed in a patient-friendly and easy-to-understand manner.

The processes of psycho-oncological diagnostics and interventions are documented in a quality manual in the quality management system of each facility.

12.2 Process Quality

12.7	Consensus-based Recommendation	modified 2023
EC	To ensure the process quality of psycho-oncology practice, the following aspects should be implemented: • Screening for psychosocial distress • Establishing counseling or treatment goals together with the patients • Inclusion of subjective needs • Networking and cooperation • Documentation of services on the basis of a suitable EDP-based system • Patient-related reporting • External supervision	
	Strong Consensus	

12.2.1 Screening for Psychosocial Distress

The screening for psychosocial distress is carried out according to the procedures outlined in [Chapter 7.2](#)

12.2.2 Establishment of Counseling or Treatment Goals

At the start of psycho-oncological counseling and/or treatment, the objectives should be discussed with the patient and the goals of the intervention should be defined together with the patient. In the course of psycho-oncological counseling and treatment, these goals should be constantly reviewed based on the progress of treatment and modified if necessary.

12.2.3 Networking and Cooperation

The networking of psycho-oncological tasks is to be defined not only with regard to facility-internal processes but also with regard to external networking and collaboration.

For the internal networking of psycho-oncological specialists, an interdisciplinary exchange takes place in the respective facilities (hospital, rehabilitation clinic, outpatient facilities) through regular organizational meetings, case discussions or ward conferences. In case or ward meetings, in addition to the medical, nursing and psycho-oncological specialists, all those involved in the treatment of the patients, such as physiotherapists, social counselors or chaplains, should be included as needed. The objective is the mutual exchange of information, coordination and planning of psycho-oncological diagnostics, counseling and treatment. If psycho-oncological services are provided by external specialists in inpatient facilities, appropriate forms of information exchange and cooperation in the above sense should be established. In the certified centers, psycho-oncological specialists should take part on the tumor boards on an as-needed basis.

The networking of inpatient and outpatient psycho-oncological services is an important task of psycho-oncological practice with regard to the provision of further psycho-oncological support and the continuity of care. Important cooperation and

networking partners include the psycho-oncological services of the clinics, the outpatient psychosocial counseling centers, oncological specialized practices, established medical and psychological psychotherapists, and rehabilitation clinics. In addition, there should be close networking and cooperation with self-help organizations. All cooperation agreements should be documented in writing.

12.2.4 Documentation

Psycho-oncological services are to be recorded using documentation specific to the respective facility (hospital, rehabilitation clinic, outpatient facility). The documentation should contain a systematic baseline and progress documentation of the core features of the psycho-oncological interventions and should be maintained regularly. **In this context, the data protection guidelines of the respective facilities must be observed with regard to the collection, storage and transmission of these data.** The core features are:

- Indication for psycho-oncological care including psychosocial distress scores from screening
- Patient preference with regard to further offerings
- Type of diagnostics
- Type of intervention
- Duration and number of contacts
- Information on the outcome of counseling and treatment
- Type of end or further referral

A networking of the psychosocial data with the medical data must be ensured. It should be possible to provide statistical evaluations with corresponding key values on the psycho-oncological services at defined intervals (at least once a year).

12.2.5 Patient Reported Outcomes

The main contents and results of psycho-oncological counseling and/or treatment should be regularly reported in writing. Reporting follows the respective specifics of the facilities (acute care, rehabilitation, outpatient follow-up care).

12.2.6 Supervision

Regular external supervision of psycho-oncological practices is an essential component of quality assurance in all areas of psycho-oncological care and must be provided in all facilities. It serves to optimize treatment, relieve and support psycho-oncology professionals, and prevent burnout. The frequency of supervision depends on the needs of the specialist staff in the respective institutions.

External supervision shall be supplemented by intervision; this cannot, however, replace external supervision.

12.3 Outcome Quality

Characteristic of outcome quality is that on the one hand, reports on the success of psycho-oncological services should be documented in writing, and on the other hand, a systematic survey of patients should be conducted with regard to the achievement of goals and satisfaction. If systematic patient surveys are carried out as part of quality assurance, the subject of psycho-oncological services should be thematically included.

13 Quality indicators

Quality indicators are measured variables whose collection serves to assess the quality of the underlying structures, processes or results. Quality indicators are an important quality management tool [1187]. The aim of their use is the continuous improvement of care by presenting the results of care, critically reflecting on them and, if necessary, improving them. The present selection of quality indicators was created according to the methodology of the German Guideline Program in Oncology [1188]. For the derivation process, a „Quality Indicators Working Group“ (WG QI) was constituted. This group created the final set of quality indicators based on the already existing quality indicators of the 2014 Guideline Psycho-oncology and, the new strong recommendations („shall“) from the updated Guideline Psycho-oncology. In addition, the group took into consideration the results of the search for existing national and international quality indicators. Results of the already existing quality indicators from the Certified Cancer Centers were not available. The methodology and composition of the WG QI are outlined in the Guideline Report (see <https://www.leitlinienprogramm-onkologie.de/leitlinien/psychoonkologie/>).

After two online meetings of this WG, two new quality indicators (QIs) were defined and one existing QI (QI 5: Psycho-oncological interventions: Concepts and general principles for the indication of psycho-oncological treatment) was deleted.

The final set thus consists of 8 QIs (QI 5 unoccupied) (see table 12).

Table 12: Overview Quality Indicators

Quality Indicator*	Reference Recommendation	Evidence Basis / Additional Information
QI 1: Structural requirements of psycho-oncological care areas: cross-sector coordination of psycho-oncological care (since 2014).		
Enumerator Denominator patients receiving information about psycho-oncology support services. Denominator All cancer patients with initial diagnosis, recurrence or first distant metastasis	Recommendation 4.10 Patient-oriented information about psycho-oncological support services shall be provided at an early stage and accompany the course of the disease.	EC Supplementary notes: Definition „Psycho-oncological support service“: psychosocial counseling, individual or group psychotherapeutic intervention, psychoeducational intervention, couples intervention, relaxation procedures, provided by the appropriately qualified person. The aim of the indicator: the facility should provide the patient with specific contacts as an example reference. This is intended to encourage the formation of networks within and across facilities.

Quality Indicator*	Reference Recommendation	Evidence Basis / Additional Information
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QI 2: Structural requirements of psycho-oncological care areas: self-help (modified 2022)

Enumerator Patients of the denominator who have received information about cancer self-help support services. Denominator All cancer patients with initial diagnosis, recurrence or first distant metastasis	Recommendation 4.7 Cancer patients and their relatives shall be informed about qualified support services offered by cancer self-help/peer-support groups (discussions with people affected by the same disease, assistance in dealing with the disease, therapies and effects of therapy in everyday life) in all phases of the care process.	EC Additional note: The information can be conveyed by flyer, the flyer should be handed over personally. In the flyer, the institution in question states specifically where which offer can be found and names contact persons.
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QI 3: Diagnostics: Screening, Diagnostic Procedures (modified 2022)

Enumerator Patients of the denominator who were screened psycho-oncologically Denominator Primary case patients + patients with new (local) recurrence and/or distant metastases	Recommendation 7.3 Psycho-oncological screening should be performed as early as possible, at appropriate intervals, during the course of the disease, when clinically indicated or if a patient's disease status changes (e.g., recurrence or progression of the disease).	Literature on validated screening instruments with a defined cut-off: see chapter 7.3.1. Distress screening includes the implementation of a valid distress instrument (analogous to BestPractice [1] or S3 guideline Psycho-oncological diagnosis, counseling and treatment of adult cancer patients: • Distress Thermometer (DT), • the Hospital Anxiety and Depression Scale (HADS), • the Cancer Patient Stress Questionnaire (FBK), • the depression module of the Patient Health Questionnaire (PHQ-9) or • the Generalized Anxiety Disorder Scale-7 (GAD-7)).
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Quality Indicator*	Reference Recommendation	Evidence Basis / Additional Information
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QI 4: Diagnostics: Diagnostic procedures (since 2014)

Enumerator Patients of the denominator with a diagnostic interview for clarification of psychosocial stress and mental comorbidity Denominator All cancer patients with initial diagnosis, recurrence or first distant metastasis and with positive screening for psychosocial distress.	Recommendation 7.6 If the screening is positive and/or there is a subjective need for support identified, a diagnostic interview shall be offered to clarify psychosocial distress, psychiatric comorbidity, as well as the need for support and treatment.	EC Definition „Diagnostic interview“: The diagnostic interview includes the identification of psychosocial stress, mental disorders and other problem situations with the aim of describing existing problems and disorders and their change. In addition, clarification is made as to whether these problem situations are subsyndromal or fulfill the criteria for a mental disorder. The clarification and classification of the existing problems and disorders is carried out according to a classification system (ICD-10 or DSM IV), whereby in the diagnosis of a clinically relevant comorbid disorder, the differentiation from somatic complaints or an appropriate psychological reaction to the tumor disease as well as the appropriate consideration of biological-organic consequences of the cancer disease or treatment must be taken into account. Actors: Specialists in psycho-oncology
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QI 5: Psycho-oncological Interventions: Concepts and general principles for the indication of psycho-oncological treatment (Deleted Version 2).

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QI 6: Psycho-oncological Interventions: Concepts and general principles for the indication of psycho-oncological treatment, psychosocial counseling (modified 2022).

Enumerator Patients of the denominator with offer of psychosocial	Recommendation 8.2 Patients with no or low distress (determined through screening and further diagnostics) shall	EC Supplementary note: Psychosocial counseling should be offered personally by social workers/social pedagogues and psycho-oncology
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Quality Indicator*	Reference Recommendation	Evidence Basis / Additional Information
counseling with psychological and social focus Denominator Cancer patients with initial diagnosis, recurrence or first distant metastasis	be offered or given patient-oriented information and psychosocial counseling.	specialists (cf. QI 2: the personal handing over of a flyer). Actors: Social workers/social pedagogues and psycho-oncology professionals.

QI 7: Patient-centered communication: training interventions to improve practitioners' communication skills and their effectiveness (modified 2022)

Enumerator All physicians and nurses with quality-assured communication skills training to improve their communication skills. Denominator All physicians and nurses working in the field of oncology.	Recommendation 11.12 Physicians and other professionals working in oncology should participate in a quality-assured communication skills training to improve their communication skills.	EC Literature: Barth and Lannen (2011) Supplementary note: Continuing education and training measures to teach specific interview skills: Postgraduate; number of teaching units must be proven (e.g. certificate of participation). Training should be at least 3 days (24 hours) in length. Reason for deviation of the QI from the guideline recommendation: In accordance with the prioritization of measures of the National Cancer Plan, the focus is on physicians and nurses, as these two professional groups are considered to have priority in patient care. It can be assumed that psychotherapeutic practitioners have been taught communication and conversation skills in their respective basic training.
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QI 8: Human resources (new 2022)

Enumerator Cumulative full-time equivalent psycho-oncology positions of the center/non-certified clinic. Denominator All cancer patients with the exception of prostate or	Recommendation 12.2 In certified centers as well as in non-certified clinics, one full-time psycho-oncological staff member shall be provided for every 300 cases per year for all oncological diagnoses	Target: ≥ 0.0033 Note: Denominator must be adapted to specific organs per entity. Prostate and melanoma patients should also be cared for, but the requirement of one full-time psycho-oncologist for 300 cases per year does not apply.
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Quality Indicator*	Reference Recommendation	Evidence Basis / Additional Information
melanoma patients with initial diagnosis, locoregional recurrence, or secondary distant metastasis at the center/non-certified clinic.	with the exception of prostate cancer or melanoma patients.	

QI 9: Suitable premises (new 2022)

Enumerator Number of suitable rooms, which are available for psycho-oncological conversations Denominator Full-time equivalent psycho-oncology = cancer patients other than prostate or melanoma patients with initial diagnosis, locoregional recurrence, or secondary distant metastasis 0.0033 at center/non-certified clinic	Recommendation 12.5 In terms of equipment, suitable space shall be provided to allow for undisturbed and confidential psycho-oncological counseling and treatment.	Annotation: Suitable rooms = Undisturbed consultation, furniture, confidential and pleasant atmosphere.
* The enumerator is always a subset of the denominator. None of the quality indicators are to be documented with the basic oncology data set of the cancer registries (as of 06/2022).		

14 List of Tables

Table 1: Participating professional associations and organizations (alphabetical)	11
Table 2: Composition of Guideline Workgroups	16
Table 3: Abbreviations Used	18
Table 4: Evidence Grading Scheme (based on the Oxford Centre of Evidence-Based Medicine scheme [available in full here]).....	22
Table 5: Scheme of recommendation grading.....	23
Table 6: Consensus strength.....	23
Table 7: Frequency of Mental Disorders in Cancer Patients	46
Table 8: Psychometric Criteria of the Screening Instruments	54
Table 9: Overview of German S3 Guidelines on Mental Disorders	62
Table 10: Contextual Factors Influencing Mental Health that Should be Considered Before and During Psychopharmacological Treatment	115
Table 11: Overview of Significant and Important Interactions:.....	122
Table 12: Overview Quality Indicators	158

15 List of Figures

Figure 1: Quality of Life Assessment 37

Figure 2: Clinical Care Algorithm 61

16 Literature References

1. Bundesgesundheitsministerium. Nationaler Krebsplan: Handlungsfelder, Ziele und Umsetzungsempfehlungen. Januar 2012; URL: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Praevention/Broschueren/Broschuere_Nationaler_Krebsplan-Handlungsfelder_Ziele_und_Umsetzungsempfehlungen_2012.pdf
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