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Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC): study protocol of a mixed method observational study

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Abstract

Introduction: Some studies indicate that persistent somatic symptoms (PSS) are more prevalent among individuals with a low socioeconomic status (SES) and a migration background. However, factors explaining social inequalities in PSS are largely unknown. It is expected that aggravating factors of PSS like illness perception, illness beliefs (health literacy, stigma), illness behaviour, and health anxiety play an important role for this explanation. The SOMA.SOC study will examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in Irritable Bowel Syndrome (IBS) and fatigue.

Methods and analysis: The project will collect both quantitative and qualitative data. Quantitative data will be gathered via a representative telephone survey in Germany (N=2,400). With a vignette design depicting patients varying in sex, condition (IBS/fatigue), occupational status (low/high), and migration (yes/no), public knowledge and beliefs (e.g. health literacy), attitudes (stigma), and personal experiences with the condition (e.g. somatic symptom burden) will be explored. Complementary, longitudinal qualitative interviews will be conducted with patients (n=32 at three time points, resulting in N=96 interviews) who will also vary according to sex, condition, occupational status and migration. Patients will be recruited from primary care practices in Hamburg. The interviews will cover origin and development of the condition, coping and help-seeking as well as social interactions and perception of the disease by others (e.g. perceived stigma). SOMA.SOC is part of the interdisciplinary research unit “Persistent SOMAtic Symptoms ACROSS Diseases (SOMACROSS)”.

Ethics and dissemination: The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff). The results will help to understand and explain inequalities in PSS and will provide an insight into the social context of PSS.

Key words: social inequalities, socioeconomic status, migration, somatic symptoms, symptom persistence, mixed methods

Strengths and limitations of this study

- This will be the first study on social inequalities in a range of factors contributing to symptom persistence (aggravating factors) in Irritable Bowel Syndrome (IBS) and fatigue.
- By combining quantitative and qualitative data, we expect a better and more comprehensive understanding of inequalities in aggravating factors of persistent somatic symptoms (PSS).
- With the longitudinal design of the qualitative study part, we expect to gain insight into the course of symptoms and changes of experiences over time.
- Due to the observational design, causal conclusions cannot be drawn from the study.
- As the study is focussed on IBS and fatigue, results cannot be generalized to other PSS.

Introduction

Background

Health inequalities according to socioeconomic status and migration

National and international studies in social epidemiology have consistently shown that socioeconomic status (SES, i.e. education, income, and / or occupational position) as well as migration and ethnicity are important social determinants of health.[1,2] Accordingly, people with a low SES generally experience worse health and wellbeing as well as higher morbidity (including higher risk of chronic disease course) and mortality rates than those with a high SES. Material (e.g. material deprivation, unfavourable working, housing, and neighbourhood conditions), psychosocial (e.g. social isolation, psychosocial stress, coping resources) and behavioural factors (e.g. smoking, exercise, alcohol consumption, nutrition) contribute to the explanation of such health inequalities. Recent studies indicate that differences in knowledge and beliefs about health and illness ("health literacy") are also important for the explanation of health inequalities.[3,4] However, results on the explanatory contribution of these factors are inconsistent as there is variation according to the disease under study. For example, socioeconomic inequalities of coronary heart disease can largely be explained by differences in classic cardiovascular risk factors (i.e. high blood pressure, high cholesterol, diabetes mellitus, and cigarette smoking)[5], while poorer coping styles, ongoing life events, stress exposure, and weaker social support are important factors to explain the higher prevalences of mental disorders in lower SES groups.[6,7]

Although migrants are often, at least initially, relatively healthy compared with the non-migrant population in the host country, available data suggest that they tend to be more vulnerable to certain communicable diseases, occupational health hazards, injuries, poor mental health, and maternal and child health problems.[2,8] Studies furthermore show that there are large differences between migrants in terms of their socioeconomic situation but these differences and their health-related consequences are far from being adequately understood. As migration status and SES reflect different aspects of social inequalities, that are not independent, it is reasonable to explore both aspects and their relation to health simultaneously.[9]

Social inequalities in somatic symptoms

Regarding persistent somatic symptoms (PSS), there are a few studies investigating inequalities according to SES and migration. Using German population survey data, Hinz et al.[10] found that a low SES is associated with a higher risk for somatic symptoms measured with the Patient Health Questionnaire (PHQ-15).[11] This result was confirmed by an analysis of the Gutenberg Health Study conducted in the Rhine-Main-Region.[12] Based on the German national Cohort study, Morawa et al.[13] showed that persons of Turkish origin report more symptoms according to the PHQ-15 compared to Germans. Moreover, psychiatric patients with a migration background had a significantly higher current symptom load, especially by somatic symptoms, compared to those without migration background.[14]

Thus, overall, results suggest that somatic symptoms are more prevalent among individuals with a low SES and a migration background in Germany. However, respective empirical studies mostly use sum scales comprising a number of symptoms but magnitude and mechanisms of inequalities may differ depending on symptom under study. Considering specific PSS with high prevalence like fatigue (about 30% in Germany[15,16]) or the Irritable Bowel Syndrome (IBS, about 10-20% in Germany[17]), research on inequalities is scarce, particularly in Germany. Jason et al.[18] found highest levels of fatigue among minority groups and persons with lower levels of education and occupational status in the US. A German population study also revealed increased rates of fatigue among low SES groups.[16] Another study indicates that there are interactions between SES and ethnicity in the association with fatigue.[19] In terms of IBS, there are studies showing higher prevalences in lower SES groups[20] but others find a reverse association or no socioeconomic inequalities.[21–23] There is a paucity of data on differences according to migration status in the epidemiology of IBS.

Social inequalities in aggravating factors of PSS

Aetiological models suggest that psychosocial, behavioural, and biomedical factors, as well as their interaction, contribute to the persistence and aggravation of somatic symptom burden.[24] Among these aggravating factors are illness beliefs, illness perception, treatment experiences, illness behaviour, and health anxiety. It can be expected that these factors also play an important role for explaining inequalities in PSS. However, empirical studies analysing social inequalities in aggravating factors are scarce and thus, there is not much known about the mechanisms that potentially can explain inequalities in PSS.

Studies on illness beliefs examine to what extent an illness is recognized as such and what beliefs about the causes, the course and the treatment of this illness are prevalent among the public. In recent years, these studies have been discussed with reference to the concept of health literacy. Health literacy entails "the public's knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare".[25] Deficits in health literacy mean that people do not know what they can do for prevention, delay or avoid seeking treatment, view recommended treatments with suspicion, or are unsure how to assist those afflicted.[26] Limited health literacy has been found among people with a low SES and migrant background.[4,27,28] For example, a study analysing differences between German and Turkish patients suffering from somatoform disorders showed that Turkish patients believed significantly stronger in supernatural causes of their disease and that these beliefs reduced the motivation to take up psychotherapy.[29] A lack of health literacy has been found to be associated with negative attitudes towards persons with mental illness,[28] which can be conceptualized as public stigma. This entails reactions of the general public towards a group based on stereotypes about this group. In this regard, results suggest that respondents with higher SES desire less social distance from the mentally ill and express more liberal views.[30] Research also suggests that public stigma is perceived and often internalized by the persons afflicted. Perceived and internalized stigma have been found to predict worse health outcomes among IBS patients.[31] With regards to fatigue, studies report higher levels of perceived stigma when compared to IBS[32] and participants report feelings of estrangement and the belief that others attribute fatigue solely to psychological causes.[33]

Only few studies examined inequalities in symptom or illness perception and health anxiety. In terms of the former, perceived symptom burden seems to be positively associated with education,[34] while results on differences according to ethnicity and migration are inconsistent.[34,35] As for health anxiety, a recent meta-analysis showed a lower risk for health anxiety in people with higher socioeconomic status[36]. Another meta-analysis indicated a higher risk of health anxiety in migrants and ethnic minorities compared to the majority population in North America.[37] Regarding illness behaviour, reviews from Germany overall indicate a lower utilization of health care among migrants, although the results vary in terms of health care sector, indicator of health care utilization and migrant population under study.[38] Low SES groups show lower utilization regarding medical specialist consultations and prevention services.[39] However, hardly any of the studies included in these reviews specifically address PSS. Thus, overall, there are some studies indicating social inequalities in aggravating factors. However, research is fragmented and mostly not related to PSS.

Objectives and hypotheses

Against this background, the present study “Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC)” was developed. The objective of the study is to examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in IBS and fatigue. We chose these two specific conditions as they appear relatively frequently in the German population. In terms of IBS, we especially refer to the cardinal symptoms of recurrent abdominal pain and altered bowel movements (as specified in the International Classification of Diseases 10th Edition, ICD-10[40]). Regarding fatigue, different symptoms like emotional and cognitive limitations (e.g. lack of motivation and reduced performance) as well as physical complaints (e.g. muscular weakness) are to be considered (as mentioned in the national guideline[15] and covered in the ICD-10[40]). The following aggravating factors will be explored: illness perception, knowledge and beliefs about the symptoms, illness and treatment experiences, illness behaviour, and health anxiety.

More specifically the following hypotheses will be explored: 1) SES and migration are associated with factors contributing to the symptom persistence (aggravating factors) of IBS and fatigue. 2) There are differences in perceptions of and beliefs about IBS and fatigue according to the SES and migration status of the afflicted person.

The SOMA.SOC study is part of the interdisciplinary research unit “Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)”. SOMACROSS aims to identify disease-overarching and disease-specific biopsychosocial risk factors and mechanisms for the persistence of somatic symptoms.[41] SOMACROSS proposes a biopsychosocial ‘PSS working model’ as a starting point for the investigation of risk factors and aetiological mechanisms, based on the model by Henningsen et al.[24] The integration of the objectives of the SOMA.SOC project into the working model of SOMACROSS is shown in Figure 1.

(Figure 1 about here)

Methods and analysis

Study design and participants

In order to gain insight in social inequalities in aggravating factors of IBS and fatigue, the project will make use of a mixed methods design by collecting both quantitative and qualitative observational data. For a better understanding of the methods, in the following, these two study parts (population survey and qualitative interviews with patients) will be presented separately. The conditions under study will be conceptualized differently in the two study parts: While we will use vignettes describing a person with typical symptoms of IBS or fatigue in the population survey, patients diagnosed with one of the conditions will be recruited for the qualitative interviews. Data collection started in April 2022 and will be finalized in summer 2024.

Population survey

To explore public knowledge, beliefs, attitudes, and experiences regarding PSS in the case of IBS and fatigue, a representative population survey will be conducted throughout Germany via computer-assisted telephone interviewing (CATI). This cross-sectional survey is going to be representative of the resident population in Germany aged 18 years and older, and utilizes a dual-frame approach, i.e. 30% of the gross sample consists of mobile numbers, while 70% will be selected from landline numbers. Thus, there is greater chance of including mobile-only users as well as target groups otherwise hard to reach. Landline numbers will be drawn from all registered private numbers at random. Additional computer-generated numbers will also allow for ex-directory household. For interviews in households with more than one potential target person, a random selection of the target person is realized using the Kish-Selection-Grid.[42] Regarding mobile telephone connections, the interview will be conducted with the person answering the phone.

(Table 1 about here)

In the beginning of the interview, a case story (vignette) will be presented to the respondents. In the vignette, a person with signs and symptoms indicative of either IBS or fatigue will be described. The vignettes will be varied according to sex (male / female), occupational status (high (lawyer) / low (cleaner)), and migration status (yes / no), resulting in 16 different case stories (please see Table 1 for an overview of the varied factors and Table 2 for resulting vignettes). The vignettes will be designed in cooperation with clinical experts. By combining a vignette design with a representative survey, social inequalities may be examined from two perspectives: first, as social characteristics of the respondents themselves (please see above, hypothesis 1) and second, of the person described in the vignette (hypothesis 2).

(Table 2 about here)

A total of N = 2,400 participants will be included in the national telephone survey. The 16 vignettes will be randomly assigned to the respondents (n = 150 per vignette). A sample size calculation showed that this number is sufficient to identify small sized differences with a statistical power of 80% and a Type-I error of 0.05 when comparing two vignettes with regards to categorical outcomes using χ^2-tests. As for continuous outcomes, a sample size of n = 150 per vignette allows for the detection of small to medium effect sizes based on t-tests, linear regression models, or analyses of variance (statistical power 80%, Type-I error = 0.05). Moreover, based on previous studies with a similar design,[43-45] this number of respondents was found to be adequate to detect significant differences in public beliefs between vignettes. Similar surveys with a vignette design resulted in response rates between 48% and 54%.[43-45]

Qualitative patient interviews

To complement the population perspective and to analyse social inequalities in factors and mechanisms of symptom persistence among patients with IBS and fatigue, qualitative interviews will be conducted using a longitudinal design. Longitudinal qualitative research (LQR) is distinct from other qualitative approaches in the way that it incorporates time into the research process. It opens the possibility to make change (or stability) a key focus in analysis.[46] LQR aims at answering questions regarding lived experiences, e.g. during the course of diseases, and how and why these experiences change over time. Against the background of the ongoing process of persistence of somatic symptoms, LQR will be helpful to capture individual courses, narratives and trajectories.

Patients will be recruited from primary care practices in the Hamburg region and will be selected according to condition (IBS / fatigue), sex (male / female), occupational status (high / low), and migration status (yes / no). With respect to the occupational status of patients, the International Socio-Economic Index of Occupational Status (ISEI) according to Ganzeboom et al.[47] will be used as a criterion for assigning scores. Scores will be dichotomized to obtain groups of high and low occupational position. Regarding the patients' migration history, we will be adapting the definition of the German Federal Statistical Office. This states that "A person has a migration background if he or she or at least one parent was not born with German citizenship".[48] For recruitment of the patients, the authors will cooperate with the Department of General Practice and Primary Care at the University Medical Center Hamburg-Eppendorf, which established a physicians' research network. Physicians are listed in a database that includes contact details of all primary care physicians residing in Hamburg and its suburbs as well as in adjacent regions (overall about 3,000 primary care physicians). The database holds information on contact data, structure of the practice (single vs. group practice), physician staff and involvement in recent research projects. 50 practices will be randomly selected and contacted (for details please see sample size estimation below and Figure 2).

(Figure 2 about here)

Semi-structured interviews with 32 patients will be conducted at three measurement points (at the time of inclusion (t0), after 6 months (t1), and after 12 months (t2)), resulting in 96 interviews. Patients will be selected based on a purposeful sampling procedure according to the four strata mentioned above (condition, sex, occupational status, and migration). This procedure was chosen as it is expected to be useful to analyse social inequalities in factors and mechanisms of symptom persistence. Patients will be recruited via primary care practices in the Hamburg region. Based on experiences in previous projects, we expect a participation rate of at least 50% of the randomly selected practices.[49] This will lead to around 25 practices taking up patient recruitment. We also estimate the participation rate of the addressed patients at 50%, meaning that the practices will have to contact 96 patients (around four patients per practice in six months), leading to 48 patients with the required combination of characteristics who supply informed consent to participate. This will allow for a drop-out rate of approximately 30% among participants during the course of the study, resulting in n = 32 patients who will be included in all three measurement points (please see Figure 2). For each of the 16 combinations (IBS / fatigue), sex (male / female), migration (yes / no), and occupational status (high / low), two semi-structured interviews will be conducted. This sampling procedure will result in an equal number of patients (n = 16) in terms of condition, sex, occupational status, and migration status interviewed at three measurement points.

There will be a two-staged recruitment process. The selected practices will be contacted via telephone by a member of the project group, the project will be briefly explained and the interest in participating in the study will be assessed. If interested in participation, the practice will receive a detailed study information, a process description, and a declaration of consent to participate. Moreover, the participating practices will be provided with all necessary study materials to be handed out to patients (e.g. study information, privacy statement, short questionnaire to collect necessary patient data (e.g. name, condition, sex, age, occupation, contact information).

Doctors are asked to inform patients who meet the diagnostic criteria (K58.1 (IBS-D), K58.2 (IBS-C), K58.3 (IBS-M), K58.8, R53, F48.0, or G93.3 according to ICD-10[40]) about the study when they present in the practice. Those patients who are interested in participation are requested to return a short questionnaire with all relevant information about eligibility including contact details to the project group (either via mail, e-mail or fax). Returned questionnaires will be sorted according to strata (condition, sex, migration status, occupational position). Thereafter, telephone calls will be conducted to provide further information if needed and to arrange an interview appointment. Informed consent will be signed by all participating patients. Participants will be free to conduct the interviews in person or by telephone. To acknowledge their participation and compensate for expenses, each patient will receive 15€ for each completed interview, the physicians will receive 50€ per patient included in the study.

Patient and public involvement

Patients and public are not involved in setting the research agenda.

Assessment and study outcomes

Population survey

The standardized questionnaire used in the telephone survey will cover the following topics (1) questions referring to knowledge and beliefs about IBS or fatigue, (2) attitudes towards persons affected from IBS or fatigue (stigma), (3) personal experiences with these symptoms, and (4) sociodemographic characteristics of respondents (please also see Table 3). In terms of knowledge and beliefs about IBS or fatigue, health literacy, illness perceptions, and illness beliefs will be assessed. Regarding personal experiences with the symptoms, questions about illness behaviour, illness and treatment experiences, somatic symptom burden, and health anxiety will be included.

(Table 3 about here)

Qualitative patient interviews

Semi-structured interviews will be conducted personally or by telephone (according to patient preference). To this end, a blend of closed and open-ended questions will be used that can be accompanied by follow-up questions to further specify mentioned topics. The precise formulation and order of the questions can be varied. This will allow to cover the main issues with all participants while also offering flexibility in discussing issues pertinent to individuals. The interviews will have a length of about 30 minutes and will be audio-recorded upon permission of the patient. A total of three sections are planned for the interview guide:

(1) Origin, causes and development of the disease: Here, aspects of symptom / illness perception as well course and severity of symptoms and aspects of health anxiety will be covered.

(2) Coping with the illness and help-seeking: In this segment, illness behaviour and experiences, health literacy as well as treatment experiences and treatment expectations will be focused.

(3) Social interaction and perception by others: This complex will cover disclosure of illness and (perceived) stigma associated with the disorder.

Data analyses

Population survey

Associations between social characteristics of the respondents and aggravating factors will be analysed by calculating regression models (hypothesis 1). Differences in perceptions, attitudes, and beliefs according to migration and occupational status of the person in the vignette (hypothesis 2) will be examined using analyses of variance. The power calculation showed that the sample size is sufficient to detect significant main effects (e.g. of migration status of the person in the vignette) as well as two-way interactions (e.g. between migration and occupational status). In terms of the latter, interaction tests will be performed. Regarding categorical outcomes (e.g. recognition of condition presented in the vignette (yes or no)), χ^2-tests will be applied. Missing data will be imputed if more than 5% of the data are missing. The number of imputations will be chosen dependent on the proportion of missing data.

Qualitative patient interviews

Subject to the consent of the participants, the interviews will be audio-recorded. Uniform transcription rules will be established before the start of the analysis, and compliance with these rules will be checked several times during the course of the process. For the analysis of the transcribed interviews, qualitative content analysis (QCA) will be used. A core aspect of QCA is to make the interpretation of text describable and verifiable by using content analysis rules previously formulated on the basis of a work plan. The technique of inductive category formation is particularly suitable for this study design. Inductive categories are developed from the interview material according to a given definition criterion, in order to reach the central aspects of the text. Step by step, categories will be formulated, which are revised within feedback loops eventually reduced to main categories and checked in respect to their reliability.[54]

The data from both study parts are seen as two complementing perspectives on social aspects that contribute to the symptom persistence of IBS and fatigue. In using these different approaches, we expect a better and more comprehensive understanding of inequalities in aggravating factors of PSS and how they are associated with patients' and the public's characteristics.

Ethics and dissemination

The study is based on data of personal or telephone interviews. Thus, ethical and legal considerations are focused on data protection. We will strictly adhere to data protection regulations. Informed consent will be obtained from all participants. Respondents will be informed that participation in the study is voluntary and that withdrawal is possible at any time. There are no specific risks for the participants in the study. The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff).

In accordance with the ethics committee approval and the German Research Foundation (DFG) guidelines for the handling of research data, deidentified quantitative individual data will be made publicly available. Data sharing will follow the FAIR Data Principles (Findable, Accessible, Interoperable and Reusable). The main findings will be submitted for publication in peer-reviewed journals within 12 months of study completion.

Conclusion

To our knowledge, this will be the first study on social inequalities in a range of factors contributing to symptom persistence (aggravating factors) in IBS and fatigue. The results will help us to understand and explain inequalities in PSS and will provide an insight into the social context of PSS. Moreover, illness perception, knowledge, beliefs, experiences and stigmatising attitudes are expected to be important to understand the mechanism of symptom persistence, especially among low SES and ethnic minority groups. By using a population perspective, public beliefs about PSS can be assessed that may have an impact on help seeking behaviour, symptom course, and outcomes. Results can be integrated into concepts of prevention and treatment of PSS, e.g. by improving public knowledge and reducing stigma.

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Contributors: OvdK and AM developed the study. OvdK is the principal investigator of the study. RB is research associate in the study. All authors contributed to the refinement of the study protocol, read and approved the final version.

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Table 1: Factors presented in the vignettes

Factor	**Specifications**	
Condition	Irritable Bowel Syndrome (IBS)	Fatigue (Fa)
Sex	Male (M)	Female (F)
Migration history	Migration history (Mh)	No Migration history (nM)
Occupational status	High (Lawyer, L)	Low (Cleaner, C)

Table 2: Vignettes presented in the survey

Vignette No.	Factor combination
1	IBS M Mh L
2	IBS M nM L
3	IBS M Mh C
4	IBS M nM C
5	IBS F Mh L
6	IBS F nM L
7	IBS F Mh C
8	IBS F nM C
9	Fa M Mh L
10	Fa M nM L
11	Fa M Mh C
12	Fa M nM C
13	Fa F Mh L
14	Fa F nM L
15	Fa F Mh C
16	Fa F nM C

For abbreviations of the factor combinations please see Table 1.

Table 3: Instruments intended to use in the population survey

	Construct	Indicator/Instrument
(1)	Health literacy	Labelling (recognition of disease); perceived causes; treatability; effectiveness of treatment options
	Illness perception	Illness Perception Questionnaire (brief version, IPQ-B)[50]
	Illness belief	E.g. "Do you think that the person in the vignette has a real disorder?"
(2)	Public stigma	Emotional reactions towards those affected by IBS or fatigue Stereotypes ascribed to persons with IBS or fatigue
	Perceived stigma	Modified version of the IBS Stigma Scale[51]
(3)	Illness behaviour	E.g. "If you have the feeling of being affected by such complaints, you should get help as soon as possible." Health care utilization
	Illness experience	Own affliction; contact to someone affected
	Treatment experience	Treatment experience
	Somatic symptom burden	Somatic Symptom Scale (SSS-8)[52]
	Health anxiety	Whiteley Index (WI-7)[53]
(4)	Sociodemographic data	Age, sex, educational attainment, occupational position, income, migration status, marital status

Figure 1: Integration of the study objectives into the working model of the Research unit “Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)” [41]

Figure 2: Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

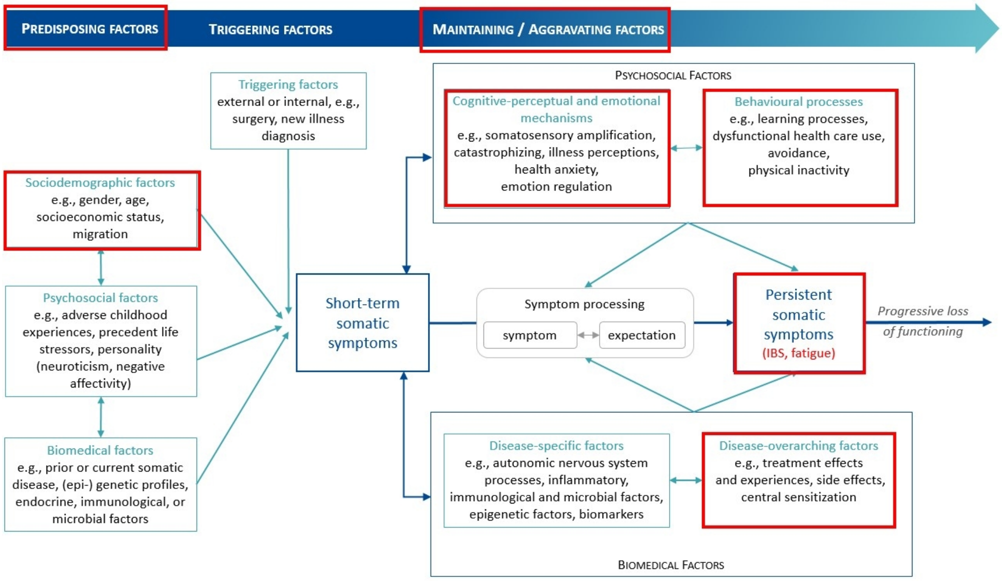

Figure 1: Integration of the study objectives into the working model of the Research unit “Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)” 41

340x200mm (96 x 96 DPI)

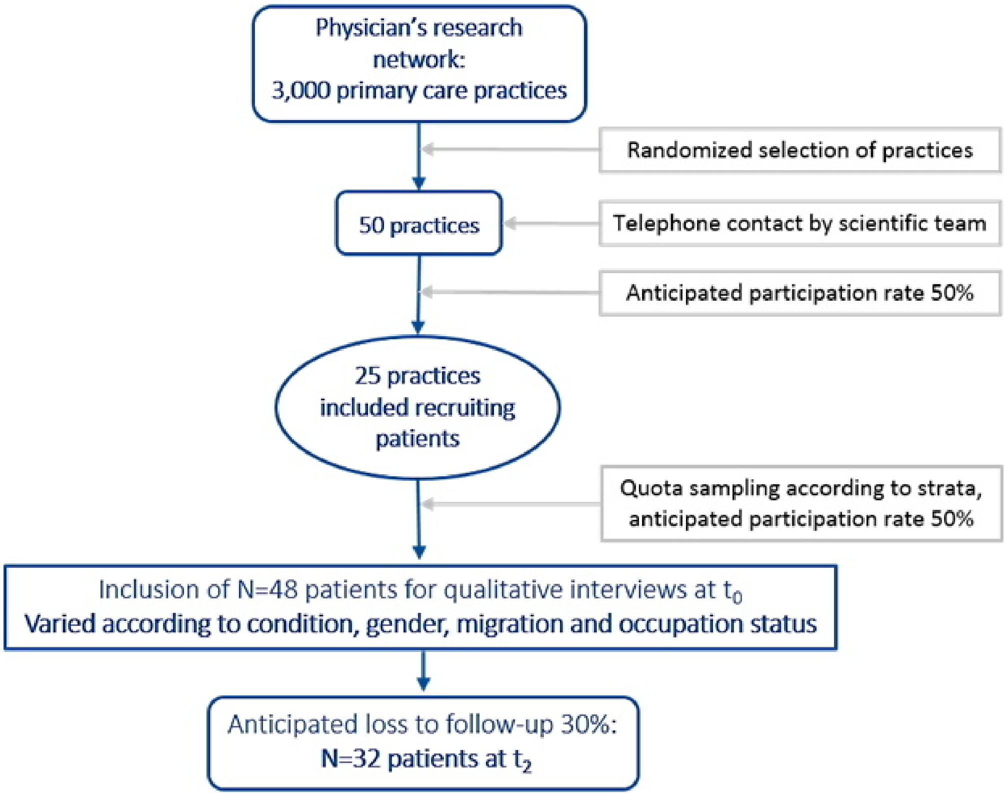

Figure 2: Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

164x129mm (96 x 96 DPI)

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Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC): study protocol of a mixed method observational study focussing on irritable bowel syndrome and fatigue

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Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC): study protocol of a mixed method observational study focussing on irritable bowel syndrome and fatigue

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Abstract

Introduction: Some studies indicate that persistent somatic symptoms (PSS) are more prevalent among individuals with a low socioeconomic status (SES) and a migration background. However, factors explaining social inequalities in PSS are largely unknown. It is expected that aggravating factors of PSS like illness perception, illness beliefs (health literacy, stigma), illness behaviour, and health anxiety play an important role for this explanation. The SOMA.SOC study will examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in Irritable Bowel Syndrome (IBS) and fatigue.

Methods and analysis: The project will collect both quantitative and qualitative data. Quantitative data will be gathered via a representative telephone survey in Germany (N=2,400). With a vignette design depicting patients varying in sex, condition (IBS/fatigue), occupational status (low/high), and migration (yes/no), we will assess public knowledge and beliefs (e.g. health literacy), attitudes (stigma), and personal experiences with the condition (e.g. somatic symptom burden) in the survey. Complementary, longitudinal qualitative interviews will be conducted with patients (n=32 at three time points, resulting in N=96 interviews) who will also vary according to sex, condition, occupational status and migration. Patients will be recruited from primary care practices in Hamburg. The interviews will cover origin and development of the condition, coping and help-seeking as well as social interactions and perception of the disease by others (e.g. perceived stigma). SOMA.SOC is part of the interdisciplinary research unit "Persistent SOMAtic Symptoms ACROSS Diseases (SOMACROSS)".

Ethics and dissemination: The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff). Informed consent will be obtained from all participants. The main findings will be submitted for publication in peer-reviewed journals within 12 months of study completion.

Key words: social inequalities, socioeconomic status, migration, somatic symptoms, symptom persistence, mixed methods, SOMACROSS

Strengths and limitations of this study

- Social inequalities according to socioeconomic status and migration in a range of aggravating factors (illness perception, symptom beliefs, illness/treatment experiences, illness behaviour, and health anxiety) in Irritable Bowel Syndrome (IBS) and fatigue will be explored.
- By combining quantitative and qualitative data, we expect a better and more comprehensive understanding of inequalities in aggravating factors of persistent somatic symptoms (PSS).
- With the longitudinal design of the qualitative study part, we expect to gain insight into the course of symptoms and changes of experiences over time.
- Due to the observational design, causal conclusions cannot be drawn from the study.
- As the study is focussed on IBS and fatigue, results cannot be generalized to other PSS.

Introduction

Background

Health inequalities according to socioeconomic status and migration

National and international studies in social epidemiology have consistently shown that socioeconomic status (SES, i.e. education, income, and / or occupational position) as well as migration and ethnicity are important social determinants of health.[1,2] Accordingly, people with a low SES generally experience worse health and wellbeing as well as higher morbidity (including higher risk of chronic disease course) and mortality rates than those with a high SES. Material (e.g. material deprivation, unfavourable working, housing, and neighbourhood conditions), psychosocial (e.g. social isolation, psychosocial stress, coping resources) and behavioural factors (e.g. smoking, exercise, alcohol consumption, nutrition) contribute to the explanation of such health inequalities. Recent studies indicate that differences in knowledge and beliefs about health and illness (“health literacy”) are also important for the explanation of health inequalities.[3,4] However, results on the explanatory contribution of these factors are inconsistent as there is variation according to the disease under study. For example, socioeconomic inequalities of coronary heart disease can largely be explained by differences in classic cardiovascular risk factors (i.e. high blood pressure, high cholesterol, diabetes mellitus, and cigarette smoking)[5], while poorer coping styles, ongoing life events, stress exposure, and weaker social support are important factors to explain the higher prevalences of mental disorders in lower SES groups.[6,7]

Although migrants are often, at least initially, relatively healthy compared with the non-migrant population in the host country, available data suggest that they tend to be more vulnerable to certain communicable diseases, occupational health hazards, injuries, poor mental health, and maternal and child health problems.[2,8] Studies furthermore show that there are large differences between migrants in terms of their socioeconomic situation but these differences and their health-related consequences are far from being adequately understood. As migration status and SES reflect different aspects of social inequalities, that are not independent, it is reasonable to explore both aspects and their relation to health simultaneously.[9]

Social inequalities in somatic symptoms

Regarding persistent somatic symptoms (PSS), there are a few studies investigating inequalities according to SES and migration. Using German population survey data, Hinz et al.[10] found that a low SES is associated with a higher risk for somatic symptoms measured with the Patient Health Questionnaire (PHQ-15).[11] This result was confirmed by an analysis of the Gutenberg Health Study conducted in the Rhine-Main-Region.[12] Based on the German national Cohort study, Morawa et al.[13] showed that persons of Turkish origin report more symptoms according to the PHQ-15 compared to Germans. Moreover, psychiatric patients with a migration background had a significantly higher current symptom load, especially by somatic symptoms, compared to those without migration background.[14]

Thus, overall, results suggest that somatic symptoms are more prevalent among individuals with a low SES and a migration background in Germany. Respective empirical studies mostly use sum scales comprising a number of symptoms but magnitude and mechanisms of inequalities may differ depending on symptom under study. Considering specific PSS with high prevalence like fatigue (about 30% in Germany[15,16]) or the Irritable Bowel Syndrome (IBS, about 10-20% in Germany[17]), research on inequalities is scarce, particularly in Germany. Jason et al.[18] found highest levels of fatigue among minority groups and persons with lower levels of education and occupational status in the US. A German population study also revealed increased rates of fatigue among low SES groups.[16] Another study indicates that there are interactions between SES and ethnicity in the association with fatigue.[19] In terms of IBS, there are studies showing higher prevalences in lower SES groups[20] but others find a reverse association or no socioeconomic inequalities.[21–23] There is a paucity of data on differences according to migration status in the epidemiology of IBS.

Social inequalities in aggravating factors of PSS

Aetiological models suggest that psychosocial, behavioural, and biomedical factors, as well as their interaction, contribute to the persistence and aggravation of somatic symptom burden.[24] Among these aggravating factors are illness beliefs, illness perception, treatment experiences, illness behaviour, and health anxiety. It can be expected that these factors also play an important role for explaining inequalities in PSS. However, empirical studies analysing social inequalities in aggravating factors are scarce and thus, there is not much known about the mechanisms that potentially can explain inequalities in PSS.

Studies on illness beliefs examine to what extent an illness is recognized as such and what beliefs about the causes, the course and the treatment of this illness are prevalent among the public. In recent years, these studies have been discussed with reference to the concept of health literacy. Health literacy entails "the public's knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare".[25] Deficits in health literacy mean that people do not know what they can do for prevention, delay or avoid seeking treatment, view recommended treatments with suspicion, or are unsure how to assist those afflicted.[26] Limited health literacy has been found among people with a low SES and migrant background.[4,27,28] For example, a study analysing differences between German and Turkish patients suffering from somatoform disorders showed that Turkish patients believed significantly stronger in supernatural causes of their disease and that these beliefs reduced the motivation to take up psychotherapy.[29] A lack of health literacy has been found to be associated with negative attitudes towards persons with mental illness,[28] which can be conceptualized as public stigma. This entails reactions of the general public towards a group based on stereotypes about this group. In this regard, results suggest that respondents with higher SES desire less social distance from the mentally ill and express more liberal views.[30] Research also suggests that public stigma is perceived and often internalized by the persons afflicted. Perceived and internalized stigma have been found to predict worse health outcomes among IBS patients.[31] With regards to fatigue, studies report higher levels of perceived stigma when compared to IBS[32] and participants report feelings of estrangement and the belief that others attribute fatigue solely to psychological causes.[33]

Only few studies examined inequalities in symptom or illness perception and health anxiety. In terms of the former, perceived symptom burden seems to be positively associated with education,[34] while results on differences according to ethnicity and migration are inconsistent.[34,35] As for health anxiety, a recent meta-analysis showed a lower risk for health anxiety in people with higher socioeconomic status.[36] Another meta-analysis indicated a higher risk of health anxiety in migrants and ethnic minorities compared to the majority population in North America.[37] Regarding illness behaviour, reviews from Germany overall indicate a lower utilization of health care among migrants, although the results vary in terms of health care sector, indicator of health care utilization and migrant population under study.[38] Low SES groups show lower utilization regarding medical specialist consultations and prevention services.[39] However, hardly any of the studies included in these reviews specifically address PSS. Thus, overall, there are some studies indicating social inequalities in aggravating factors. However, research is fragmented and mostly not related to PSS.

Objectives and hypotheses

Against this background, the present study "Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC)" was developed. The objective of the study is to examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in IBS and fatigue. We chose these two specific conditions as they appear relatively frequently in the German population. In terms of IBS, we especially refer to the cardinal symptoms of recurrent abdominal pain and altered bowel movements (as specified in the International Classification of Diseases 10th Edition, ICD-10[40]). Regarding fatigue, different symptoms like emotional and cognitive limitations (e.g. lack of motivation and reduced performance) as well as physical complaints (e.g. muscular weakness) are to be considered (as mentioned in the national guideline[15] and covered in the ICD-10[40]). The following aggravating factors will be explored: illness perception, knowledge and beliefs about the symptoms, illness and treatment experiences, illness behaviour, and health anxiety.

More specifically the following hypotheses will be explored: 1) SES and migration are associated with factors contributing to the symptom persistence (aggravating factors) of IBS and fatigue. 2) There are differences in public perceptions of and public beliefs about IBS and fatigue according to the SES and migration status of the person expressing the symptoms.

The SOMA.SOC study is part (project 6) of the interdisciplinary research unit "Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)". SOMACROSS aims to identify disease-overarching and disease-specific biopsychosocial risk factors and mechanisms for the persistence of somatic symptoms.[41] SOMACROSS proposes a biopsychosocial 'PSS working model' as a starting point for the investigation of risk factors and aetiological mechanisms, based on the model by Henningsen et al.[24] The integration of the objectives of the SOMA.SOC project into the working model of SOMACROSS is shown in Figure 1.

(Figure 1 about here)

Methods and analysis

Study design and participants

In order to gain insight in social inequalities in aggravating factors of IBS and fatigue, the project will make use of a mixed methods design by collecting both quantitative and qualitative observational data. For a better understanding of the methods, in the following, these two study parts (population survey and qualitative interviews with patients) will be presented separately. The conditions under study will be conceptualized differently in the two study parts: While we will use vignettes describing a person with typical symptoms of IBS or fatigue in the population survey, patients diagnosed with one of the conditions will be recruited for the qualitative interviews. Data collection started in April 2022 and will be finalized in summer 2024.

Population survey

To explore public knowledge, beliefs, attitudes, and experiences regarding PSS in the case of IBS and fatigue, a population survey will be conducted throughout Germany via computer-assisted telephone interviewing (CATI). This cross-sectional survey is going to be representative of the resident population in Germany aged 18 years and older, and utilizes a dual-frame approach, i.e. 30% of the gross sample consists of mobile numbers, while 70% will be selected from landline numbers. Thus, there is greater chance of including mobile-only users as well as target groups otherwise hard to reach. Landline numbers will be drawn from all registered private numbers at random. Additional computer-generated numbers will also allow for ex-directory household. For interviews in households with more than one potential target person, a random selection of the target person is realized using the Kish-Selection-Grid.[42] Regarding mobile telephone connections, the interview will be conducted with the person answering the phone. To gain a representative sample of the adult population living in Germany, data will be weighted by using an approach that includes a correction for household sizes, selection probabilities and distributions of specific socio-demographic characteristics.[43]

(Table 1 about here)

In the beginning of the interview, a case story (vignette) will be presented to the respondents. In the vignette, a person with signs and symptoms indicative of either IBS or fatigue will be described. The vignettes will be varied according to sex (male / female), occupational status (high (lawyer) / low (cleaner)), and migration status (yes / no), resulting in 16 different case stories (please see Table 1 for an overview of the varied factors and Table 2 for resulting vignettes). The vignettes will be designed in cooperation with clinical experts. By combining a vignette design with a survey, social inequalities may be examined from two perspectives: first, as social characteristics of the respondents themselves (please see above, hypothesis 1) and second, of the person described in the vignette (hypothesis 2). In terms of the first hypothesis, associations between social characteristics of the respondents and aggravating factors (e.g. illness and treatment experiences, illness behaviour, health anxiety) will be analysed, while for the second hypothesis, differences in perceptions, attitudes, and beliefs according to migration and occupational status of the person in the vignette will be examined.

(Table 2 about here)

A total of N = 2,400 participants will be included in the national telephone survey. The 16 vignettes will be randomly assigned to the respondents (n = 150 per vignette). A sample size calculation showed that this number is sufficient to identify small sized differences with a statistical power of 80% and a Type-I error of 0.05 when comparing two vignettes (hypothesis 2) with regards to categorical outcomes using χ^2-tests. As for continuous outcomes, a sample size of n = 150 per vignette allows for the detection of small to medium effect sizes based on t-tests, linear regression models, or analyses of variance (statistical power 80%, Type-I error = 0.05). Moreover, based on previous studies with a similar design,[44-46] this number of respondents was found to be adequate to detect significant differences in public beliefs between vignettes. Similar surveys with a vignette design resulted in response rates between 48% and 54%.[44-46]

Qualitative patient interviews

To complement the population perspective and to analyse social inequalities in factors and mechanisms of symptom persistence among patients with IBS and fatigue, qualitative interviews will be conducted using a longitudinal design. Longitudinal qualitative research (LQR) is distinct from other qualitative approaches in the way that it incorporates time into the research process. It opens the possibility to make change (or stability) a key focus in analysis.[47] LQR aims at answering questions regarding lived experiences, e.g. during the course of diseases, and how and why these experiences change over time. Against the background of the ongoing process of persistence of somatic symptoms, LQR will be helpful to capture individual courses, narratives and trajectories.

Patients will be recruited from primary care practices in the Hamburg region and will be selected according to condition (IBS / fatigue), sex (male / female), occupational status (high / low), and migration status (yes / no). With respect to the occupational status of patients, the International Socio-Economic Index of Occupational Status (ISEI) according to Ganzeboom et al.[48] will be used as a criterion for assigning scores. Scores will be dichotomized to obtain groups of high and low occupational position. Regarding the patients' migration history, we will be adapting the definition of the German Federal Statistical Office. This states that "A person has a migration background if he or she or at least one parent was not born with German citizenship".[49] For recruitment of the patients, the authors will cooperate with the Department of General Practice and Primary Care at the University Medical Center Hamburg-Eppendorf, which established a physicians' research network. Physicians are listed in a database that includes contact details of all primary care physicians residing in Hamburg and its suburbs as well as in adjacent regions (overall about 3,000 primary care physicians). The database holds information on contact data, structure of the practice (single vs. group practice), physician staff and involvement in recent research projects. 50 practices will be randomly selected and contacted (for details please see sample size estimation below and Figure 2).

(Figure 2 about here)

Semi-structured interviews with 32 patients will be conducted at three measurement points (at the time of inclusion (t0), after 6 months (t1), and after 12 months (t2)), resulting in 96 interviews. Patients will be selected based on a purposeful sampling procedure according to the four strata mentioned above (condition, sex, occupational status, and migration). This procedure was chosen as it is expected to be useful to analyse social inequalities in factors and mechanisms of symptom persistence. Patients will be recruited via primary care practices in the Hamburg region. Based on experiences in previous projects, we expect a participation rate of at least 50% of the randomly selected practices.[50] This will lead to around 25 practices taking up patient recruitment. We also estimate the participation rate of the addressed patients at 50%, meaning that the practices will have to contact 96 patients (around four patients per practice in six months), leading to 48 patients with the required combination of characteristics who supply informed consent to participate. This will allow for a drop-out rate of approximately 30% among participants during the course of the study, resulting in n = 32 patients who will be included in all three measurement points (please see Figure 2). For each of the 16 combinations (IBS / fatigue), sex (male / female), migration (yes / no), and occupational status (high / low), two semi-structured interviews will be conducted. This sampling procedure will result in an equal number of patients (n = 16) in terms of condition, sex, occupational status, and migration status interviewed at three measurement points.

There will be a two-staged recruitment process. The selected practices will be contacted via telephone by a member of the project group, the project will be briefly explained and the interest in participating in the study will be assessed. If interested in participation, the practice will receive a detailed study information, a process description, and a declaration of consent to participate. Moreover, the participating practices will be provided with all necessary study materials to be handed out to patients (e.g. study information, privacy statement, short questionnaire to collect necessary patient data (e.g. name, condition, sex, age, occupation, contact information).

Doctors are asked to inform patients who meet the diagnostic criteria (K58.1 (IBS-D), K58.2 (IBS-C), K58.3 (IBS-M), K58.8, R53, F48.0, or G93.3 according to ICD-10[40]) about the study when they present in the practice. Those patients who are interested in participation are requested to return a short questionnaire with all relevant information about eligibility including contact details to the project group (either via mail, e-mail or fax). Returned questionnaires will be sorted according to strata (condition, sex, migration status, occupational position). Thereafter, telephone calls will be conducted to provide further information if needed and to arrange an interview appointment. Informed consent will be signed by all participating patients. Participants will be free to conduct the interviews in person or by telephone. To acknowledge their participation and compensate for expenses, each patient will receive 15€ for each completed interview, the physicians will receive 50€ per patient included in the study.

Assessment and study outcomes

Population survey

The standardized questionnaire used in the telephone survey will cover the following topics (1) questions referring to knowledge and beliefs about IBS or fatigue, (2) attitudes towards persons affected from IBS or fatigue (stigma), (3) personal experiences with these symptoms, and (4) sociodemographic characteristics of respondents (please also see Table 3[51-54]). As for social inequalities, highest educational attainment, occupational position, monthly equivalence household income, and migration status (no migration background, 1st and 2nd generation migrants) will be assessed.[55] In Germany, about 25% of the general population have a migration background. Accordingly, in our sample (N=2,400), we expect about 600 respondents to have a migration background. In terms of knowledge and beliefs about IBS or fatigue, health literacy, illness perceptions, and illness beliefs will be measured. Regarding personal experiences with the symptoms, questions about illness behaviour, illness and treatment experiences, somatic symptom burden, and health anxiety will be included.

(Table 3 about here)

Qualitative patient interviews

Semi-structured interviews will be conducted personally or by telephone (according to patient preference). To this end, a blend of closed and open-ended questions will be used that can be accompanied by follow-up questions to further specify mentioned topics. The precise formulation and order of the questions can be varied. This will allow to cover the main issues with all participants while also offering flexibility in discussing issues pertinent to individuals. The interviews will have a length of about 30 minutes and will be audio-recorded upon permission of the patient. A total of three sections are planned for the interview guide:

(1) Origin, causes and development of the disease: Here, aspects of symptom / illness perception as well course and severity of symptoms and aspects of health anxiety will be covered.

(2) Coping with the illness and help-seeking: In this segment, illness behaviour and experiences, health literacy as well as treatment experiences and treatment expectations will be focused.

(3) Social interaction and perception by others: This complex will cover disclosure of illness and (perceived) stigma associated with the disorder.

Data analyses

Population survey

Associations between social characteristics of the respondents and aggravating factors will be analysed by calculating regression models (hypothesis 1). Furthermore, structural equation model approaches will be utilized to explore to what extent social inequalities in PSS are mediated by the aggravating factors under study and to what extent variance is mediated by other (unconsidered) factors. Differences in public perceptions, attitudes, and beliefs according to migration and occupational status of the person in the vignette (hypothesis 2) will be examined using analyses of variance. The power calculation showed that the sample size is sufficient to detect significant main effects (e.g. of migration status of the person in the vignette) as well as two-way interactions (e.g. between migration and occupational status). In terms of the latter, interaction tests will be performed. Regarding categorical outcomes (e.g. recognition of condition presented in the vignette (yes or no)), χ^2-tests will be applied. Missing data will be imputed if more than 5% of the data are missing. The number of imputations will be chosen dependent on the proportion of missing data.

Qualitative patient interviews

Subject to the consent of the participants, the interviews will be audio-recorded. Uniform transcription rules will be established before the start of the analysis, and compliance with these rules will be checked several times during the course of the process. For the analysis of the transcribed interviews, qualitative content analysis (QCA) will be used. A core aspect of QCA is to make the interpretation of text describable and verifiable by using content analysis rules previously formulated on the basis of a work plan. The technique of inductive category formation is particularly suitable for this study design. Inductive categories are developed from the interview material according to a given definition criterion, in order to reach the central aspects of the text. Step by step, categories will be formulated, which are revised within feedback loops eventually reduced to main categories and checked in respect to their reliability.[56]

The data from both study parts are seen as two complementing perspectives on social aspects that contribute to the symptom persistence of IBS and fatigue. In using these different approaches, we expect a better and more comprehensive understanding of inequalities in aggravating factors of PSS and how they are associated with patients' and the public's characteristics. Integration of data of the two study parts will be feasible as there are overlaps in design (variation of social characteristics) and content of the survey/interview (please see assessment and study outcomes). To this end, results of the quantitative part will be triangulated with corresponding statements from the qualitative interviews.[57]

Patient and public involvement

None.

Ethics and dissemination

The study is based on data of personal or telephone interviews. Thus, ethical and legal considerations are focused on data protection. We will strictly adhere to data protection regulations. Informed consent will be obtained from all participants. Respondents will be informed that participation in the study is voluntary and that withdrawal is possible at any time. There are no specific risks for the participants in the study. The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff).

In accordance with the ethics committee approval and the German Research Foundation (DFG) guidelines for the handling of research data, deidentified quantitative individual data will be made publicly available. Data sharing will follow the FAIR Data Principles (Findable, Accessible, Interoperable and Reusable). The main findings will be submitted for publication in peer-reviewed journals within 12 months of study completion.

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Contributors: OvdK and AM developed the study. OvdK is the principal investigator of the study. RB is research associate in the study. All authors contributed to the refinement of the study protocol, read and approved the final version.

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Table 1: Factors presented in the vignettes

Factor	**Specifications**	
Condition	Irritable Bowel Syndrome (IBS)	Fatigue (Fa)
Sex	Male (M)	Female (F)
Migration history	Migration history (Mh)	No Migration history (nM)
Occupational status	High (Lawyer, L)	Low (Cleaner, C)

Table 2: Vignettes presented in the survey

Vignette No.	Factor combination
1	IBS M Mh L
2	IBS M nM L
3	IBS M Mh C
4	IBS M nM C
5	IBS F Mh L
6	IBS F nM L
7	IBS F Mh C
8	IBS F nM C
9	Fa M Mh L
10	Fa M nM L
11	Fa M Mh C
12	Fa M nM C
13	Fa F Mh L
14	Fa F nM L
15	Fa F Mh C
16	Fa F nM C

For abbreviations of the factor combinations please see Table 1.

Table 3: Instruments intended to use in the population survey

	Construct	Indicator/Instrument
(1)	Health literacy	Labelling (recognition of disease); perceived causes; treatability; effectiveness of treatment options
	Illness perception	Illness Perception Questionnaire (brief version, IPQ-B)[51]
	Illness belief	E.g. "Do you think that the person in the vignette has a real disorder?"
(2)	Public stigma	Emotional reactions towards those affected by IBS or fatigue Stereotypes ascribed to persons with IBS or fatigue
	Anticipated stigma	Modified version of the IBS Stigma Scale[52]
(3)	Illness behaviour	E.g. "If you have the feeling of being affected by such complaints, you should get help as soon as possible." Health care utilization
	Illness experience	Own affliction; contact to someone affected
	Treatment experience	Treatment experience
	Somatic symptom burden	Somatic Symptom Scale (SSS-8)[53]
	Health anxiety	Whiteley Index (WI-7)[54]
(4)	Sociodemographic data	Age, sex, educational attainment, occupational position, income, migration status, marital status

Figure 1: Integration of the study objectives into the working model of the Research unit “Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)” [41]

Figure 2: Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

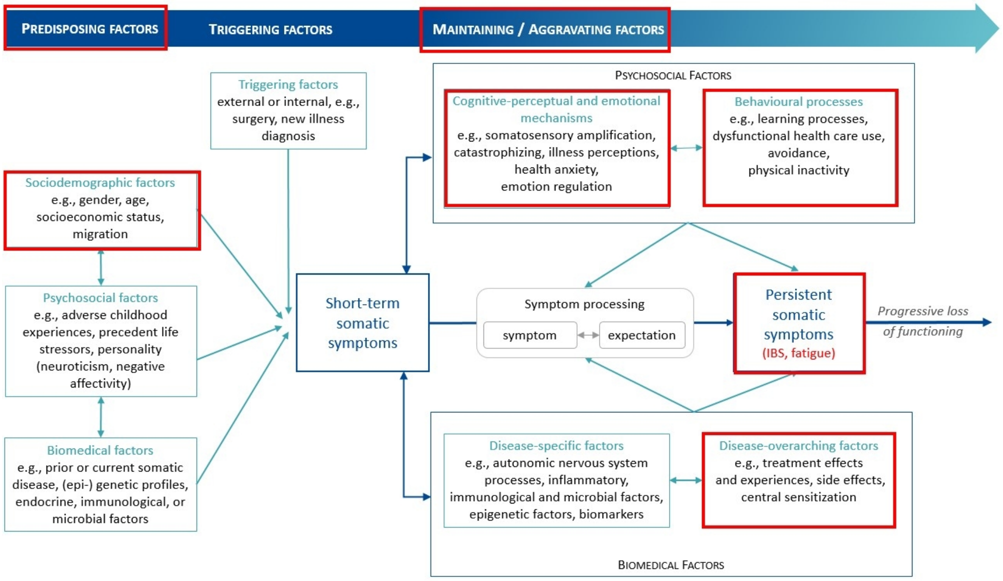

Figure 1: Integration of the study objectives into the working model of the Research unit “Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)” 41

340x200mm (96 x 96 DPI)

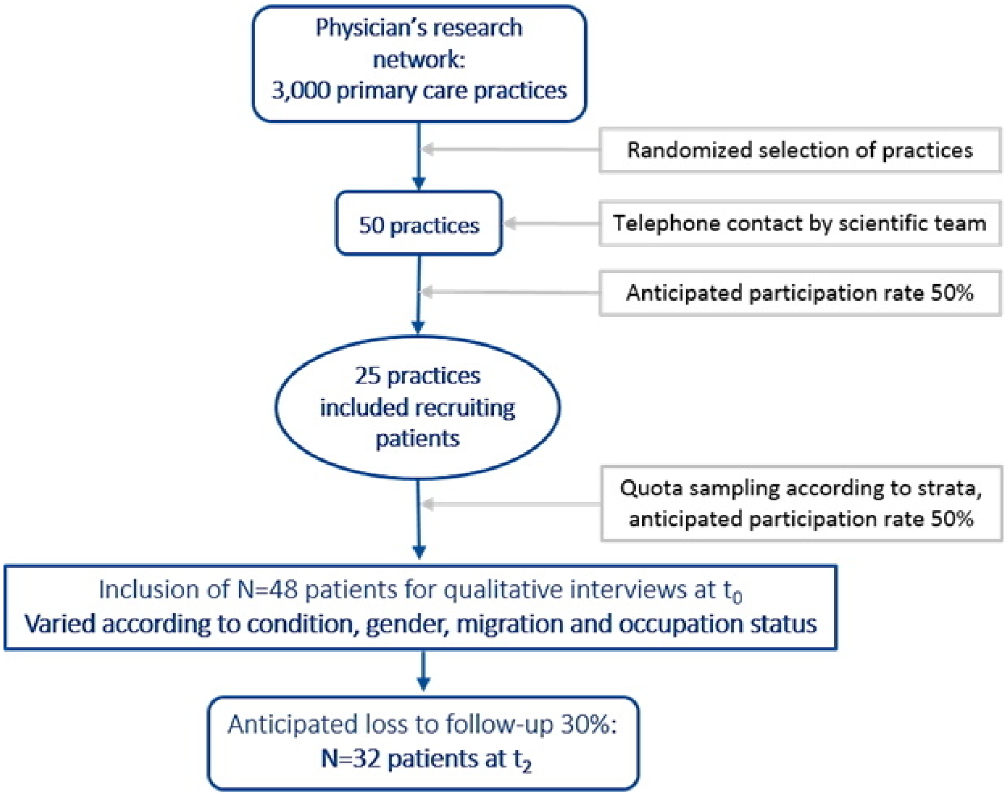

Figure 2: Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

164x129mm (96 x 96 DPI)

Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC): study protocol for a mixed method observational study focussing on irritable bowel syndrome and fatigue

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Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC): study protocol for a mixed method observational study focussing on irritable bowel syndrome and fatigue

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Abstract

Introduction: Some studies indicate that persistent somatic symptoms (PSS) are more prevalent among individuals with a low socioeconomic status (SES) and a migration background. However, factors explaining social inequalities in PSS are largely unknown. It is expected that aggravating factors of PSS like illness perception, illness beliefs (health literacy, stigma), illness behaviour, and health anxiety may play an important role for this explanation. The SOMA.SOC study will examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in irritable bowel syndrome (IBS) and fatigue.

Methods and analysis: The project will collect both quantitative and qualitative data. Quantitative data will be gathered via a representative telephone survey in Germany (N=2,400). A vignette design will be used depicting patients varying in sex, condition (IBS/fatigue), occupational status (low/high), and migration (yes/no). In the survey, we will assess public knowledge and beliefs (e.g. health literacy), attitudes (stigma), and personal experiences with the condition (e.g. somatic symptom burden). Complementary, longitudinal qualitative interviews will be conducted with patients (n=32 at three time points, resulting in N=96 interviews) who will also vary according to sex, condition, occupational status and migration. Patients will be recruited from primary care practices in Hamburg. The interviews will cover origin and development of the condition, coping and help-seeking as well as social interactions and perception of the disease by others (e.g. perceived stigma). SOMA.SOC is part of the interdisciplinary SOMACROSS (Persistent SOMAtic Symptoms ACROSS Diseases) research unit.

Ethics and dissemination: The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff). Informed consent will be obtained from all participants. The main findings will be submitted for publication in peer-reviewed journals within 12 months of study completion.

Keywords: social inequalities, socioeconomic status, migration, somatic symptoms, symptom persistence, mixed methods, SOMACROSS

Strengths and limitations of this study

- Social inequalities according to socioeconomic status and migration in a range of aggravating factors (illness perception, symptom beliefs, illness/treatment experiences, illness behaviour, and health anxiety) in irritable bowel syndrome (IBS) and fatigue will be explored.
- By combining quantitative and qualitative data, we expect a better and more comprehensive understanding of inequalities in aggravating factors of persistent somatic symptoms (PSS).
- With the longitudinal design of the qualitative study part, we expect to gain insight into the course of symptoms and changes of experiences over time.
- Due to the observational design, causal conclusions cannot be drawn from the study.
- As the study is focussed on IBS and fatigue, results cannot be generalized to other PSS.

Introduction

Background

Health inequalities according to socioeconomic status and migration

National and international studies in social epidemiology have consistently shown that socioeconomic status (SES, i.e. education, income, and/or occupational position) as well as migration and ethnicity are important social determinants of health.[1,2] Accordingly, people with a low SES generally experience worse health and wellbeing as well as higher morbidity (including higher risk of chronic disease course) and mortality rates than those with a high SES. Material (e.g. material deprivation, unfavourable working, housing, and neighbourhood conditions), psychosocial (e.g. social isolation, psychosocial stress, coping resources) and behavioural factors (e.g. smoking, exercise, alcohol consumption, nutrition) contribute to the explanation of such health inequalities. Recent studies indicate that differences in knowledge and beliefs about health and illness ("health literacy") are also important for the explanation of health inequalities.[3,4] However, results on the explanatory contribution of these factors are inconsistent as there is variation according to the disease under study. For example, socioeconomic inequalities of coronary heart disease can largely be explained by differences in classic cardiovascular risk factors (i.e. high blood pressure, high cholesterol, diabetes mellitus, and cigarette smoking)[5], while poorer coping styles, ongoing life events, stress exposure, and weaker social support are important factors to explain the higher prevalences of mental disorders in lower SES groups.[6,7]

Although migrants are often, at least initially, relatively healthy compared with the non-migrant population in the host country, available data suggest that they tend to be more vulnerable to certain communicable diseases, occupational health hazards, injuries, poor mental health, and maternal and child health problems.[2,8] Studies furthermore show that there are large differences between migrants in terms of their socioeconomic situation but these differences and their health-related consequences are far from being adequately understood. As migration status and SES reflect different aspects of social inequalities, that are not independent, it is reasonable to explore both aspects and their relation to health simultaneously.[9]

Social inequalities in somatic symptoms

Regarding persistent somatic symptoms (PSS), there are a few studies investigating inequalities according to SES and migration. Using German population survey data, Hinz et al.[10] found that a low SES is associated with a higher risk for somatic symptoms measured with the Patient Health Questionnaire (PHQ-15).[11] This result was confirmed by an analysis of the Gutenberg Health Study conducted in the Rhine-Main-Region.[12] Based on the German national Cohort study, Morawa et al.[13] showed that persons of Turkish origin report more symptoms according to the PHQ-15 compared to Germans. Moreover, psychiatric patients with a migration background had a significantly higher current symptom load, especially by somatic symptoms, compared to those without migration background.[14]

Thus, overall, results suggest that somatic symptoms are more prevalent among individuals with a low SES and a migration background in Germany. Respective empirical studies mostly use sum scales comprising a number of symptoms but magnitude and mechanisms of inequalities may differ depending on symptom under study. Considering specific PSS with high prevalence such as fatigue (about 30% in Germany[15,16]) or irritable bowel syndrome (IBS, about 10-20% in Germany[17]), research on inequalities is scarce, particularly in Germany. Jason et al.[18] found highest levels of fatigue among minority groups and persons with lower levels of education and occupational status in the US. A German population study also revealed increased rates of fatigue among low SES groups.[16] Another study indicates that there are interactions between SES and ethnicity in the association with fatigue.[19] In terms of IBS, there are studies showing higher prevalences in lower SES groups[20] but others find a reverse association or no socioeconomic inequalities.[21–23] There is a paucity of data on differences according to migration status in the epidemiology of IBS.

Associations between social inequalities and aggravating factors of PSS

Aetiological models suggest that psychosocial, behavioural, and biomedical factors, as well as their interaction, contribute to the persistence and aggravation of somatic symptom burden.[24] Among known psychosocial maintaining or aggravating factors in PSS are health anxiety, treatment experiences, and illness beliefs, perception and behaviour. We expect that these factors may partially mediate any differences that might be seen in rates of PSS between those with differential socioeconomic or migration status. However, empirical studies analysing associations between social inequalities and aggravating factors are scarce and thus, there is not much known about the mechanisms that potentially can explain inequalities in PSS.

Studies on illness beliefs examine to what extent an illness is recognized as such and what beliefs about the causes, the course and the treatment of this illness are prevalent among the public. In recent years, these studies have been discussed with reference to the concept of health literacy. Health literacy entails “the public’s knowledge, motivation, and competence to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare”.[25] Deficits in health literacy mean that people do not know what they can do for prevention, delay or avoid seeking treatment, view recommended treatments with suspicion, or are unsure how to assist those afflicted.[26] Limited health literacy has been found among people with a low SES and migrant background.[4,27,28] For example, a study analysing differences between German and Turkish patients suffering from somatoform disorders showed that Turkish patients believed significantly stronger in supernatural causes of their disease.[29] These beliefs reduced the motivation to take up psychotherapy. A lack of health literacy has been found to be associated with negative attitudes towards persons with mental illness,[28] which can be conceptualized as public stigma. This entails reactions of the general public towards a group based on stereotypes about this group. In this regard, results suggest that respondents with higher SES desire less social distance from the mentally ill and express more liberal views.[30] Research also suggests that public stigma is perceived and often internalized by the persons afflicted. Perceived and internalized stigma have been found to predict worse health outcomes among IBS patients.[31] With regards to fatigue, studies report higher levels of perceived stigma when compared to IBS[32] and participants report feelings of estrangement and the belief that others attribute fatigue solely to psychological causes.[33]

Only few studies examined inequalities in symptom or illness perception and health anxiety. In terms of the former, perceived symptom burden seems to be positively associated with education,[34] while results on differences according to ethnicity and migration are inconsistent.[34,35] As for health anxiety, a recent meta-analysis showed a lower risk for health anxiety in people with higher socioeconomic status.[36] Another meta-analysis indicated a higher risk of health anxiety in migrants and ethnic minorities compared to the majority population in North America.[37] Regarding illness behaviour, reviews from Germany overall indicate a lower utilization of health care among migrants, although the results vary in terms of health care sector, indicator of health care utilization and migrant population under study.[38] Low SES groups show lower utilization regarding medical specialist consultations and prevention services.[39]

Objectives and hypotheses

Against this background, the present study, Social inequalities in aggravating factors of somatic symptom persistence (SOMA.SOC), was developed. The objective of the study is to examine social inequalities (according to SES and migration) in factors contributing to symptom persistence in IBS and fatigue. We chose these two specific conditions as they appear relatively frequently in the German population. In terms of IBS, we especially refer to the cardinal symptoms of recurrent abdominal pain and altered bowel movements (as specified in the International Classification of Diseases 10th Edition, ICD-10[40]). Regarding fatigue, different symptoms like emotional and cognitive limitations (e.g. lack of motivation and reduced performance) as well as physical complaints (e.g. muscular weakness) are to be considered (as mentioned in the national guideline[15] and covered in the ICD-10[40]). The following aggravating factors will be explored: illness perception, knowledge and beliefs about the symptoms, illness and treatment experiences, illness behaviour, and health anxiety.

More specifically the following hypotheses will be explored: 1) SES and migration are associated with factors contributing to the symptom persistence (aggravating factors) of IBS and fatigue. 2) There are differences in public perceptions of and public beliefs about IBS and fatigue according to the SES and migration status of the person expressing the symptoms.

The SOMA.SOC study is part (project 6) of the interdisciplinary research unit Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS). SOMACROSS aims to identify disease-overarching and disease-specific biopsychosocial risk factors and mechanisms for the persistence of somatic symptoms.[41] SOMACROSS proposes a biopsychosocial ‘PSS working model’ as a starting point for the investigation of risk factors and aetiological mechanisms, based on the model by Henningsen et al.[24] The integration of the objectives of the SOMA.SOC project into the working model of SOMACROSS is shown in Figure 1 (objectives of the SOMA.SOC study are framed in red). Accordingly, specific focus will be on sociodemographic predisposing factors and psychosocial maintaining/aggravating factors (Figure 1).

Methods and analysis

Study design and participants

In order to gain insight in social inequalities in aggravating factors of IBS and fatigue, the project will make use of a mixed methods design by collecting both quantitative and qualitative observational data. For a better understanding of the methods, in the following, these two study parts (population survey and qualitative interviews with patients) will be presented separately. The conditions under study will be conceptualized differently in the two study parts: While we will use vignettes describing a person with typical symptoms of IBS or fatigue in the population survey, patients diagnosed with one of the conditions will be recruited for the qualitative interviews. Data collection started in April 2022 and will be finalized in summer 2024.

Design of the population survey

To explore public knowledge, beliefs, attitudes, and experiences regarding PSS in the case of IBS and fatigue, a cross-sectional population survey will be conducted throughout Germany via computer-assisted telephone interviewing (CATI). In the beginning of the interview, a case story (vignette) will be presented to the respondents. In the vignette, a person with signs and symptoms indicative of either IBS or fatigue will be described. The vignettes will be varied according to sex (male/female), occupational status (high (lawyer)/low (cleaner)), and migration status (yes/no), resulting in 16 different case stories (see Table 1 for an overview of the varied factors and Table 2 for resulting vignettes). The vignettes will be designed in cooperation with clinical experts. By combining a vignette design with a survey, social inequalities may be examined from two perspectives: first, as social characteristics of the respondents themselves (please see above, hypothesis 1) and second, of the person described in the vignette (hypothesis 2). In terms of the first hypothesis, associations between social characteristics of the respondents and aggravating factors (e.g. illness and treatment experiences, illness behaviour, health anxiety) will be analysed, while for the second hypothesis, differences in perceptions, attitudes, and beliefs according to migration and occupational status of the person in the vignette will be examined.

Participants of the population survey

The survey is going to be representative of the resident population in Germany aged 18 years and older, and utilizes a dual-frame approach, i.e. 30% of the gross sample consists of mobile numbers, while 70% will be selected from landline numbers. Thus, there is greater chance of including mobile-only users as well as target groups otherwise hard to reach. Landline numbers will be drawn from all registered private numbers at random. Additional computer-generated numbers will also allow for ex-directory household. For interviews in households with more than one potential target person, a random selection of the target person is realized using the Kish-Selection-Grid.[42] Regarding mobile telephone connections, the interview will be conducted with the person answering the phone. To gain a representative sample of the adult population living in Germany, data will be weighted by using an approach that includes a correction for household sizes, selection probabilities and distributions of specific socio-demographic characteristics.[43] A total of N = 2,400 participants will be included in the national telephone survey. The 16 vignettes will be randomly assigned to the respondents (n = 150 per vignette). A sample size calculation showed that this number is sufficient to identify small sized differences with a statistical power of 80% and a Type-I error of 0.05 when comparing two vignettes (hypothesis 2) with regards to categorical outcomes using χ^2-tests. As for continuous outcomes, a sample size of n = 150 per vignette allows for the detection of small to medium effect sizes based on t-tests, linear regression models, or analyses of variance (statistical power 80%, Type-I error = 0.05). Moreover, based on previous studies with a similar design,[44-46] this number of respondents was found to be adequate to detect significant differences in public beliefs between vignettes. Similar surveys with a vignette design resulted in response rates between 48% and 54%.[44-46]

Design of the qualitative interviews

To complement the population perspective and to analyse social inequalities in factors and mechanisms of symptom persistence among patients with IBS and fatigue, qualitative, semi-structured interviews will be conducted using a longitudinal design. Longitudinal qualitative research (LQR) is distinct from other qualitative approaches in the way that it incorporates time into the research process. It opens the possibility to make change (or stability) a key focus in analysis.[47] LQR aims at answering questions regarding lived experiences, e.g. during the course of diseases, and how and why these experiences change over time. Against the background of the ongoing process of persistence of somatic symptoms, LQR will be helpful to capture individual courses, narratives and trajectories. Accordingly, interviews will be conducted at three measurement points (at the time of inclusion (t0), after 6 months (t1), and after 12 months (t2)).

Participants of the qualitative interviews

Patients will be recruited from primary care practices in the Hamburg region and will be selected according to condition (IBS/fatigue), sex (male/female), occupational status (high/low), and migration status (yes/no). With respect to the occupational status of patients, the International Socio-Economic Index of Occupational Status (ISEI) according to Ganzeboom et al.[48] will be used as a criterion for assigning scores. Scores will be dichotomized to obtain groups of high and low occupational position. Regarding the patients' migration history, we will be adapting the definition of the German Federal Statistical Office. This states that "A person has a migration background if he or she or at least one parent was not born with German citizenship".[49] For recruitment of the patients, the authors will cooperate with the Department of General Practice and Primary Care at the University Medical Center Hamburg-Eppendorf, which established a physicians' research network. Physicians are listed in a database that includes contact details of all primary care physicians residing in Hamburg and its suburbs as well as in adjacent regions (overall about 3,000 primary care physicians). The database holds information on contact data, structure of the practice (single vs. group practice), physician staff and involvement in recent research projects. 50 practices will be randomly selected and contacted (Figure 2). If interested in participation, the practice will receive a detailed study information, a process description, and a declaration of consent to participate. Moreover, the participating practices will be provided with all necessary study materials to be handed out to patients (e.g. study information, privacy statement, short questionnaire to collect necessary patient data (e.g. name, condition, sex, age, occupation, contact information).

Patients will be selected based on a purposeful sampling procedure according to the four strata mentioned above (condition, sex, occupational status, and migration). This procedure was chosen as it is expected to be useful to analyse social inequalities in factors and mechanisms of symptom persistence. Doctors are asked to inform patients who meet the diagnostic criteria (K58.1 (IBS-D), K58.2 (IBS-C), K58.3 (IBS-M), K58.8, R53, F48.0, or G93.3 according to ICD-10[40]) about the study when they present in the practice. Those patients who are interested in participation are requested to return a short questionnaire with all relevant information about eligibility including contact details to the project group (either via mail, e-mail or fax). Returned questionnaires will be sorted according to strata (condition, sex, migration status, occupational position). Thereafter, telephone calls will be conducted to provide further information if needed and to arrange an interview appointment. Informed consent will be signed by all participating patients. Participants will be free to conduct the interviews in person or by telephone. To acknowledge their participation and compensate for expenses, each patient will receive 15€ for each completed interview (i.e. 45€ for the three interviews).

Based on experiences in previous projects, we expect a participation rate of at least 50% of the randomly selected practices.[50] This will lead to around 25 practices taking up patient recruitment. Physicians will receive 50€ per patient included in the study. We also estimate the participation rate of the addressed patients at 50%, meaning that the practices will have to contact 96 patients (around four patients per practice in six months), leading to 48 patients with the required combination of characteristics who supply informed consent to participate. This will allow for a drop-out rate of approximately 30% among participants during the course of the study, resulting in n = 32 patients who will be included in all three measurement points (see Figure 2). For each of the 16 combinations (IBS/fatigue), sex (male/female), migration (yes/no), and occupational status (high/low), two semi-structured interviews will be conducted. This sampling procedure will result in an equal number of patients (n = 16) in terms of condition, sex, occupational status, and migration status interviewed at three measurement points. Thus, altogether 96 interviews will be conducted.

Assessment and study outcomes

Population survey

The standardized questionnaire used in the telephone survey will cover the following topics: (1) questions referring to knowledge and beliefs about IBS or fatigue, (2) attitudes towards persons affected from IBS or fatigue (stigma), (3) personal experiences with these symptoms, and (4) sociodemographic characteristics of respondents (also see Table 3[51-54]). As for social inequalities, highest educational attainment, occupational position, monthly equivalence household income, and migration status (no migration background, 1st and 2nd generation migrants) will be assessed.[55] In Germany, about 25% of the general population have a migration background. Accordingly, in our sample (N=2,400), we expect about 600 respondents to have a migration background. In terms of knowledge and beliefs about IBS or fatigue, health literacy, illness perceptions, and illness beliefs will be measured. Regarding personal experiences with the symptoms, questions about illness behaviour, illness and treatment experiences, somatic symptom burden, and health anxiety will be included.

Qualitative patient interviews

Semi-structured interviews will be conducted personally or by telephone (according to patient preference). To this end, a blend of closed and open-ended questions will be used that can be accompanied by follow-up questions to further specify mentioned topics. The precise formulation and order of the questions can be varied. This will allow to cover the main issues with all participants while also offering flexibility in discussing issues pertinent to individuals. The interviews will have a length of about 30 minutes and will be audio-recorded upon permission of the patient. A total of three sections are planned for the interview guide:

(1) Origin, causes and development of the disease: Here, aspects of symptom/illness perception as well course and severity of symptoms and aspects of health anxiety will be covered.

(2) Coping with the illness and help-seeking: In this segment, illness behaviour and experiences, health literacy as well as treatment experiences and treatment expectations will be focused.

(3) Social interaction and perception by others: This complex will cover disclosure of illness and (perceived) stigma associated with the disorder.

Data analyses

Population survey

Associations between social characteristics of the respondents and aggravating factors will be analysed by calculating regression models (hypothesis 1). Furthermore, structural equation model approaches will be utilized to explore to what extent social inequalities in PSS are mediated by the aggravating factors under study and to what extent variance is mediated by other (unconsidered) factors. Differences in public perceptions, attitudes, and beliefs according to migration and occupational status of the person in the vignette (hypothesis 2) will be examined using analyses of variance. The power calculation showed that the sample size is sufficient to detect significant main effects (e.g. of migration status of the person in the vignette) as well as two-way interactions (e.g. between migration and occupational status). In terms of the latter, interaction tests will be performed. Regarding categorical outcomes (e.g. recognition of condition presented in the vignette (yes or no)), χ^2-tests will be applied. Missing data will be imputed if more than 5% of the data are missing. The number of imputations will be chosen dependent on the proportion of missing data.

Qualitative patient interviews

Subject to the consent of the participants, the interviews will be audio-recorded. Uniform transcription rules will be established before the start of the analysis, and compliance with these rules will be checked several times during the course of the process. For the analysis of the transcribed interviews, qualitative content analysis (QCA) will be used. A core aspect of QCA is to make the interpretation of text describable and verifiable by using content analysis rules previously formulated on the basis of a work plan. The technique of inductive category formation is particularly suitable for this study design. Inductive categories are developed from the interview material according to a given definition criterion, in order to reach the central aspects of the text. Step by step, categories will be formulated, which are revised within feedback loops eventually reduced to main categories and checked in respect to their reliability.[56]

Mixed methods integration

Although data from both study parts are collected and analysed separately, they are seen as two complementing perspectives on social aspects that contribute to the symptom persistence of IBS and fatigue. In using these different approaches, we expect a better and more comprehensive understanding of inequalities in aggravating factors of PSS and how they are associated with patients' and the public's characteristics. Integration of findings of the two study parts will be feasible as there are overlaps in design (variation of social characteristics) and content of the survey/interview (please see assessment and study outcomes). The process of integrating findings from the two methods will take place at the interpretation stage when both data sets have been analysed separately. Accordingly, findings from the two components of the study will be listed in a "convergence coding matrix". [57] That means, it will be considered where results from the two study parts agree, offer complementary information on the same issue, or seem to contradict each other.

Patient and public involvement

None.

Ethics and dissemination

The study is based on data of personal or telephone interviews. Thus, ethical and legal considerations are focused on data protection. We will strictly adhere to data protection regulations. Informed consent will be obtained from all participants. Respondents will be informed that participation in the study is voluntary and that withdrawal is possible at any time. There are no specific risks for the participants in the study. The study protocol was approved by the Ethics Committee of the Hamburg Medical Association on 25 January 2021 (reference number: 2020-10194- BO-ff), including financial compensations for patients and physicians.

In accordance with the ethics committee approval and the German Research Foundation (DFG) guidelines for the handling of research data, deidentified quantitative individual data will be made publicly available. Data sharing will follow the FAIR Data Principles (Findable, Accessible, Interoperable and Reusable). The main findings will be submitted for publication in peer-reviewed journals within 12 months of study completion.

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Contributors: OvdK and AM developed the study. OvdK is the principal investigator of the study. RB is research associate in the study. All authors contributed to the refinement of the study protocol, read and approved the final version.

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Patient consent for publication: Not applicable.

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Table 1. Factors presented in the vignettes

Factor	**Specifications**	
Condition	Irritable bowel syndrome (IBS)	Fatigue (Fa)
Sex	Male (M)	Female (F)
Migration history	Migration history (Mh)	No migration history (nM)
Occupational status	High (Lawyer, L)	Low (Cleaner, C)

Table 2. Vignettes presented in the survey

Vignette No.	Factor combination
1	IBS M Mh L
2	IBS M nM L
3	IBS M Mh C
4	IBS M nM C
5	IBS F Mh L
6	IBS F nM L
7	IBS F Mh C
8	IBS F nM C
9	Fa M Mh L
10	Fa M nM L
11	Fa M Mh C
12	Fa M nM C
13	Fa F Mh L
14	Fa F nM L
15	Fa F Mh C
16	Fa F nM C

For abbreviations of the factor combinations please see Table 1.

Table 3. Instruments intended to use in the population survey

	Construct	Indicator/Instrument
(1)	Health literacy	Labelling (recognition of disease); perceived causes; treatability; effectiveness of treatment options
	Illness perception	Illness Perception Questionnaire (brief version, IPQ-B)[51]
	Illness belief	E.g. "Do you think that the person in the vignette has a real disorder?"
(2)	Public stigma	Emotional reactions towards those affected by IBS or fatigue Stereotypes ascribed to persons with IBS or fatigue
	Anticipated stigma	Modified version of the IBS Stigma Scale[52]
(3)	Illness behaviour	E.g. "If you have the feeling of being affected by such complaints, you should get help as soon as possible." Health care utilization
	Illness experience	Own affliction; contact to someone affected
	Treatment experience	Treatment experience
	Somatic symptom burden	Somatic Symptom Scale (SSS-8)[53]
	Health anxiety	Whiteley Index (WI-7)[54]
(4)	Sociodemographic data	Age, sex, educational attainment, occupational position, income, migration status, marital status

Figure 1. Integration of the study objectives into the working model of the Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS) research unit [41]

Figure 2. Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

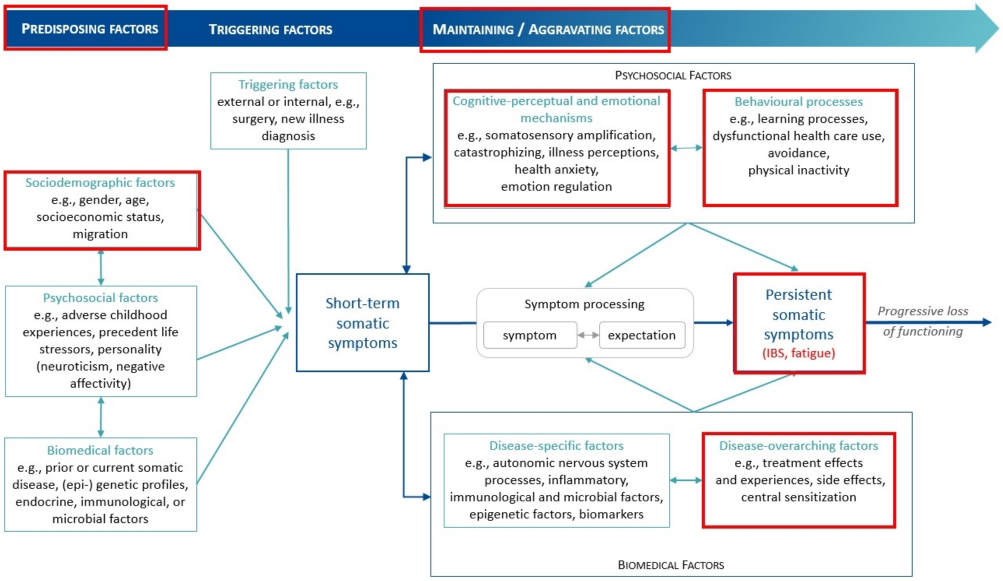

Figure 1: Integration of the study objectives into the working model of the Research unit "Persistent SOMAtic symptoms ACROSS diseases — from risk factors to modification (SOMACROSS)" 41

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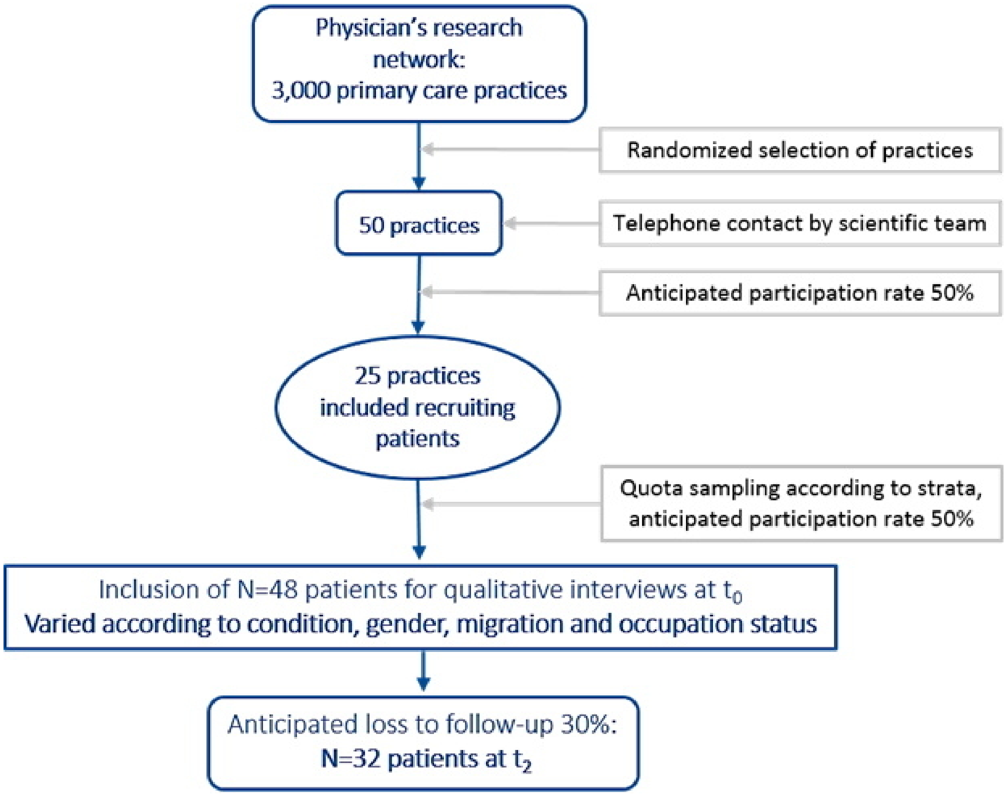

Figure 2: Two-stage recruitment process of patients for the qualitative interviews via primary care practices in Hamburg

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