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Evaluating a rehabilitative intervention for substance-dependent patients with and without their accompanying children in Germany (KontextSucht): study protocol for a non-randomised trial

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ABSTRACT

Introduction People suffering from substance use disorders often live in social contexts with children or are parents themselves. Addicted parents show specific substance-related problems while raising their children, which often leads to various lifelong consequences for the children. The German rehabilitative treatment system allows bringing children to inpatient treatment centres. This mixed-methods study evaluates a newly developed intervention, called 'KontextSucht' or 'AddictionContext', for parents in rehabilitation treatment centres concerning the effectiveness of the intervention in parenting and abstinence outcome.

Methods and analysis The study uses a two-stage parallel mixed-methods design. A feasibility study (stage 1) and a benefit assessment (stage 2) will be conducted to evaluate the intervention. Both parts of the study will be carried out with qualitative and quantitative work packages. German-speaking parents of children 0–14 years will be included in this study. Qualitative data will be analysed using qualitative content analyses, whereas quantitative data will be analysed descriptively using regression analysis as well as linear mixed models.

Ethics and dissemination All participants will receive detailed information on the study and sign informed consent before data collection. The research team has obtained the approval of the Ethical Review Committee at the Technical University of Munich in Germany and will follow all legislation rules regarding data protection. The study results will be published in peer-reviewed national and international journals. Furthermore, the study results will be included in an intervention manual distributed to treatment centres.

Trial registration number DRKS00030950.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Using a mixed-methods approach provides the opportunity to combine two methodologically complementary perspectives.
⇒ A longitudinal study design in qualitative and quantitative research methods optimises the evaluation approach.
⇒ A two-stage evaluation best fits the research needs in implementing an addiction intervention programme and adapting methods to changes of a project that develops and implements an intervention.
⇒ The expressive power of the study is limited to an adult perspective, as only parents and professionals participate in the study.

INTRODUCTION

Substance abuse: epidemiology and effects on society

Worldwide, about 35 million people between the ages of 15 and 64 years are affected by substance use disorder (SUD).[1] In Germany, about 8.2 million people are addicted to (il) legal substances or gambling.[2] There are several adverse effects of substance abuse on the consumers themselves and the social context in which they live. These include physical and mental comorbidities as well as psychosocial and social difficulties.[3–7] Regarding the societal impact of substance abuse, these physical and psychological consequences cause substantial economic and social burdens, for example, early retirement.[8 9] In 2018, the overall costs of the use of tobacco, alcohol and cannabis were estimated at up to three-digit billion euros in Germany.[2] These numbers do not consider costs for families and their social environment or side effects of drug use, productivity losses, as well as individual pain and grief. Alcohol abuse costs German society around €57 billion a year.[10] Each year, more than €40 billion can be allocated to indirect costs related to

alcohol abuse (eg, due to unemployment, need for care and rehabilitation services) in Germany.[10] In addition, the direct costs, defined by accidents and healthcare costs, are quantified at about €17 billion in Germany.[10] Furthermore, 17.6% of the German study population's Epidemiological Survey of Substance Abuse showed problematic alcohol use.[11]

Estimating statistics for illegal substances is more complicated. Due to self-report bias and stigma, numbers are probably underestimated.[12] US data from 2020 showed that about 13% of US Americans were using an illicit drug the past month, that is, defined as 'current use'.[13] In Germany, problematic substance use of at least one illegal drug (using the criteria of the Severity of Dependence Scale) has a 12-month prevalence of 2.9%.[14] A prevalence of cannabis use is observed at 2.5%, and cocaine and amphetamine at 0.4%.[14]

Substance-abusing parents

Epidemiology

Reliable numbers of children affected by parents with SUD are rarely available due to several study bias aspects, for example, social desirability reporting bias in patients with SUD.[15] The German drug report quantifies the number of children living together with at least one parent with SUD, including all legal and illegal substances, to more than 3 million.[16] Another German study found that about 3.8 million mothers and fathers practise risky alcohol consumption.[17] Gomes de Matos *et al* estimate that about 8.0 million adult relatives, including children until the age of 14 years, live together with a substance-addicted person based on German data from 2012.[18] In the USA, the National Survey on Drug Use estimates that 10.5% of the population younger than 17 years are living with at least one parent with SUD.[19 20] A further study estimates the number of children living with parents with SUD to be between 11.2% and 20.2% using German data from 2018.[21]

Effects on children

Regarding the effects of SUD on children of addicted parents, studies have shown that they often face substantial difficulties raising their children. This is strongly related to the parents' addiction and social environment. Children living with addicted parents face criminal structures (eg, acquisition crime), physically and mentally absent or abusive parents, chronic diseases and interrupted relationships.[22–25] Family conflicts and domestic violence are also seen in drug-affected families, as well as the presence of 'unhealthy' friends and partners that children are exposed to.[23 25 26] These processes often lead to socioeconomic discrimination, social exclusion, separation from the parents, out-of-home care, homelessness, parentification and neglect.[23 24 27] In addition, some studies found associations between children of addicted parents and the development of own psychiatric diseases like attention deficit hyperactivity disorder, depression or anxiety disorders.[16 22 28]

Moreover, these children are at higher risk of developing an addiction themselves.[22 24 27 29] Regarding alcohol use disorder, there is evidence that the stronger adults are affected by alcohol use disorder in a household, the weaker the academic achievement of their children.[22 24] Other studies argue that weaker outcomes in children's skills are caused by the psychopathology and psychiatric comorbidity of the parents and not only by the addiction itself.[30] In general, Solis *et al* found that children of addicted parents are often faced with poorer academic functioning.[22] Moreover, the authors found that parental risk factors for children's social and emotional functioning can be minimised by constant contact with a non-addicted parent and abstinence or remission of the addicted parents,[22] as well as other emotionally stable social contacts.[27] SUD can also lead to parent–child attachment difficulties. Parenting behaviour equipped with warmth, responsiveness and engagement,[27 29] on the one hand, and sensitivity and effective discipline, on the other hand, is less often seen in parents with SUD compared with parents without SUD.[22] This can lead to weaker parent–child attachment.[27 29 30]

Rehabilitative interventions for parents with SUD in Germany

All presented effects and the cumulated risks of children raised by parents with SUD indicate the need for specific interventions.[27] A review of 21 studies shows that addicted parents sometimes are aware of their negatively affecting behaviour on their children but need more skills to handle challenging situations.[19] In Germany, the high potential for a parent-specific intervention in inpatient rehabilitation is seen.[28] Still, there is a lack of specific interventions for inpatient care that are used primarily to improve educational skills, parent–child bond, parental behaviour and abstinence. Mainly outpatient interventions for parents with SUD with children under 14 years exist in Germany. In inpatient rehabilitation treatment, the focus is restricted to patients, without respecting their parenting role or accompanying children. The accompanying children are hosted in the rehabilitation clinics without profiting from treatment offers regarding their special needs. It can be stated that missing this group of affected children and parents is a gap that needs to be closed to decrease the adverse effects that can arise in SUD families. Patients with SUD stay in rehabilitative treatment after detoxification for 12–26 weeks,[31] particularly this relatively extended stay offers the opportunity to go into detail about parenting skills.

Regarding the rehabilitative treatment of parents with SUD, studies show that the awareness of the impact of drug addiction of parents with SUD on their children is a strong catalyst for the parents to overcome their addiction.[23 25] In Germany, some rehabilitation clinics offer parents the possibility to bring along their children. Moreover, this is why parenting skills with immediate contact with their children can be trained in these treatment centres, focusing on all relevant aspects of SUD

parenting in depth. To date, inpatient healthcare professionals have been forced to manage the needs of parents with SUD on their own without access to previously evaluated and standardised approaches. Therefore, it was up to the personal capabilities and individual competencies of healthcare workers to provide support.

The project 'KontextSucht' will develop and implement an evaluated intervention for parents with SUD that contains the option to be rolled out to other comparable rehabilitation clinics in Germany afterwards. The intervention aims to improve parenting skills, parent–child bond and parenting behaviour to the degree that children will be raised in an age-adequate way, depending on the developmental challenges and the needs of children between 0 and 14 years (eg, learning to walk and speak, following rules, settling in kindergarten or school). To improve parenting skills and reduce overwhelming feelings, the goal is to improve working skills through extended, hopefully lifelong, drug abstinence and employability. As a result of fewer parenting problems, the overall costs will be reduced for all parts of the public healthcare system.

METHODS AND ANALYSIS

Study background

The 'KontextSucht' intervention (KSI) will be evaluated and supervised by this prospective multicentric study. The intervention will be developed and executed by the healthcare professionals of two rehabilitative clinics (MEDIAN Klinik Römhild and Barbarossa Klinik Kelbra) in central Germany. The project is led by the German pension insurance of central Germany (Deutsche Rentenversicherung Mitteldeutschland). The research team of the Technical University of Munich (TUM), Chair of Social Determinants of Health, will scientifically accompany the project by collecting data and analysing its effectiveness. The whole project is funded by the Federal Ministry of Labor and Social Affairs (Bundesministerium für Arbeit und Soziales) (grant number 662S0053X1-1). 'KontextSucht' is a model project in the funding line 'rehapro' executed between November 2021 and October 2026.[32]

Patient and public involvement

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

KontextSucht intervention

The intervention is based on the assumption that the addictive behaviour of parents leads to poor parenting and a disrupted parent–child bond,[22 23 27] thereby leading to overall negative effects (eg, poor educational functioning[22]). The KSI focuses on parents of children until the age of 14 years. Furthermore, the KSI will support parents with and without accompanying children in inpatient care on the same level. This will efficiently help inpatient care address as many parents as possible. If the participants are parents with accompanying children, the children will stay with their parents in a separate parent–child room in the facility for the whole duration of their parent's treatment.

KontextSucht Intervention (KSI)	
Module 1	Parenting skills (theoretical, seminar, group session)
Module 2	Leisure activities (practical, group session)
Module 3	Parents forum (practical, group session)
Module 4	Parents (theoretical, group session)
Module 5	Parent-child-time (practical, therapeutically guided self-study unit)

Figure 1 Aspects of the KontextSucht intervention.

The overall project contains a three-step procedure, starting with a *developing stage* to draft KSI by professionals from two rehabilitative treatment centres in central Germany. Following the development stage, KSI will *be tested in the second step* and *implemented in the third step*. Steps two and three are supervised by the research team using feedback and evaluation study processes. The result of the developing stage is the first version of the KSI (figure 1), which will include five modules containing 12 sub-elements each.

As can be seen in figure 1, the five modules 'parenting skills', 'leisure activities', 'parents forum', 'parents' and 'parent–child time' will focus on different aspects of parenting and convey other skills. Every element will take 60–90 min and is conducted in a group intervention setting. Some of the elements (modules 2 and 5) will be held with the accompanying children (0–14 years old) to practise the developed parental skills (module 5). Others (modules 1 and 4) will be held theoretically so parents without accompanying children can further improve their skills and knowledge. Module 3 targets the parents' co-determination of the rehabilitation process and issues of parents and children in the clinics. Moreover, the goal is to take over responsibility and improve organising skills. As can be seen, parents with accompanying children will participate in all modules, whereas parents without their children in the facility will only participate in two modules with theoretical input. This is why both parent groups with and without their children in the facility will probably benefit from the KSI to different degrees.

Design, aims and research questions

The prospective, multicentric evaluation study uses a parallel mixed-methods design for both stages.[33 34] Mixed-methods studies provide an option to enhance the understanding needed for multiple research questions present in this study.[35] This approach offers the opportunity to highlight multiple perspectives on the same topic and consequently betters comprehension. The methodological approach is supported by using data, method and investigator triangulation.[36]

The aim of the two-stage study is to evaluate the KSI developed by two rehabilitation treatment centres (intervention clinics). The exact research questions for each stage of the study can be found in online supplemental file 1. The study includes a *feasibility study* while KSI is tested by the healthcare professionals and a *benefit assessment* during the implementation in the clinics. Qualitative and quantitative

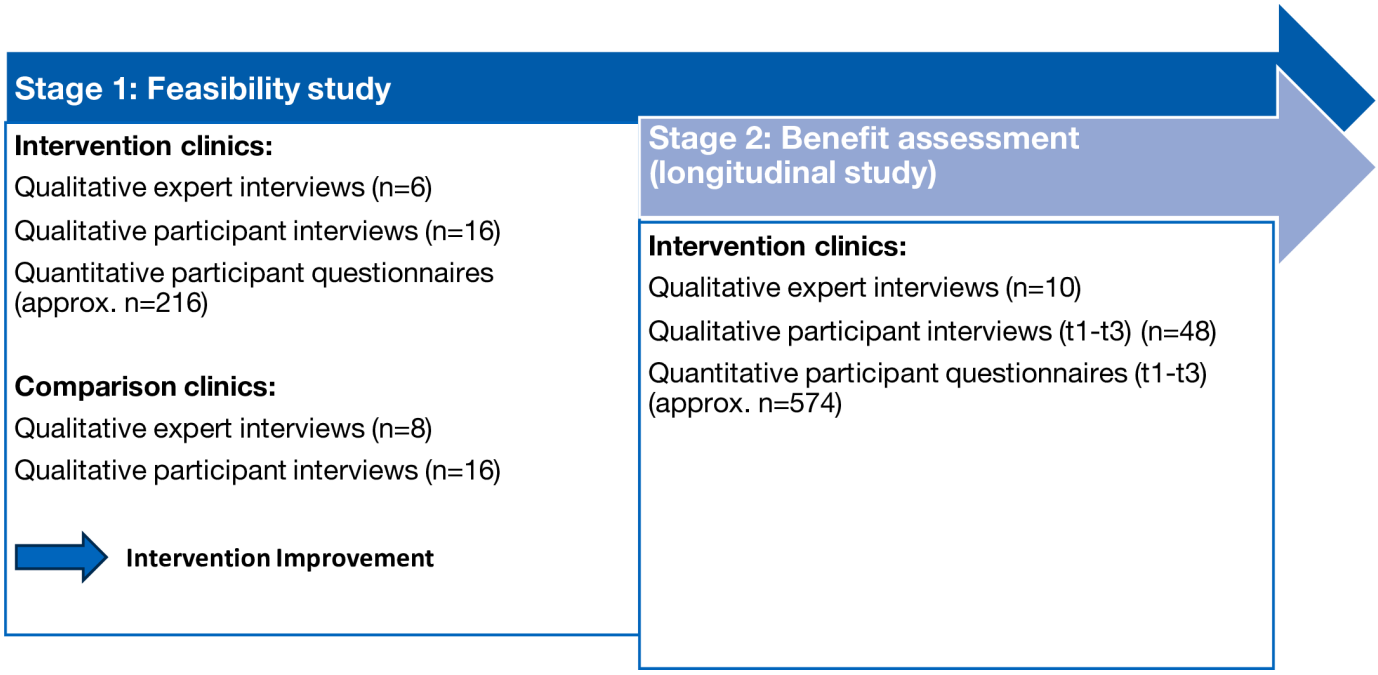

Figure 2 Study design. t1, beginning of the intervention; t2, end of the intervention; t3, 1-year follow-up.

data collection of both study stages are presented in figure 2. The provided quantitative numbers adhered to the limits of treatment capacity over the duration of the project from 2023 to 2026. The goal is to include all participants in the quantitative sample. In qualitative research, theoretical saturation is one of the key aspects of the decision on sample size. Studies have shown that theoretical saturation in qualitative research can be reached within 9–17 narrow interviews, dependent on the research field and homogeneity of the participants.[37] This is why we strive for the numbers presented in figure 2. However, we decide to continue collecting data until theoretical saturation is reached.

In total, six rehabilitation clinics will participate in the study. As part of the project team, the two intervention clinics treat parents with and without accompanying children. The four comparative clinics are split into two clinics with and two without the option for parents to bring their accompanying children. The comparative clinics do not have an evaluated concept for parents with SUD. This gives an overview of the situation of parents with and without accompanying children reflecting their needs in rehabilitative treatment. The goal of the first stage of the study (ie, the feasibility study) is to give evidence-based, high-quality feedback to improve the KSI. The feedback focuses on parenting skills, personal needs of parents with SUD in rehabilitation clinics and framework conditions of the KSI. To reach this aim, experts and patients of the two intervention clinics, as well as from four comparative inpatient clinics, will be interviewed to assess the needs of parents with SUD during the rehabilitation process.

In the second stage (benefit assessment), the KSI will undergo a qualitative and quantitative evaluation to evaluate the utility of the KSI with respect to the target group in the intervention clinics only. It aims at assessing the usability of the KSI regarding the SUD, employment and parenting of the participants.

The outcomes are predefined by the overall project. The main outcomes are the following: abstinence, occupation, parenting skills, parent–child bond and parenting behaviour.

The quantitative part enhances the understanding of statistically relevant relationships between the study outcomes, for example, abstinence and workability. The qualitative part of the study evaluates different research aspects (eg, missing aspects of the intervention, optimisation potential, satisfaction of the participants, confidence in the ability to stay abstinent after participation in KSI) in depth and will use semistructured (online) interviews with experts and patients.[38] They will be analysed following a deductive content analysis approach.[39] Both analyses are necessary to understand the influences on the intervention, for example, description of the target group, understanding of personal needs and barriers to the implementation.

Further, single elements can be discussed and improved (eg, explore deficits and positive aspects of well-being), which is especially important when developing a manual that is intended to be transferred to other organisations in Germany after the evaluation. Moreover, the quantitative questionnaires for the study will provide information on the frequency and strength of specific aspects of KSI and its target group.

During the feasibility study, the interviews will take place in the two intervention (Barbarossa Klinik Kelbra and MEDIAN Klinik Römhild) and four comparative clinics. The interview guide contains questions that are

equal to the different target groups (participants in the intervention and comparative clinics) to compare the situations as well as additional questions on the KSI that can only be answered in the intervention clinics. Detailed information about the KSI participants will be provided using quantitative questionnaires in the intervention clinics. During the benefit assessment, quantitative and qualitative data collection will take part in the intervention clinics only. All detailed research questions of stage 1 and stage 2, experts as well as participants, and qualitative and quantitative data collection can be found in the online supplemental file 1.

Identification of participation and sample size for both study stages

During the feasibility study, the KSI participants will take part in the qualitative and quantitative data collection, while professionals (doctors, therapists, etc) will only participate in expert interviews. We will further conduct interviews with patients of the comparison clinics. Additionally, we will interview members of the outpatient addiction care system. Due to German insurance regulations, all intervention clinics can accommodate accompanying children until 12 years with the parents with SUD in treatment. Only two of the four comparison clinics need to be able to accommodate accompanying children. However, the project manager and clinics decided to also include parents with accompanying children until the age of 14 years respecting formal and internal rules. This gives the option to include more parents to the KSI. Therefore, German-speaking parents with SUD of children until the age of 14 years, and experts who have professional contact with parents with SUD in their daily work will be included in the study.

During the benefit assessment, the KSI participants in the intervention clinics will undergo a qualitative interview and quantitative questionnaires. Expert interviews will be conducted with the executing healthcare professionals of the KSI in the intervention clinics and will be recruited by the research team. The recruitment strategy as well as the inclusion criteria remain the same for both study stages.

In sum, 790 participants will participate in KSI between 2023 and 2026 reasoned by the capacity in the intervention clinics. The study tries to include all participants of the KSI that can be treated during the time of the project. Overall, we will conduct about 100 interviews with participants and experts. Those interviews are split into about 22 interviews taking place during the feasibility study and a further 58 interviews in the benefit assessment in the intervention clinics. Moreover, 24 interviews will be conducted in the comparison clinics. It is planned to continue the qualitative data collection until theoretical saturation is reached.[37] The sample size for the quantitative dataset can reach up to a maximum of 790 (216 stage 1, 574 stage 2) participants, as many patients with SUD are challenging to reach for study participation during follow-up at home in t3 (1-year follow-up). About half of the participants in contextual rehabilitation treatments do not finish their rehabilitation treatment in Germany.[40] Therefore, a lot of loss to follow-up must be expected for the study participant expectations. To reduce loss to follow-up, participants will be informed about the importance of a complete dataset. Furthermore, participants will be reminded via email, post or telephone by the research team, and the date of the third qualitative interview will be set at the end of the second interview.

Recruitment and data collection

The recruitment of the patients participating in the study during the feasibility study as well as t1 (beginning of the intervention) and t2 (end of the intervention) of the benefit assessment study will be executed by the (medical) staff of the intervention and comparative clinics. Every participant in both stages will get informed about the intervention and the evaluation study. An information sheet will be delivered, and if the patients agree to participate, the gatekeepers will contact the researchers. This is especially important for quantitative data collection as (online) questionnaires must also be handed out to the study participants by the gatekeepers. For t3 of the longitudinal study, the researchers will contact the participants directly as they will not be in inpatient treatment at this point.

A semistructured interview guide will be developed for the different target groups (doctors, patients, therapists and outpatient consultants) for all qualitative interviews. An incentive coupon will be handed out to the patients by raffle. The face-to-face interviews will take place at the clinics in an undisturbed environment. The possibility of online interviews is guaranteed upon request. For t3, qualitative online interviews will be preferred before visiting the participants in their regional outpatient treatment centre. Every specific interview guide, as well as the quantitative questionnaires, will be pretested. The interview guides will be developed following the literature of Helfferich and, in addition, Gray *et al* for online interviews.[41 42] Quantitative data will be collected by offering an online survey as well as a pencil–paper approach. Already established and tested assessment tools are used. Quantitative and qualitative research quality criteria will be respected.[43 44]

Data analysis

Qualitative analyses

The semistructured interviews will be conducted by the research team member (AS), audio-taped and professionally transcribed. Analyses of the interviews will be executed with MAXQDA V.2022 analytics pro software using the methods for qualitative content analyses by Mayring.[45] MAXQDA analytics pro provides a good solution to analyse mixed-methods approaches.[34] Qualitative content analysis by Mayring is a systematic technique to examine texts with rules and contributes to the intersubjectivity

of the procedure of analysis regarding the defined questions. Interview material will be coded deductively using purposive categories, such as the defined study outcomes (abstinence, parenting skills, etc). Categories will be built following the research questions. The research associate (AS) will undertake the coding while practising intense exchange with another research associate (LH) and the qualitative research group of the Chair of Social Determinants of Health. In closing, the examination of the Consolidated criteria for Reporting Qualitative research will be used to respect qualitative quality criteria.[46]

Quantitative analyses

Quantitative data will be collected using an online as well as a paper–pencil survey, which will be merged into one data file. The collected data in the cross-sectional data collection in stage 1 and the longitudinal data collection in stage 2 will contain personal variables, for example, age, gender, number of children, housing and sociodemographic variables. Moreover, self-made and pretested items on KSI-specific features (eg, group size, frequency and time of intervention units) are added to the questionnaire in both stages. Additionally, already evaluated assessment tools such as the Parenting Behaviours and Dimensions Questionnaire[46] or Perceived Stress Scale-10 in German version[47 48] are used for stage 2.

Analyses of the quantitative data will be done using statistics software 'R for data science'. After completion of data collection, data will be checked for consistency and missing values. Missing values that remain from incomplete questionnaires, non-answering and early discharge from the clinic will be replaced using multiple imputation. This procedure resolves the problem of falsified data resulting from single imputation methods (eg, mean replacement) through biased variance and covariances.[49]

During the first stage of the study, the data will be analysed descriptively, and correlations among the study variables will be calculated. Therefore, the strength of the associations between abstinence, ability to work, and parenting variables and the different independent variables will be examined.[50] In the second stage of the study, the longitudinal data will be analysed using linear mixed models. Using this technique, the hierarchical structure of the data will be considered, allowing to estimate variability within and across participants. Thus, it is an adequate way to analyse repeated observations for the dependent variables, abstinence, occupation and parenting variables, which are correlated over time[51] and will allow to predict the impact of the intervention.[52] All analyses will be controlled for possible confounders (eg, age, gender, education, duration of SUD, comorbidities). The results will be discussed within the quantitative research group of the Chair of Social Determinants of Health.

Consolidation of qualitative and quantitative analyses

During each stage of the study, qualitative and quantitative data will be analysed separately before bringing the information together. In the second step, results from the data analyses will be interpreted together regarding similarities and differences of the study outcomes. This triangulation will help to precisely explain the study outcomes and to reduce limitations remaining from the separated analysis.

ETHICS AND DISSEMINATION

The TUM, Chair of Social Determinants of Health, has obtained approval for the study from the Ethical Review Committee of the Department of Sport and Health Sciences of the TUM (reference number: 2022-624 s-KH). The study will be conducted according to the principles of the Declaration of Helsinki and will follow the standards of good scientific practice. Before conducting the interviews, patients will sign an informed consent form. If needed, the researcher provides further information and explanation to the participants. At any time, participation is voluntary and can be withdrawn and discontinued without negative consequences.

For data management, a legal requirement in the German version of DSGVO (General Data Protection Regulation) is used, and the data management concept was submitted to the TUM internal department for data security approval. All external services, for example, transcription of the interviews, must follow the legal requirements. Pseudonymisation (through a code) ensures data protection of all quantitative and qualitative data. The pseudonym will also be used to gather information from different data collection dates. Through this approach, the risk of identification can be minimised and data are protected. All data containing identification aspects (eg, record, declaration of consent, pseudonym assignment list) are secured separately from study data in locked, key-protected locations at the Chair of Social Determinants of Health. The pseudonym assignment list can only be accessed by a few research team members. All data will be deleted once the study has been completed, after 10 years at the latest. In case of withdrawal, all information collected concerning the participant is deleted immediately.

The results of the study will be disseminated in national and international, high-quality peer-reviewed journals and at several national and international conferences. Furthermore, all study results will be shared with the developers of the KSI itself and included in the intervention manual.

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Contributors AS wrote the initial draft of the manuscript, will conduct the interviews and collect quantitative data, and is responsible for data analyses. LH and MR were involved in the grant application. AS and LH wrote the study protocol for the Ethical Review Committee. JG, JS, LH and MR critically reviewed the article several times and gave advice on the whole process of this study protocol and research. The authors have read and approved the final version of the manuscript.

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