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Smoking patterns and the intention to quit in German patients with cancer: study protocol for a cross-sectional observational study

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ABSTRACT

Introduction Patients who continue to smoke cigarettes after a cancer diagnosis can experience poorer treatment tolerance and outcomes than those who quit immediately. Identifying risk factors specific to patients with cancer who smoke, as well as their smoking behaviours (eg, frequency of use, types of tobacco products), dependency level and quit intentions, is necessary to better inform patients and encourage quitting smoking after a cancer diagnosis. This study aims to examine the occurrence of smoking in patients with cancer treated at specialised oncology departments and outpatient clinics based within the metropolitan region of Hamburg, Germany, and presents an analysis of their smoking patterns. This understanding is the first step in developing an adequate smoking cessation intervention and shall contribute to a sustainable improvement in the treatment results, long-term survival and quality of life of patients with cancer.

Methods and analysis A questionnaire will be administered to patients with cancer (N=865) aged 18 years and above in the catchment area of Hamburg, Germany. Data acquisition includes sociodemographic, medical and psychosocial data as well as information on current smoking patterns. To identify the associations between smoking patterns and sociodemographic characteristics, disease-related variables, and psychological risk factors, descriptive statistics and multiple logistic as well as multinomial regressions will be performed.

Ethics and dissemination This study was registered at Open Science Framework (https://doi.org/10.17605/OSF.IO/PB5Y8). It was approved by the ethics committee of the local psychological Ethic committee at the centre of psychosocial medicine Hamburg, Germany (LPEK) (tracking number: LPEK-0212). The study will be carried out in accordance with the Code of Ethics of the Declaration of Helsinki. The results will be published in peer-reviewed scientific journals.

INTRODUCTION

Recent estimates indicate cancer is one of the main leading causes of death worldwide accounting for over 9.6 million deaths per year.1 As smoking is responsible for more than 19% of all cancer diagnoses and for over 80% of lung cancer diagnoses,2 attention to smoking and smoking cessation in cancer care is highly needed. Indeed, a growing body of research has been examining interventions developed specifically for patients with cancer, which are intended to help patients stop smoking. Nonetheless, a current meta-analysis reveals that to date, there are only few effective smoking cessation programmes for patients with cancer.3,4 Main reasons for the poor success of smoking cessation programmes in oncological patients could be the lack of attention to the specific and complex needs of patients with cancer.5,6 Even for patients with cancer, who successfully manage to give up smoking, studies show that it often takes longer than 7.5 years to do so.7,8
Continuing to smoke after being diagnosed with cancer can lead to poor treatment outcomes. Particularly, smoking is shown to reduce the efficacy of systemic and radiotherapy.\textsuperscript{3–13} Patients with cancer who continue to smoke after a cancer diagnosis experience poorer wound healing than non-smoking patients after surgical cancer treatment\textsuperscript{10–12,13} and experience more side effects during cancer treatment.\textsuperscript{14} Furthermore, continued smoking increases the risk of death compared with patients who stopped smoking after diagnosis or who have never smoked.\textsuperscript{15–16} Patients with head and neck cancer who continue to smoke were found to have an increased risk of developing a secondary primary tumour such as lung, oral cavity or a pharynx carcinoma.\textsuperscript{17,18} In addition, smoking reduces cancer patients’ reported quality of life (QOL),\textsuperscript{19,20} with higher pain levels and fatigue, and those who quit smoking after cancer diagnosis experience a greater reduction in depressive symptoms.\textsuperscript{20}

Despite the growing evidence that smoking cessation after a cancer diagnosis is associated with more effective treatment and better prognosis, up to 60% of patients do not stop smoking after being diagnosed with cancer.\textsuperscript{21,22} Interestingly, a Canadian study of patients with bladder cancer shows that also only up to 60% of patients with cancer are being informed by their doctors or nurses about the consequences of smoking during cancer treatment.\textsuperscript{23} Finally, many patients who are motivated to quit smoking find it difficult to do so even years after their diagnosis.\textsuperscript{6}

Unfortunately, data on smoking continuation after cancer diagnosis are not yet available for patients with cancer in Germany.

According to the Transtheoretical Model of Behavior Change (TTM)\textsuperscript{24} making an intentional change in behaviour requires one to pass through several different stages of change (1) precontemplation, (2) contemplation, (3) determination, (4) action and (5) maintenance. The transitions between the individual stages are influenced by various activities and events that are associated with different cognitions and emotions. A distinction can be made between cognitive-affective processes (eg, increase in problem awareness, perception of positive and conducive environmental conditions), which are associated with the stages of intention formation and preparation for further stages, and behavioural processes (such as self-commitment, utilisation of helpful relationships), which are important in later action-oriented stages. Cognitive-affective processes are particularly important in early stages of change, while behavioural-oriented processes are particularly important in later stages of change. When addressing smoking in patients with cancer, the TTM can be helpful as a theoretical framework to motivate behaviour change and assist in support cessation. However, when measuring the stages of motivational changes, the described five levels are often summarised. The change motivation questionnaire used in this study only requires three levels, which are based on the results of factor analyses.\textsuperscript{25,26}

In the literature, several factors have been associated with continued, reduced or ceased smoking after a cancer diagnosis, respectively. Being surrounded by other smokers, especially living in a household with at least one other smoker, appears to be related to continued smoking after a tumour diagnosis.\textsuperscript{27} Hence, it is crucial to involve relatives in the smoking cessation process and further educate and support smoking relatives to stop smoking in the presence of patients with cancer.\textsuperscript{28} The potential influence of being in a partnership has so far been shown mainly in not explicitly cancer-related samples: Living with one’s partner and/or being married shows an association with increased likelihood of quitting smoking over a 4-year period.\textsuperscript{29} Next to being in a partnership, having children also plays a major role in not explicitly cancer-related samples. Pregnancy or childbirth is a common mentioned reason to stop smoking.\textsuperscript{30} Also, the health of the family and the function as a role model for one’s own children seems to play an important role in quitting.\textsuperscript{31} For patients with cancer, there is so far no investigation of this association in the literature. Nevertheless, having own children could also play a role in the question of whether someone continues smoking after a cancer diagnosis.

Furthermore, it has been shown that social support can increase patients’ success in quitting smoking.\textsuperscript{32} Also, in the smoking population without cancer diagnosis, social support is associated with a higher intention to quit smoking\textsuperscript{33} and support from one’s partner as well as the perceived availability of general support were linked to cessation and maintaining abstinence for up to 3 months after treatment.\textsuperscript{34}

Also, an association was found between the alcohol intake and the likelihood of continued smoking after a carcinoma diagnosis.\textsuperscript{35} Kim et al\textsuperscript{36} show that scoring higher than eight points (very strong consumption) on the Alcohol Use Disorders Identification Test (AUDIT)\textsuperscript{37} was associated with a four times higher rate of continuing to smoke after cancer diagnosis compared with lower scores on the AUDIT.

The literature shows inconsistent associations between other potential risks and protective factors and the smoking pattern of patients with cancer, which need to be further investigated, such as gender and age.\textsuperscript{7,8,38–38}

However, regarding educational status, it appears that higher educational attainment is associated with a higher likelihood of quitting smoking after a cancer diagnosis.\textsuperscript{39}

While the diagnosed tumour type might play a role in smoking cessation in patients with cancer, the connection is not yet clearly understood. Some studies reveal that patients with a non-tobacco-related tumour have an increased probability of cessation, whereas some evidence indicates that people are more likely to quit smoking when they have been diagnosed with a tobacco-related cancer type.\textsuperscript{4,38} Schnoll et al\textsuperscript{48} speculated whether the presence of depressive symptoms may be a contributory factor that
might make it harder to quit smoking. They were able to demonstrate in their data that patients with non-tobacco-associated tumours reported lower levels of depressive symptoms than patients with smoking-associated tumour types. Also, smoking cancer patients with tumours whose development is closely related to smoking tobacco, such as lung cancer, often exhibit signals of a severe nicotine addiction, which is further one of the most common barriers to smoking cessation.27

Lastly, another relevant aspect might be the knowledge about the consequences of continuing to smoke after a cancer diagnosis. There are some studies testing the knowledge in medical staff40 41 but so far there are no studies testing the knowledge of the consequences of continued smoking in patients with cancer. It would be interesting to know to what extent patients with cancer are being educated, how much they know about these consequences and whether the level of knowledge is related to quitting smoking after cancer diagnosis. For regular smokers, it is known that misperceptions about cigarettes and smoking are associated with an increased likelihood of having multiple unsuccessful quit attempts.42

Overall, current evidence on barriers to participation in smoking cessation programmes among patients with cancer is sparse and not sufficiently reliable. However, they may provide a first indication of possible barriers, which will be further investigated in this study.

The present study will be the first to assess the prevalence of smoking in a large sample of patients at a German Comprehensive Cancer Center. The study also aims to further identify risk factors and risk groups that are more likely to continue smoking after a cancer diagnosis. As all smoking patients with cancer in all different motivational stages will be included, the study will generate knowledge about the prevalence of each motivational stage and the risk factors associated with each stage.

It is important to determine the smoking patterns of patients with cancer, as this will help to improve the design of targeted smoking cessation programmes.

By enrolling all smoking patients with cancer at all different motivational stages, the study will generate knowledge about the prevalence of each motivational stage and the risk factors associated with each stage. Finally, this study will also identify the needs and preferred conditions of smoking patients with cancer from their own perspective. This will help to create a framework (format and design) that patients with cancer can participate in and benefit from in the long term. All of the above should be considered when planning the content of a smoking cessation intervention.

Objectives
To address smoking in patients with cancer, it is important to understand the smoking patterns of patients with cancer, their intentions to quit and obstacles to quitting smoking. This study yields to identify smoking patterns and the intention to quit smoking in patients with cancer. Here, smoking patterns will include current smoking products, amount smoked per day, smoking years, smoking breaks, level of cigarette addiction and level of smoking cessation motivation.

Additionally, the study will assess health-related factors such as self-assessed health and QOL, reported distress and other factors such as secondhand smoke exposure, knowledge of consequences of continued smoking after cancer diagnosis as well as received social support and current alcohol consumption to review known and identify yet unknown associations with smoking patterns of patients with cancer.

Specifically, we seek to understand:
1. What is the proportion of adult patients with cancer who smoke, and how can their smoking patterns (level of cigarette addiction, level of smoking cessation motivation, smoked products, smoking breaks, smoked amount per day and overall smoking years) be characterised?
2. What sociodemographic, medical, psychological and other covarying factors are associated with current smoking status after a cancer diagnosis?
3. What sociodemographic, medical, psychological and other covarying factors are associated with the level of nicotine addiction (weak and strong addiction) in current smoking patients with cancer?
4. Based on the stages of change of the adapted version of the Transtheoretical Model (lack of intention, intention formation and action), what are the quit intentions of patients with cancer who smoke and what sociodemographic, medical, psychological and other covarying factors are associated with the respective stage?
5. What is the perceived need for a specific smoking cessation programme for patients with cancer, and how should this programme be designed?

METHODS AND ANALYSIS
Design
This cross-sectional study will examine the research questions (RQs) by means of a patient reported assessment among patients with cancer undergoing diagnosis, treatment or follow-up treatment in Hamburg, Germany. This study was registered at https://doi.org/10.17605/OSF.IO/PGBY8 by the authors.

Participants
A total of at least 865 patients with cancer (see sample size and power section) with all tumour entities will be surveyed. Participants will be divided into four groups: former smokers who quit before their cancer diagnosis, former smokers who quit after their cancer diagnosis, current smokers and never-smokers. According to our definition, never-smokers are those who have smoked no more than 100 cigarettes in their lifetime. Although it is not certain that the ex-smokers identified by our classification will remain indeed permanently abstinent for good, there is also no generally accepted period of time, that would indicate long-term abstinence without further
relapses in ex-smokers, so we have chosen the above-mentioned criteria for never-smokers.

The participation in this study is voluntary and there will be no financial compensation. Patients with cancer with all tumour entities who are over 18 years of age and understand sufficient German to complete the questionnaire are eligible to participate. Patients will be recruited at any stage of their course of the disease, either being newly diagnosed, in treatment or having follow-up appointments.

Recruitment and procedure
Participants will be directly recruited at various inpatient and outpatient clinics of the University Medical Center Hamburg Eppendorf and at cooperating office-based practices and non-academic hospitals of the University Cancer Center Hamburg network. Once eligibility has been confirmed by the research assistants, written informed consent will be obtained. Participants are then given the questionnaire to complete independently in their own time. The questionnaire will then be deposited in the study mailbox, which is meant to provide anonymity to help reduce social desirability bias.43 Research assistants will record any eligible patients who refuse to participate and their reasons for doing so. This will provide a way to later determine the participation rate. There is no established electronic record of smoking status in the digital systems of the clinics. Therefore, all information will come directly from the participating patients with cancer.

Current status
Pilot testing has been conducted with a scientific researcher whereby patients were asked to think aloud and express their thoughts aloud while filling out the questionnaire.44 Any concerns or issues during the pilot testing was adjusted for the main study. Patient recruitment for the main study began in 2021 and data collection is planned to be complete by June 2023.

Measurements
A questionnaire consisting of validated instruments and own developments was compiled. The questionnaire is a self-evaluation tool that will be filled out independently by patients. The questionnaire consists of different parts for different target groups based on their smoking status (see Table 1). A classification of the patients is based on self-ratings: Never-smokers (less than 100 cigarettes in their lifetime), former smokers or current smokers. Among

Table 1 Overview study measures

<table>
<thead>
<tr>
<th>Description</th>
<th>Instrument and subscale</th>
<th>Population</th>
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<tbody>
<tr>
<td></td>
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<td>Never-smokers</td>
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<tr>
<td>Sociodemographic characteristics</td>
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<td>Sociodemographic characteristics</td>
<td>Self-developed</td>
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<tr>
<td>Health-related factors</td>
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<tr>
<td>Medical data</td>
<td>Self-developed</td>
<td>x</td>
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<tr>
<td>QOL and health status</td>
<td>EORTC QLQ C30</td>
<td>x</td>
</tr>
<tr>
<td>Psychosocial burden</td>
<td>Distress thermometer</td>
<td>x</td>
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<tr>
<td>Social support</td>
<td>SSUK</td>
<td>x</td>
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<tr>
<td>Alcohol consumption</td>
<td>AUDIT-C</td>
<td>x</td>
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<tr>
<td>Smoking-related factors</td>
<td></td>
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<tr>
<td>Knowledge regarding the consequences of continuing to smoke after cancer diagnosis</td>
<td>Self-developed KSC-8</td>
<td>x</td>
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<tr>
<td>Passive smoking</td>
<td>National Health Survey—BGS98</td>
<td>x</td>
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<tr>
<td>Current and former smoking patterns</td>
<td>German National Cohort</td>
<td>x</td>
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<tr>
<td>Opinion on a smoking cessation programme for patients with cancer</td>
<td>Self-developed OSCC</td>
<td>x</td>
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<tr>
<td>Intention to quit smoking</td>
<td>FÄR</td>
<td>x</td>
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<td>Cigarette dependence</td>
<td>FTCD</td>
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AUDIT-C, Alcohol Use Disorders Identification Test—version C; EORTC QLQ C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire; FÄR, Questionnaire for measuring the intention to quit smoking; FTCD, Fagerström Test for Cigarette Dependence; KSC-8, Knowledge of Smoking after Cancer; OSCC, Opinion on a Smoking Cessation Program for Cancer Patients; QOL, quality of life; SSUK, Social Support with Illness Scales in Cancer Patients.
smokers, all consumed smoking products will be recorded and descriptively presented. The evaluation of nicotine addiction is restricted to smokers using cigarettes.

The first part of the questionnaire contains sociodemographic (sex, age, partnership, number of children, living situation, degree of graduation and occupational situation) and medical data (cancer diagnoses, date of diagnosis, and number of recurrences, completed, current and planned cancer treatment as well as comorbidities). The questionnaire is based on anonymity to help reduce bias due to social desirability. A filter question is used to determine the current smoking status. Smoking status then further defines which additional items each patient is asked to complete. The never-smoker’s version is the shortest and has no exclusive items and instruments for its group. The three versions are printed on different colored paper to simplify the procedure of finding the right items to complete for each patient. The colours have no other meaning. The second part of the assessment consists of the following validated and self-developed instruments:

The ‘European Organization for Research and Treatment of Cancer Quality of Life Questionnaire’ (EORTC QLQ C30) is an instrument developed for assessing health-related QOL in oncological patients. \(^3\) Items 29 and 30 from the ‘EORTC QLQ C30’ are the two global items that obtain a self-assessment of the state of health and QOL during the last week and were used here.

To explore secondhand smoking exposure, two items from the ‘German Health-Survey 1998’ will be used.47

We further developed an 8-item instrument to test knowledge about the consequences of continued smoking after cancer diagnosis and during treatment. We named the instrument ‘Knowledge of Smoking after Cancer’. Eight statements outline the consequences of continued smoking in patients with cancer. The answer scale consists of five options of approval levels (‘I don’t agree at all’, ‘I don’t agree’, ‘I partly agree’, ‘I agree’, ‘I totally agree’). To validate the knowledge test, 11 experts (2 oncologists, 3 psycho-oncologists, 6 scientific staff) as well as 3 oncological patients (1 never-smoker, 1 former smoker and 1 current smoker) were involved in the development, for example, completing and/or evaluating the questionnaire (see online supplemental S1).

The 8-item abbreviated version of the ‘Social Support with Illness Scales in Cancer Patients’ (SSUK-8) records the ‘social support’ patients receive from relatives and friends. We used the validated German short version. \(^4\) It consists of eight items measuring positive support (four items) and detrimental interactions (four items). Both scales yield internal consistencies measured with Cronbach’s alpha of 0.88 and 0.68. All items are rated on a 5-point Likert scale, which ranges from ‘never’ (0) to ‘always’.\(^1\)

Furthermore, the ‘alcohol consumption’ is recorded using the ‘Alcohol Use Disorders Identification Test—version C’, a short screening instrument consisting of three items.\(^3\)

In addition, we use the German version of the single-item visual analogue scale of the German version of the ‘National Comprehensive Cancer Network distress thermometer’ to measure experienced ‘distress’ in patients with cancer.\(^4\) \(^6\) The scale will be used to quantify the level of distress during the last week, ranging from 0 (‘no distress’) to 10 (‘extreme distress’).

Additional instruments and subscales will be assessed only in former smokers and smokers. These include items of the ‘German National Cohort’. Former smokers will complete questions about their ‘smoking patterns in the past’. This includes six items about the age at which they started smoking, when they stopped smoking, about possible smoking breaks and the reason for smoking cessation, taken from the subscale ‘former smoker’. For smokers only, we use five items from its subscale ‘current smoker’ to ask about the ‘current smoking patterns’ (product, amount, frequency, breaks, etc).\(^5\) We furthermore formulated several closed questions to find out what former and current smokers think about a potential smoking cessation programme. We called this instrument ‘Opinion on a Smoking Cessation Program for Cancer Patients’. It contains questions on various aspects of smoking cessation aimed at patients with cancer (eg, the importance of education, the usefulness of a smoking cessation programme for patients with cancer). Current smokers will be asked to answer additional questions concerning potential participation in a smoking cessation programme (see online supplemental S2). To determine a possible nicotine addiction of current smokers, the German translation of the ‘Fagerström Test for Cigarette Dependence’ (FTCD) will be used.\(^6\) The FTCD contains six items regarding the smoking patterns to categorise cigarette addiction.

Additionally, the ‘Questionnaire for assessing motivation to change’ (FÄR),\(^7\) a German questionnaire to measure ‘the intention to quit smoking’, which is based on the “Transtheoretical Model for Behavioral Change”,\(^8\) is used to assess the motivation to quit in current smokers. The questionnaire consists of 12 items measuring the three factor analytically derived dimensions: lack of intention, intention formation and action.\(^9\) The internal consistency for the scale ‘lack of intention’ is \(\alpha=0.70\), for the scale ‘intention’ is \(\alpha=0.69\) and for the scale ‘action’ is \(\alpha=0.75\). Each of the scale’s ranges from −8 to 8. Respondents are assigned to the dimension that has the highest value in each case.\(^7\) See table 1 for an overview of the study measures and the assignments to the three groups (ie, never-smokers, former smokers and smokers).

Sample description and statistical analysis
The study sample will be described in terms of their sociodemographic characteristics, health-related factors and smoking-related variables. Sociodemographic and medical data, QOL and Distress thermometer as well as the SSUK variables. Categorical data will be summarised by absolute and relative frequencies. Depending on the distribution, continuous data will be summarised by
mean and SD or (for highly skewed data) median and range. The proportion of those currently smoking and those who quit smoking but continued to smoke after diagnosis as well as the smoking pattern (level of addiction, smoking cessation motivation, smoked products, smoking breaks, smoked amount per day and overall smoking years) in current smoking patients with cancer (RQ1), will be reported in per cent.

Covariates associated with the current smoking status (i.e., former smokers who quit after diagnosis or current smokers, RQ2) will be analysed by using a multivariate logistic regression that includes the following potential predictors: sex, age, education, partnership, having children, tobacco-associated cancer type, alcohol consumption and social support. The binary dependent variable is the smoking status (current smoker vs ex-smoker who stopped smoking after the cancer diagnosis). This analysis will not be performed for former smokers who quit before diagnosis, as these patients are not the target group of a smoking cessation programme to be developed.

A subgroup analysis of covariates that might be associated with the level of cigarette addiction in current smokers (RQ3) will be conducted. Due to expected small sample sizes and unequal group sizes, the criterion levels strong and very strong addiction will be combined, resulting into three overall categories (no addiction, medium addiction and strong to very strong addition). There is insufficient evidence in the literature to date on factors related to levels of cigarette dependence. Subsequently, a multinomial logistic regression will be performed that includes the same predictors as in the prior RQ.

For RQ4, a multinomial regression will be performed. The criterion variable is the stage of change in the adapted version of the Transtheroretical Model by Hannöver (lack of intention, intention formation, action), which is calculated by means of the questionnaire on willingness to perform that includes the same predictors as in the previous questions. However, due to the expected small sample size, the variables education and social support were omitted, and the knowledge test will be used instead. As described in the Introduction section, there is little evidence on the knowledge level of smoking after cancer. The same predictors were used as in the previous questions. For this reason, the perceived necessity of a suited smoking cessation programme (RQ5) will be analysed using descriptive statistics (mean and SD, or median and range, depending on distribution of data).

Statistical analysis will be completed using SPSS V.27.0. All persons who filled out less than 30% of the quantitative items will be excluded. Under the assumption that missing values follow the missing at random principle, missing data will be imputed using unbiased estimation (expectation–maximisation algorithm). Variables used in the imputation model will be all relevant data. To check the robustness of the findings against different approaches to dealing with missing data, sensitivity analyses with complete cases only will be performed (without imputing missing values).

### Sample size and power

The procedure requiring the largest sample size in our study is the analysis of the prevalence of current smokers: A sample size of 865 produces a two-sided 95% CI with a width of 4%, assuming a sample proportion of current smokers of 10%.

### Patient and public involvement

There will be no patient or public involvement in the design, conduct or reporting of this research study. Also, in the future, they will also not be involved in the further conducting or dissemination plans of this study.

### ETHICS AND DISSEMINATION

The study will be carried out in accordance with the Code of Ethics of the Declaration of Helsinki and was approved by the ethics committee of the local psychological Ethic committee at the centre of psychosocial medicine Hamburg, Germany (LPEK) (tracking number: LPEK-0212). Patients will receive verbal information and a written document describing the study. Informed consent will be obtained prior to participation. Data collected and the consent forms will be stored separately to preserve anonymity. The results of this study will be published in peer-reviewed scientific journals and presented at international conferences.

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### Competing interests

None declared.

### Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

### Patient consent for publication

Not applicable.

### Provenance and peer review

Not commissioned; externally peer reviewed.

### Supplemental material

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