


BMJ Open Healthcare needs among unaccompanied minor refugees: a study protocol of a qualitative study explaining access and utilisation across place and gender

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ABSTRACT

Introduction Several studies have identified that unaccompanied minor refugees (UMRs) are allegedly ‘vulnerable’ and belong to a high-risk group in terms of psychological distress and post-traumatic stress disorder due to their preflight, perflight and postflight experiences. Psychosocial care (PSC) is of high importance for UMRs, but little is known about barriers to access and utilisation of PSC across place and gender. The aims of this gender-sensitive qualitative study will be to build on the existing body of literature and to provide qualitative evidence on the contexts and mechanisms of PSC for male and female UMRs in Germany by comparing two German regions.

Methods and analysis Following the study preparing realist review, a qualitative study will be undertaken in Berlin and Central German cities. Approximately 24 experts from the field of PSC and 12 lay UMRs will participate in face-to-face, semistructured interviews. Data will be transcribed and analysed based on the grounded theory research paradigm.

Ethics and dissemination Only participants who have been informed in both German and their native tongue and who have signed a declaration of consent will be included in the study. The study will comply rigorously with German data protection standards. Approval from the Ethical Review Committee at Martin Luther University Halle-Wittenberg, Germany has been obtained and granted. The results of the study will be presented at several conferences and will be published in high-quality, peer-reviewed international journals. The results will display a differentiated picture of the PSC of UMRs in Germany. Such knowledge is a precondition for a ‘science of change’ that translates explanations into practical recommendations on how to improve healthcare policies.

Trial registration number DRKS00018080.

INTRODUCTION

According to Directive 2011/95/EU of the European Parliament, an unaccompanied minor refugee (UMR) is a person under 18 years of age who enters the territory of a member state ‘unaccompanied by an adult responsible for him or her under the law or practice of the member state concerned, as

Strengths and limitations of this study

- The synthesis of expert and lay knowledge will inform health services research and practitioners.
- The study preparing realist review provides a comprehensive overview of interconnected psychosocial care (PSC) contexts, mechanisms and outcomes.
- The qualitative approach of the study will include reflection of discourses and health policies as well as unaccompanied minor refugees’ social positions and will enrich epidemiological research.
- The underlying structural and discursive processes will be unravelled with the help of the qualitative approach.
- The regional focus on medium-sized cities in Central Germany (Leipzig, Halle/Saale, Jena and Erfurt) and Berlin limits the study, as evidence may be regionally specific and there is a high variability in PSC programmes.

long as he or she is not effectively taken into the care of such an adult, including minors left unaccompanied after entering the territory of a member state’.¹

According to the United Nations Refugee Agency, approximately half of the refugee population worldwide are persons below the age of 18 years.² In 2015 and 2016, Germany received the highest number of UMR applications (35 939), compared with 3000 UMR applications in 2010 and 12 201 UMR applications in 2018.^{2–4}

UMRs are considered to be a high-risk group for post-traumatic stress disorders (PTSD), major depression, anxiety and several somatic (co)morbidities.^{5–9} Due to their preflight burden (including war and displacement), their migration experiences and the circumstance of entering the receiving country alone, resilience and protective factors are often missing and intersect with other determinants of health, such as adolescent age, gender,⁵ preflight, perflight and postflight

experiences, and residential permit status.^{9 10} More than 50% of UMRs show distress symptoms,¹⁰ but providing psychosocial healthcare poses challenges.^{6 11 12} For instance, studies from Germany have found that psychosocial care (PSC) for UMRs is provisionally provided by emergency and refugee relief⁶ and in so-called clearing centres^{7 12} and is legally administered by youth and social welfare services.¹² Health services research has identified a multitude of legal, cultural and language barriers in access to and utilisation of PSC for (adult) refugees,^{11 13 14} but UMRs and their PSC processes have scarcely been studied so far. In light of the current situation of young refugees on the Greek islands and the efforts of the non-governmental organisations that are advocating for their admission to Germany so that they may be cared for, this research project is of high importance and topicality. In the socioepidemiological research context, it is one of the rare theory-informed studies that reflect the influence of discourses as well as take in consideration the social positions of UMRs from the perspectives of both the UMRs and their caregivers.

Need for explaining and optimising PSC access and utilisation for UMRs

Generally, PSC can be defined as services that aim to deal with the psychological and social interactions of people in need and to contribute to preventing the worsening of mental disorders and psychological distress. Alongside psychological aid, PSC promotes the integration and social participation of people, as it aims to improve and stabilise the physical and mental state of health as well as provide support for problem-solving processes such as bureaucratic procedures.¹⁵ With inadequate PSC, there is a risk of PTSD chronification and thus the development of complex PTSD symptoms and ongoing personality changes. UMRs may experience persistent feelings of hopelessness, nervousness or alienation.¹⁶

To date, most quantitative^{7 12 17 18} and qualitative^{6 12 17 18} studies on UMRs have documented either epidemiological^{12 17 18} data or access to psychosocial healthcare services based on expert assessments and have not included lay perspectives.^{6 7 12 17 18}

Witt *et al.*,¹⁸ for example, did not include any Germany-based studies in their systematic review, and Walg *et al.*⁷ analysed ambulance reports but did not carry out a qualitative study with lay interviewees.

Theoretical explanations and practical policy recommendations for optimising access and utilisation based on lay perspectives have not been studied within the German health service context.¹⁷ Moreover, since most studies have focused on either a singular city or region and have treated UMRs as a homogeneous entity,^{5 7 12} there is a limited body of studies so far that grasps the ‘heterogeneity’¹⁷ of psychosocial healthcare services across place and gender.^{12 17 19} Finally, there is a lack of comparative and intersectional (eg, class-sensitive, gender-sensitive and age-sensitive) studies exploring the context of processes and outcomes in access and utilisation for

UMRs, since different legal and sociospatial contexts might trigger different mechanisms and outcomes. For example, largely varying patterns in application procedures for UMRs result in unequal access opportunities, since German asylum laws (AsylBLG §4–6) and social security bills (SGB VIII §40–42) entail entirely different healthcare claims for UMRs.

This multidisciplinary monocentric study is a collaboration of medical sociology, paediatrics, linguistics and epidemiology. The qualitative study aims to explain psychosocial healthcare and its contextual circumstances, mechanisms and outcomes with regard to access to, utilisation of and barriers to PSC directed at UMRs. The study will be performed in four medium-sized cities and one metropole region. Berlin, being the capital of Germany, and three medium-sized Central German cities, Leipzig (Saxony), Erfurt and Jena (Thuringia) and Halle/Saale (Saxony-Anhalt), will be studied by combining qualitative and realist methods.^{20 21} These places have been chosen for two reasons. First, local structures differ (otherness) in terms of accommodating and handling registered UMRs in Germany, and on average Berlin has higher rates of occurrence of mental health problems compared with the Central German region.²² Second, both areas offer comparable urban structures (sameness) for refugees and UMRs to derive best practice recommendations for PSC.

Questions of how UMRs’ access to PSC is contextualised, how such PSC works in practice, how the effects of PSC alter UMRs’ lives and which barriers to PSC might occur have neither been asked nor answered in this scope before.

Aims: place-sensitive and gender-sensitive policy recommendations

This study will be the first to provide much-needed evidence on access to, utilisation of and barriers to PSC services for UMRs across different actors, places and contexts in Germany. Based on the evidence, realistic policy recommendations will be provided to reduce existing—and often invisible or clandestine—disparities, which is a prerequisite for equity-oriented healthcare services. The qualitative and intersectional approach of this study has strengths in explaining unexplored fields, giving voice to and supporting UMRs themselves, and offering solutions for optimising existing strategies.^{5 9 20} The subjective perceptions of the UMRs should be collected in a participatory way and thus create subject-centred research that can grasp multifaceted levels of identity and its political dimensions. The intersectional approach allows us to analytically grasp the interrelations of (structural) discrimination and barriers based on age, education/class, nationality, cultural affiliation and sex/gender. The study aims to paint a differentiated picture of the PSC of UMRs that does justice to their heterogeneity. Such knowledge is a precondition for a ‘science of change’²⁰ that translates explanations on ‘what works

under which circumstances²¹ into recommendations on how to improve healthcare for UMRs.

The final synthesis aims to provide policy recommendations for the PSC of UMRs based on the critiques, reflections and insights of the interviewed respondents. Above all, the results that transcend regional boundaries will be synthesised with a gender-specific analytical view. The participation in multidisciplinary international conferences and constant feedback on the results to the stakeholders in the subsystems of policy and non-governmental fields will advance the policy implementation of the research results to drive forward the enhancement of the PSC of UMRs.

Objectives

This qualitative project aims to explain psychosocial healthcare access, utilisation and barriers for UMRs across place and gender. Therefore, a methodologically dual approach will be applied by collecting data from PSC stakeholders and local policy makers (expert knowledge) as well as integrating the perspectives of UMRs (lay knowledge) in four medium-sized cities and one metropole region.

The following research questions will be addressed:

- ▶ What are the contextual circumstances, mechanisms and outcomes with regard to access to, utilisation of and barriers to PSC directed at UMRs?
- ▶ Which perceptions and expectations do experts and UMRs have regarding current needs in access to, utilisation of and barriers to PSC among UMRs?
- ▶ Do expert and lay perceptions differ with regard to intersectional concepts such as place and gender?
- ▶ What kind of realistic potential can be deduced to further optimise adequate access and treatment based on the experiences and assessments of professionals and UMRs?

METHODS AND ANALYSIS

The study applies a ‘realist methodology’,^{20 21} which is an increasingly influential methodology in critical social epidemiology.²⁰ Realism aims to unravel the inner workings of social realities by explaining context-mechanism-outcome configurations (CMOs),²¹ which means that certain strategies or services might work differently for specific people and (minority) groups under different circumstances.²¹ Four medium-sized cities and one metropole region—such as Berlin and the Central German region—offer local structures in PSC for refugees and UMRs,^{23 24} which might alter different place-dependent CMOs. The research process (figure 1) will be methodologically divided into three steps: performing a realist review (first step), conducting expert interviews (second step) and collecting lay data (third step). As we apply the framework method, we will proceed through the analysis as inductively and openly as possible. However, during the development of the interview guide, we will adopt thematic blocks that are derived deductively, since we will incorporate the main findings of the realist review into

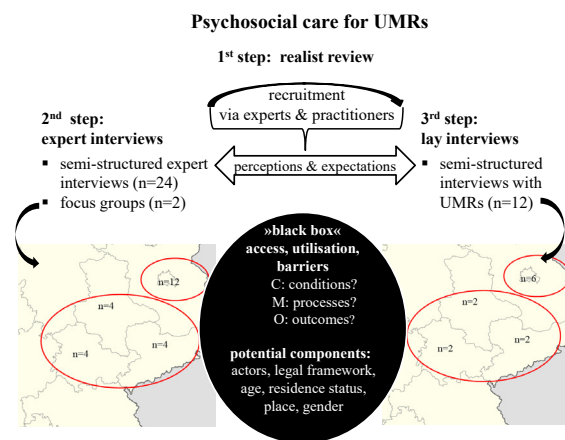


Figure 1 Research process of the study. UMRs, unaccompanied minor refugees.

the qualitative topic guides. The open and axial coding used during the analysis will also include some deductive elements, for instance, realist-informed categories such as context, mechanisms, outcomes of PSC, and intersectional dimensions such as sex/gender, class/education or age. This approach will be helpful in the systematic management and organisation of the generated data within the qualitative procedure and the theory-informed analysis. In an iterative process, the expert knowledge of local professionals from different sectors of (psychosocial) healthcare will be gathered and then collated with the (lay) experiences of UMRs.

Patient and public involvement

The study design does generally not include prior participation of the interviewees (experts or lays). Due to its qualitative nature it aims at generating indepth knowledge and giving as little as possible scientific assumptions or preconceptions prior to the data collection. The topic guides are constructed with the results of the realist review. The guiding principles of good qualitative practice will later in the research process include an inclusive and culture-sensitive approach to communicate and discuss the findings. Study results and publications will therefore be sent to the stakeholders, their institutions and the interviewed lays on request. To improve the respondents' involvement in the analysis step, we are planning to hold a participatory meeting and focus group at the end of the project period to present and discuss the study results. Expert and lay data will be collated and discussed with the UMRs. As a potential method for knowledge exchange, we would like to implement the abovementioned focus group at the end of the study period to strengthen the participatory approach of this study. Therefore, we would like to meet again with the lay respondents after we gathered the initial preliminary results. By doing this, we will collect important information about the respondents' perceptions of the results that could further enrich our migration-sensitive and diversity-sensitive research. Moreover, sharing and discussing our results with our

respondents could be viewed as an agency-fostering measure. Furthermore, the publications will be sent to key care facilities and networks of social and psychosocial care.

Realist review

First, a realist review of peer-reviewed evidence and grey literature with regard to access to, utilisation of and barriers to psychosocial healthcare services directed at UMRs will be conducted.¹⁵ Six methodological steps of the RAMESES publication standards for realist synthesis²⁵ will be followed by extracting theory-informed CMOs. During the second methodological step of the realist review, intersectional theories inform our initial theory. We integrate intersectional perspectives on sex/gender, age, class, education and migration status by explicitly querying social discourses about UMRs and considering issues of discrimination, structural interdependencies and power relations involving various actors within the PSC system. Based on the uncovering of causal mechanisms leading to PSC barriers, the underlying processes will be revealed based on a middle-range approach with a medium level of abstraction and comprehensive, coherent theory building.²⁶ Microstructural and macrostructural levels of PSC will be studied in their intersections (ie, when UMRs' personal and cultural development tasks such as acculturation are confronted with the limitations of asylum laws), as they may produce specific (un)intended outcomes such as undersupply and may result in further social support needs of UMRs. The identified theoretical CMOs of the realist review will be incorporated as thematic blocks of the qualitative topic guides for experts and UMRs.

Expert interviews

Second, based on the identified theoretical CMOs in the realist review and careful stakeholder mapping, 24 expert interviews will be conducted.²⁷ Policy makers and stakeholders working in the healthcare sector will be included in order to explore current strategies, challenges and needs.

At least two focus groups²⁷ (n=2) are planned in order to collate the theoretical CMOs and identify stakeholders' needs with decision makers' resources in the studied local contextual circumstances. Approximately 6–12 policy makers and stakeholders will participate in focus groups held in Berlin and Leipzig. Focus groups are a resource-efficient form of group discussions that allow collectively shared knowledge concerning dissent on a topic to be captured and challenged while opening up new subject views.²⁷ We believe that a participatory approach can strengthen the study, as some caregivers have migrated themselves and might therefore have additional insightful information to share. We would also like to ask those providing care to indicate the extent to which existing culturally sensitive guidelines have influenced their work and have enriched UMRs' access to the care system.

Interviews with lay UMRs

Based on the topics and aspects of PSC elaborated in the review, expert interviews and focus group discussions, topic guides for lay UMRs will be prepared. In the final step, 12 semistructured²⁷ face-to-face interviews with UMRs (figure 1), who will be recruited via expert networks and the snowballing principle, will be conducted. UMRs who have had contact with the healthcare system or PSC structures will add the most-needed lay perspectives to the theoretical CMO model, where they can be collated with expert views.

During the interviews with UMRs and the final focus group with lays and those with PSC experts, we would like to particularly discuss the possibilities offered by language and cultural mediation within the experienced care structures. These possibilities may be linked to the extent to which the contextual factors of care promote these individuals' understanding of and engagement in care.²⁸

The comparison of the perspectives enables us to grasp both the structural and everyday contexts and the problems of PSC. An expert's view adds indepth information to the professional and aspects of UMR experiences and—alongside the lay UMR perspectives—enables proximity to the research topic and keeps the results as close as possible to the existing needs, demands and problems of UMRs.

Participant recruitment and inclusion criteria

All experts and UMRs and their legal guardians will be informed about the research objectives and study results of the project as well as the handling of the collected data. As participants must be protected from institutional and structural discrimination,²⁹ they will also be clearly informed and assured that neither the information given nor, in case of the UMRs, the results obtained will affect their residence permit or current application for asylum. This will be explained at the outset in the declaration of consent (in German, Farsi and Arabic) and continuously insured and complied with.

A written declaration of consent will be obtained in printed form from all participants prior to their participation in the study and kept together safely with the personal data. In the case of minors and their associated limited ability to give consent due to their age, the consent of a guardian is required for the interview.

Since participation is voluntary, the declaration of consent can be withdrawn at any time without giving a reason. In this case, any data already collected will be irrevocably deleted. Non-participation and revocation will have no legal consequences for UMRs. The data collection phase will involve the project leaders, interviewers and language-translating mediators, who will all have to agree to a written confidentiality and non-disclosure agreement at the beginning of the project. After the date of the survey, the language mediators will no longer be granted access to the data.

In the data-processing phase, access to sensitive data should be kept as limited as possible, which will be

guaranteed by limiting the number of data-processing researchers. Persons responsible for data protection will continuously check and document access to the collected data. The respondents will be informed that the personal data (name, year of birth, age, nationality, gender) will be stored separately from the relevant data (biographical history, clinical picture, experience and so on) and will only be linked via an identification number (personal identification number 1, 2 and so on) so that identification based on the relevant data is not possible.

Expert recruitment

Experts from different psychosocial sectors will be identified by stakeholder mapping.³⁰ The selection criteria of the experts are based on the structures of youth welfare initiated by legislation and underlying asylum and youth welfare law. According to SGB VIII Art 42, the sectors include institutions with free sponsorship, administrative entities such as social welfare offices, and ministries that are political (eg, commissioners for integration, migration and refugees, and ministries of labour, social affairs and integration) and state (eg, youth welfare offices) institutions. These are expanded with the fields of civil society and their actors (eg, caring private persons, guardians, non-governmental associations in contact with UMRs, and civil counselling centres such as PSC units and their umbrella organisations). The field of research comprises a heterogeneous selection of various professionalised occupations, organisations and associations. Precisely the comparison of the diverging perspectives of experts in the abovementioned occupations is of particular interest in enhancing knowledge on PSC structures and contexts. The experts also display the selected network actors through whom contact with the UMRs will be established. The personal experience of the experts and their knowledge of the individual needs and behaviour patterns of UMRs will be extensively included in this study design and qualitative analysis.

Lay recruitment

Even if access to UMRs is to be facilitated by the gatekeeper function of the experts, the sensitive and critical situation of young people must nevertheless be taken into account.

UMRs are recruited through expert networks, including civil society institutions and their personnel, and through the distribution of information and invitation leaflets. These flyers will be written in German, translated into Arabic and Farsi, and distributed at selected locations and passed on via gatekeepers.

In addition to the information flyer, we have created an easily understandable and illustrated fact sheet (online supplemental file 1) to potentially reach UMRs who have lower literacy levels. We explain our study aims and the topics to be discussed using the slogan 'Your opinion, your experiences, your ways to advice, your problems and wishes'. We described the conditions and aims of the interviews using the term 'conversation' as follows: 'for

research, confidential, voluntary, anonymous, wherever you want'. We concluded the fact sheet with the sentence 'Our goal is to improve the psychosocial care of unaccompanied minor refugees' and provided our contact details.

We generally anticipate a difficult environment when recruiting UMRs. One barrier concerns the temporality of the reachability of these young people, as they might not remain in the youth welfare institutions for a long period of time. Another critical aspect relates to their possible concerns regarding participating in the interview, as UMRs might think that their asylum status could be endangered and that additional emotional stress could arise from the interview situation. Moreover, the term 'interview' might hold a relatively negative connotation for refugees due to their state of asylum, which is why we call the lay interviews with the UMRs 'conversations' in the information fact sheet.

We would like to address the difficulties of recruiting enough young people through the snowball sample principle. Our goal is to reach UMRs who have had little or no access to PSC, and we hope to accomplish this by snowballing within the friend and peer circles of potential participants by employing the help of our interviewees if they agree. Furthermore, in the information flyer, we invite a relatively broad range of UMRs who 'have received psychosocial care, have not found help, have tried to find help, or have not tried to receive help'.

To ensure that participants with varying literacy levels understand the wording of the study information, we ensure to provide that information in four different languages and formulate it using plain language. Furthermore, we will explain and answer any questions that arise during the face-to-face interviews. Inclusion criteria for the UMRs as interview partners include knowledge of German, English, Farsi or Arabic and being minors when they entered Germany (this can only be applied retrospectively and could mean that the interviewees will be between 16 and 23 years old at the time of the interview). Furthermore, UMRs who have had contact with or experience with health and psychosocial care facilities and personnel within the scope of their legal claim to care according to AsylBLG or SGB VIII will be included. The aim of each interview will be the perception and reception of a comprehensive spectrum of mental, somatic and psychosocial health (depending on the participating UMR). With regard to the sampling plan, the inclusion of both male and female UMRs in a balanced ratio is planned; the recruitment of female refugees must be carried out through gender-sensitive strategies, such as approaching female UMRs at women's meeting groups, in women's refuges or via family members and friends.³⁰

Since retraumatisation should be avoided at all costs,²⁹ with particular caution paid in work with vulnerable groups, an interview will be immediately interrupted if retraumatising episodes are being recounted or if there are obvious signs of emotional distress. The interview situation will only be continued if the participants are willing to continue after a rest period. The interview should

Table 1 Timeline

	First year				Second year				Third year			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
First milestone: study preparation												
Ethical approval for study	Shaded											
Study protocol	Shaded	Shaded										
Preparation (eg, topic guide)			Shaded									
Recruitment of experts			Shaded									
Realist review of evidence				Shaded								
Dissemination at conference					Shaded				Shaded			
Second milestone: data collection												
Consecutive expert interviews			Shaded									
Recruitment of lay participants			Shaded									
Lay participant interviews				Shaded								
Expert focus groups					Shaded							
Third milestone: data entry/analysis												
Transcription and qualitative analysis of expert interviews				Shaded								
Transcription and qualitative analysis of lay interviews					Shaded							
Fourth milestone: publication												
Paper 1: study protocol				Shaded								
Paper 2: realist review					Shaded							
Paper 3: expert views						Shaded						
Paper 4: lay views							Shaded					
Fifth milestone: final dissemination												
Submission of final report												Shaded

The shaded cells indicate at what time the project tasks will be completed.
Q, quarter.

always correspond to the UMR's wish for the continuation, suspension or discontinuation of the interview. The danger of secondary (re)traumatisation of the language mediators³¹ is taken into account by means of a prior preparation workshop and the empathetic and understanding treatment of these persons' needs. In the case of a respondent feeling unwell or being retraumatised or dissociated, we will ensure that an emergency contact person is available over the phone during each interview. This emergency contact person is a psychologist at the local PSC centre (PSZ), and is collaborating with us for this study. This person has cultural-sensitive knowledge and skills as well as experiences with crisis intervention and will be informed about our interviews before they start.

In general, ethical commitment within the study is considered a balancing process and in critical self-reflection by the researchers. Factors such as the tendency of PTSD sufferers to not recognise their own emotional limits will be taken into consideration and constantly reflected on. Furthermore, UMRs will be considered as individual persons, not as 'others', in order to reduce the possibility of 'othering'³² within the research and analysis processes.

Interview language

Interviews will be carried out in the native tongue of the interview partners (German, English, Farsi or Arabic) preferably with assistance from language and cultural mediators. Individual lay interviews with the researcher will be conducted in German with professionals with a background in international migration studies and mediated by native speakers of other languages and cultures trained in qualitative interviews.^{29–31} The native-speaking interviewers will be instructed at a 2-day workshop in Halle (Saale) to ensure reliability during fieldwork data collection.

Topic guides

The interview guide for the expert interviews will be developed based on a mapping of the literature and the identified CMOs of the realist review, whereas the stakeholder and policy maker focus groups will be based on the results of the first stage of expert interviews. Semi-structured interviews will be performed with UMRs based on thematic blocks of the analysed expert data. The topic guides will cover thematic blocks such as access, utilisation, perceived barriers and needs, and the perceived quality of PSC.

Data management and data analysis

Interviews and focus groups will be audio-recorded and transcribed verbatim.³³ The translation of non-German data will be organised in interdisciplinary collaboration with linguistics.³³ Qualitative data will be synthesised with MAXQDA V.18 software according to the research questions by applying an inductive-deductive ‘framework methodology’,²⁷ with the overall aim of identifying empirically grounded CMO typologies. The Consolidated criteria for Reporting Qualitative research (COREQ) guidelines will be strictly followed when reporting qualitative results.³⁴

Timeline

A 3-year period including four milestones (M) is planned (table 1). First, ethical approval has to be obtained from the ethical board of the medical faculty of the Martin Luther University Halle-Wittenberg, Germany. The first year will be mostly dedicated to a literature synthesis and the preparation of the qualitative study (M1), including preparing the study protocol (publication 1), finalising the realist review (publication 2) and recruiting experts and lay participants. The second year will mainly focus on data collection (M2) and the time-intensive transcription, translation and qualitative analysis of expert and lay data (M3). The publication of the qualitative results (publications 3 and 4) in international journals and the public dissemination of the findings will be finished in the last year (M4). The results will be presented at different project stages at international and national symposia and conferences.

ETHICS AND DISSEMINATION

The study will be conducted in accordance with the principles of the Helsinki Declaration and COREQ.^{34 35} The study will comply rigorously with German data protection standards. The approval of the Ethical Review Committee at Martin Luther University Halle-Wittenberg, Germany, was obtained and granted. The results of the study will be presented at several conferences and will be published in high-quality, peer-reviewed international journals.

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Contributors H-SU is the first author of the paper and drafted all manuscripts for the research process. H-SU will conduct further interviews and analyse the data in collaboration with EK and MM. MM, EK, H-SU and E-MF drafted the original study protocol. MM is the principal investigator of the project, has led the grant application and has critically reviewed the manuscript with the support of MR and JS. All the authors have read and approved the final version of the manuscript.

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