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Evaluating effects of the structural reform of outpatient psychotherapy for patients with mental disorders in Germany: comparing patients with and without comorbid chronic physical condition – rationale and study protocol of the ES-RiP project

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ABSTRACT

Introduction In 2017, in Germany, a structural reform of the outpatient psychotherapy guideline took place, aiming to reduce waiting times, to facilitate flexible low-threshold access (eg, general reachability by phone) and to lower access barriers for specific patient groups. The reform included new service elements, such as the implementation of additional psychotherapeutic consultations, acute short-term psychotherapeutic interventions and relapse prophylaxis as well as the promotion of group therapies, the facilitation of psychotherapists' availability, and the installation of appointment service centres. The ES-RiP project aims to thoroughly evaluate the effects of the reform with a special focus on patients with a comorbidity of mental disorders and chronic physical conditions (cMPs) compared with patients with a mental disorder but no long-term physical condition (MnoP). The project aims to evaluate (a) the extent to which the reform goals were achieved in the large group of patients with cMPs compared with MnoP, (b) the barriers that might hinder the implementation of the new guideline and (c) the procedures required for further developing and improving outpatient psychotherapy.

Methods and analysis A mixed-methods design (quantitative, qualitative) along with a multilevel approach (patients, service providers, payers) triangulating several data sources (primary and secondary data) will be applied to evaluate the reform from different perspectives.

Ethics and dissemination Ethical approval was obtained from the coordinating committee as well as one local ethics committee, Justus Liebig University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-466/2020). The results of this study will be disseminated through expert panels, conference presentations and publications in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ By applying the conceptual framework of the throughput model, this study will conduct both outcome and process evaluation, and thus, will allow for deeper insights and a founded understanding of the results and possible limitations of the structural reform of the psychotherapy guideline in 2017.
⇒ Based on a mixed-methods design (quantitative and qualitative) along with a multilevel approach (patients, service providers and payers), the different perspectives and various data sources (primary and secondary data) will be triangulated to evaluate the reform.
⇒ Analyses of statutory health insurance data come with inherent limitations such as possibly invalid diagnoses or clinically meaningless statistically significant results due to the large number of included cases.
⇒ Data from the representative population-based survey (substudy II) are based on participants' self-reports and a broad retrospective inquiry period (starting from 2012); therefore, the results will have to be interpreted with caution.
⇒ The validity of results on the provider perspective will highly depend on the participation rate in focus groups, surveys, interviews and observations.

Trial registration number DRKS00020344.

INTRODUCTION

In Germany, nearly 18 million people are affected by mental disorders every year.[1] Psychotherapy is the preferred treatment for these disorders and is commonly offered in

inpatient, day-care or outpatient settings, with approximately 30% of patients with mental disorders attending outpatient psychotherapy.[2] In Germany, costs for these treatments are usually covered by the respective health insurance schemes.[3] Which interventions are accepted and financed is regulated by the psychotherapy guideline ('Psychotherapierichtlinie'); for example, the type of psychotherapy (psychodynamic and cognitive behavioural psychotherapy) or its duration (short-term and long-term psychotherapy as well as the corresponding probatory sessions) (for details on the German psychotherapeutic system see[3 4]).

In 2017, this guideline was reformed, and new elements, such as additional psychotherapeutic consultation times, acute short-term psychotherapeutic interventions and relapse prophylaxis, were implemented. Furthermore, more group therapies were promoted, the availability of psychotherapists by telephone was facilitated, and appointment-service points were set up to convey psychotherapeutic consultations directly.[5] These measures were intended to improve overall outpatient psychotherapeutic care by aiming to reduce long waiting times and help overcome access barriers (eg, general practitioners' (GPs') reluctance to diagnose mental health problems and to refer to psychotherapists) for outpatient treatment, especially for undersupplied groups. Among those with mental disorders, approximately 46% also suffer from at least one long-term physical condition.[6] This is a serious healthcare problem as they are often in particular need of treatment. Compared with patients with mental disorders but no chronic physical condition (MnoP), patients with a comorbidity of mental disorders and chronic physical conditions (cMPs) do not only have a significantly lower quality of life[7–9] but also significantly increased morbidity and mortality rates[10–12] and they also require additional multidisciplinary care[13] and incur significantly higher treatment costs.[14–18] In addition, if the mental disorder remains untreated, the patient's physical condition often deteriorates. Depression, for example, may decrease adherence to treatment of the somatic disease, thus leading, for example, to more hypoglycaemic incidents and possible coma in type 1 diabetes,[19] or transplant rejection in organ recipients.[20] Despite the increased need for care, patients with cMPs frequently experience worse access to psychotherapy as they are more likely to be unable to attend treatments due to their illness.[21]

To improve access to psychotherapeutic care, it is important to understand the access routes to outpatient psychotherapy in Germany. In terms of stepped care, GPs are of particular importance for patients with mental disorders as they are usually the first and main contact person.[22] Three-quarters of patients with mental disorders are treated exclusively by their GP,[23 24] indicating high barriers for referral to psychotherapy in primary care.[25] The afore-mentioned difficulties in accessing a psychotherapist, long waiting times, and low flexibility prior to the reform often caused reluctance among GPs to recommend psychotherapy to patients.[24] Furthermore, patients either feared stigmatisation should they attend psychotherapy or did not have an appropriate understanding of what psychotherapy options were available or of the routes of access to treatment.[26] In particular, for patients with cMPs the diagnosis of a mental disorder is often challenging for the GP due to the symptomatic overlap of mental disorders and physical diseases.[24] The new option of short-term consultations and assessment sessions with a psychotherapist could help to overcome such diagnostic problems. Consequently, patients with cMPs should particularly benefit from the reform due to the reduced waiting times and improved access to psychotherapy.

Since the introduction of the reform, preliminary evidence shows that the number of patients having contact with a psychotherapist has increased and the time to first contact has decreased, but initiation of psychotherapy itself has decreased.[27 28] This concurs with the results of a survey of psychotherapists, in which more than half of them report that the reform has not resulted in significant improvements of care for their patients.[29] However, other than these general and short-term results, no studies have been conducted on the extent to which the care situation has changed for specific subgroups, such as patients with cMPs. There are no objective analyses with routine data, nor are there any from the subjective perspectives of GPs, psychotherapists, or patients with cMPs compared with patients with MnoPs. In addition, insights into the practical implementation of the new elements (eg, psychotherapeutic consultation times, acute short-term psychotherapeutic interventions or relapse prophylaxis) offered by the psychotherapists are currently lacking. Finally, it remains unclear whether the new measures actually shortened waiting times and reduced access barriers for patients at higher risk, such as patients with cMPs.

Conceptual framework

The ES-RiP evaluation concept of the reform of the psychotherapy guideline is based on the theoretical 'throughput model' by Schrappe and Pfaff[30] which describes relevant interacting factors in the healthcare system and can be used to analyse the success of healthcare interventions. The model differentiates four phases: In the 'input phase', a significant organisational intervention such as the reform of the psychotherapy guideline first meets up with specific patient and provider groups. Following the input phase, the model describes the transformation process of such a reform ('throughput phase'), the resulting treatment offers ('output phase') and the direct outcomes for patients and society ('outcome phase'). The ES-RiP project specifically considers the various modifying factors by including different perspectives as well as different data sources to identify facilitating factors as well as barriers for implementation. The success of the transformation process and the benefits of the reform are reflected by societally relevant objective treatment parameters and patients' subjective treatment results.

Therefore, based on the throughput model the ES-RiP approach pursues an *outcome evaluation* (throughput model: outcome) and a *process evaluation* (throughput model: throughput and output) while giving special attention to patients with cMPs.

Aim

The aim of the ES-RiP project is a comprehensive evaluation of the reform of the psychotherapy guideline and its effects on patients with cMPs compared with patients with MnoPs. Considering pre-reform to post-reform changes, a multilevel approach which triangulates different data sources and mixed methods will be applied to investigate the following objectives:

- Based on secondary data from the statutory health insurance (SHI) company BARMER, we will test the hypotheses that contacts with psychotherapists increased while waiting times for psychotherapy decreased more in patients with cMPs compared with patients with MnoPs (substudy I).
- Regarding the patients' perspectives, we will examine their present health problems, morbidity, medical referral, possible barriers for accessing psychotherapy and patient satisfaction with waiting times and care among patients with cMPs and MoPs pre-reform and post-reform (substudy II). Based on secondary data from the National Association of Statutory Health Insurance Physicians, we will examine changes from the providers' perspective in terms of offered services, the spectrum of diagnoses, variability across psychotherapists (eg, medical or psychological psychotherapists), therapeutic settings, therapy duration, therapy procedures, and regional impacts (substudy III).
- Regarding the service providers' perspective (GPs and psychotherapists), we will assess reform-associated changes in the delivery and perception of psychotherapeutic interventions (substudy IV).
- Regarding the payers' perspective, we will analyse health economic changes in terms of direct and indirect costs of outpatient psychotherapy (substudy I).

METHODS AND ANALYSIS

Study design

The reform of the psychotherapy guideline is considered a complex intervention, and therefore, its evaluation follows different methodological approaches.[31 32] A sequential QUANT-qual mixed-methods design along with a multilevel approach (patients, service providers, payers) triangulating several data sources (primary and secondary data) will be applied to evaluate the reform from different perspectives. With respect to the underlying data sources, the overall project is divided into four substudies (for more information on the respective data sources, see the Substudies and samples section). The throughput model offers a theoretical framework for this approach, making it possible to conduct an outcome evaluation (which is the primary objective of the ES-RiP project) of the reform as well as an evaluation of the reform process:

- For the *outcome evaluation*, changes in the waiting time for patients with cMPs and MnoPs from pre-reform to post-reform will be compared. Analyses of the patients' perspectives will be based on secondary data from the SHI company BARMER (substudy I) and primary patient reports (substudy II).
- For the *process evaluation*, perspectives and attitudes of the service providers (psychotherapists and GPs) towards uptake and integration of the new elements will be examined with special regard to patients with cMPs and MnoPs. Evaluations will be based on secondary SHI data from the National Association of Statutory Health Insurance Physicians (substudy III) as well as primary data from focus groups, surveys, interviewsm and observations (substudy IV).
- A *health economics evaluation* is intended to reveal changes in the cost structure of treatments pre-reform to post-reform with special regard to patients with cMPs and MnoPs. The analyses will be based on accounting data from the SHI company BARMER (substudy I).

The multilevel approach, including the respective data sources, major outcomes, and corresponding substudies, is presented in figure 1.

Substudies and samples

The ES-RiP project (funding period: June 2020 to May 2022) consists of a very complex evaluation scheme that is based on four independent substudies whose results will be triangulated to answer the study aims from different perspectives and by using distinct data sources. We will use primary data collected as part of the ES-RiP project from patients (substudy II) and providers (substudy IV). In addition, our analyses will be based on routine data collected by the health insurance company BARMER (=BARMER SHI data) as well as the SHI data from the National Association of Statutory Health Insurance Physicians. In Germany, both data sources are considered SHI data. BARMER SHI data only include information on insures of the BARMER company, allowing for analyses from patients' and payers' perspectives.

SHI data from the National Association of Statutory Health Insurance Physicians (=overall SHI data) are structured according to care providers and include data of all those insured with the SHI in Germany (including BARMER data but also data from other health insurance companies). For example, BARMER SHI data allow for analyses regarding the proportion of patients diagnosed with depression. We thereby might analyse whether a person has actually made use of psychotherapy. Overall SHI data, however, will only allow for analyses of those persons treated by, for example, a psychotherapist, and therefore, offering information on only those persons diagnosed with, for example, depression who are already in psychotherapy. We provide detailed information regarding the samples from the four substudies (see also

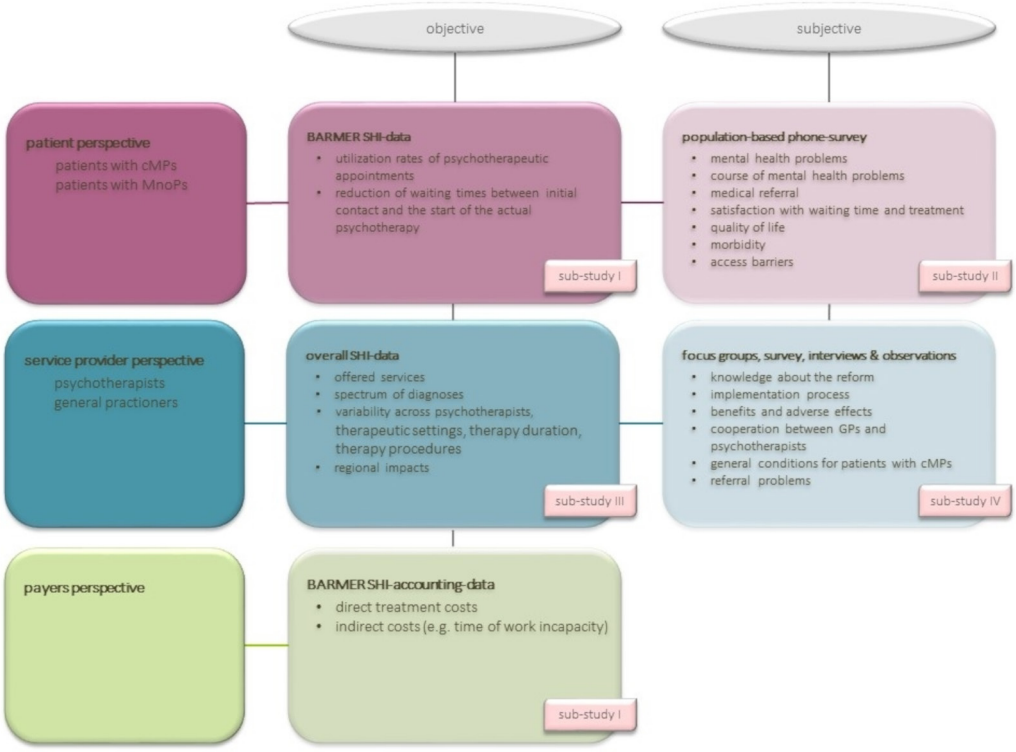

Figure 1 An overview of the three ES-RiP-perspectives (patients, service providers and payers) integrated in a multi-level approach, also including the respective data sources, major outcomes and corresponding substudies. cMPs, comorbidity of mental disorders and chronic physical conditions; GPs, general practitioners; MnoPs, mental disorders but no chronic physical conditions.

table 1; note that the year of the reform (2017) will be considered a transition period):

Substudy I: based on the BARMER SHI data, analyses will be conducted to address the patients' and payers' perspectives. BARMER is a nationwide SHI company with over 8 million policyholders (>10% of the German population). For research purposes, BARMER holds pseudonymised data on nearly every aspect of health-related services in a scientific data warehouse. To evaluate the effects of the reform, we will compare patients with cMPs to patients with MnoPs pre-reform (2009–2016) to post-reform (2018–2019).

Substudy II: a representative population-based phone survey of patients with cMPs as well as patients with MnoPs will be conducted to gather subjective patient information. The survey will include a screening of approximately 28 600 people to ensure that the participants will belong to one of the following three groups:

- Group (A): n=600 participants who wanted to see a psychotherapist but were unable to achieve psychotherapeutic face-to-face contact pre-reform or post-reform.
- Group (B): n=1000 participants who had at least one psychotherapeutic intervention from the first quarter of 2012 to the first quarter of 2017 (pre-reform).
- Group (C): n=1000 participants who had at least one psychotherapeutic intervention from the first quarter of 2018 to the fourth quarter of 2019 (post-reform).

Substudy III: based on overall SHI data, we will analyse data from the providers' perspective. The data cover all SHI insured persons in Germany (only residents with private health insurance are excluded), which amounts to approximately 70 million individuals. Sample selection will be aligned to substudy I using diagnostic codes of the International Classification of Diseases 10th revision (ICD-10) to identify all patients with relevant somatic and mental diagnoses (see below for the detailed inclusion and exclusion criteria). We will compare patients with cMPs to patients with MnoPs pre-reform (2015–2016) to post-reform (2018–2019).

Substudy IV: to gather additional service provider information on the treatment of patients with cMPs and patients with MnoPs, focus groups, a nationwide survey, interviews and observations of psychotherapists will be conducted:

- Focus groups: four group discussions with n=10 participants at a time, separately for each profession (GPs and psychotherapists), will be used to generate themes for the survey questionnaire.
- Surveys: GPs and psychotherapists (each n=1200) who were affected by the reform.
- Interviews and observations on current practice postreform: n=40 psychotherapists will be interviewed and n= 10 will be observed.

In 2021 and therefore 4 years after the reform, providers will be asked about the extent of perceived differences in

Table 1 Overview of the most important characteristics of the respective substudies

	Data source	Perspective	Evaluation	Inclusion and exclusion criteria	Outcomes	Sample size
Substudy I	BARMER SHI data	Patients	Outcome evaluation	18–79 years old insured persons with specified mental disorders within the years 2015, 2016, 2018 and 2019; exclusion of persons with contact with a psychotherapist within the 2 preceding years or with documented organic, including symptomatic, mental disorders (ICD-10: F00-F09) or with mental retardation (ICD-10: F70-F79)	▶ Proportion of persons with first contact with a psychotherapist within 1 year ▶ Waiting time between first contact and start of a regular psychotherapy ▶ Estimates of pre-reform to post-reform changes in subgroups of patients with or without long-term physical conditions	Available health insurance data from the BARMER company (approximately 8 million policyholders)
		Payers	Health economic evaluation		▶ Health economic changes (direct treatment costs as well as indirect costs)	Available health insurance data from the BARMER company
Substudy II	Population-based phone survey	Patients	Outcome evaluation	Sufficient German language skills; cognitive proficiency; informed verbal consent to study participation group (A) participants who wanted to see a psychotherapist but were unable to achieve a primary psychotherapeutic face-to-face contact group (B) participants who had at least one psychotherapeutic intervention from the first quarter of 2012 to the first quarter of 2017 (pre-reform) group (C) participants who had at least one psychotherapeutic intervention from the first quarter of 2018 to the fourth quarter of 2019 (post-reform)	▶ Health problems ▶ The course of health problems ▶ Medical referral ▶ Satisfaction with waiting time and treatment ▶ Quality of life ▶ Morbidity ▶ Access barriers	28 600 phone contacts incl. screenings, thereof 2600 phone interviews: group (A) n=600 group (B) n=1000 group (C) n=1000
Substudy III	Overall SHI data	Service providers	Process evaluation	From 2015 to 2019; included treated patients: age range 18–79 years; absence of organic, including symptomatic, mental disorders (ICD-10: F00-F09) or mental retardation (ICD-10: F70-F79)	▶ Offered services (including the new psychotherapeutic measures) ▶ Spectrum of diagnoses ▶ Variability across psychotherapists, therapeutic settings, therapy duration, therapy procedures ▶ Regional impacts	Nation-wide complete survey of the available service providers and insurance holders (approximately 70 million individuals)
Substudy IV	Psychotherapists: focus groups, survey, interviews and observations	Service providers	Process evaluation	Entry in the medical register of the National Association of Statutory Health Insurance Physician under 'psychological psychotherapists' or 'medical psychotherapists'; treatment of adults; psychotherapeutic practice since at least 2015 (2 years prior to reform); informed consent	▶ Knowledge about the reform ▶ Process and degree of implementation ▶ Perceived benefits and adverse effects ▶ Cooperation between GPs and psychotherapists ▶ Perceived differences for patients with cMPs compared with MnoPs ▶ Formal aspects and content of new measures (methods and techniques, networking, best practice examples)	Focus groups: N=40 (4 groups with n=10 participants) interviews: n=40 survey: n=1200
	GPs: focus groups and survey	Service providers	Process evaluation	Entry in the medical register of the National Association of Statutory Health Insurance Physician under 'general practitioner' (internal or general medicine); primary care work since at least 2015 (2 years prior to reform); informed consent		Focus groups: N=40 (4 groups with n=10 participants) survey: N=1200

cMPs, comorbidity of mental disorders and chronic physical conditions; GP, general practitioner; MnoPs, mental disorders but no chronic physical conditions; SHI, statutory health insurance.

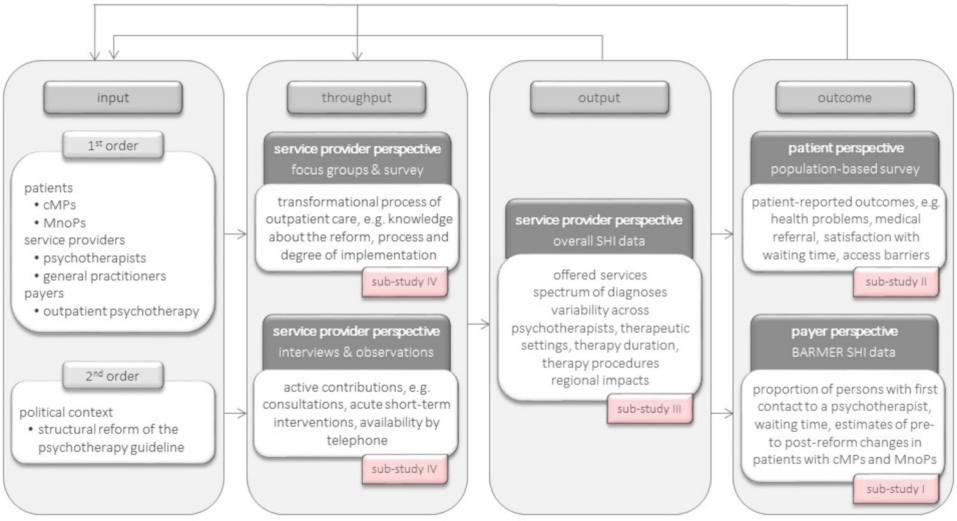

Figure 2 The ES-RiP approach embedded in the throughput model. cMPs, comorbidity of mental disorders and chronic physical conditions; MnoPs, mental disorders but no chronic physical conditions; SHI, statutory health insurance.

the care of patients with cMPs and with MnoPs before and after the reform.

Table 1 gives a detailed overview of the substudies and the respective data sources, perspectives, types of evaluation, inclusion/exclusion criteria, outcomes and sample sizes, while figure 2 offers an overview of the ES-RiP approach integrated into the throughput model.

Sample size calculation

For substudies I and III, the full available routine data sets of the BARMER and the National Association of Statutory Health Insurance Physicians will be used. This allows for sufficient statistical power to detect even small effect sizes.

For substudies II and IV, sample sizes are based on number of cases in similar studies and considerations on clinical relevance as well as empirically founded recommendations[25 33]:

Substudy II: for the population-based phone survey, three target groups are to be differentiated. The group most difficult to reach (group C) due to the shortness of the survey period (2018–2019) was the basis for the calculations. With a preplanned sample size of n=1000 (post-reform) we estimated the numbers needed to be contacted in the population-based survey of patients. Given an incidence of 3.5% new cases in the general population of Germany who are in need of psychotherapy,[34] this leads to n=28 571 screenings necessary to be performed for identifying them. Rounding up, we planned for N=28 600 screenings to reach sufficient interviews for group C. Based on these considerations, the estimated N for the other groups would result in n=2286 interviews (group B) and n=1430 interviews (group A), respectively.

Substudy IV: we followed empirically based recommendations for sample sizes when using qualitative methods.[35 36] For the quantitative surveys, we aimed at high precision of the results with at least 90% confidence for estimates even when the two groups of psychotherapists (medical and psychological psychotherapists) were analysed separately. Therefore, n=1200 participating psychotherapists and GPs were determined to be sufficient. Based on experiences from our own prior studies, we expected a participation rate of 30%, thus, resulting in 4000 invitation letters each.

Inclusion and exclusion criteria

For substudies I to III, we will only include participants who are 18–79 years old. We will exclude participants if they have an organic, including symptomatic, mental disorder (ICD-10: F00-F09) or mental retardation (ICD-10: F70-F79).

The following specific inclusion and exclusion criteria will be applied for the subsequent substudies:

Substudy I: we will include persons with specified mental disorders diagnosed in 2015, 2016, 2018 or 2019 and exclude persons with contact with a psychotherapist within the two preceding years.

Substudy II: we will include participants with sufficient German language skills, cognitive proficiency and informed verbal consent to participate in the study. Furthermore, participants will be screened to fulfil the requirements of belonging to either group A (no face-2-face contact), group B (psychotherapy pre-reform) or group C (psychotherapy post-reform) (for further details, see the Substudies and samples section).

Substudy IV: psychotherapists and GPs who will be included in the focus groups, interviews (psychotherapists only) and surveys have to fulfil the following criteria:

- Psychotherapists: entry in the medical register of the National Association of Statutory Health Insurance Physicians under ‘psychological psychotherapists’ or ‘medical psychotherapists’; treatment of adults; psychotherapeutic practice since at least 2015 (2 years prior to reform); informed consent.
- GPs: entry in the medical register of the National Association of Statutory Health Insurance Physicians under the group ‘GP’ (internal or general medicine);

primary care work since at least 2015 (2 years prior to reform); informed consent.

Data collection

For substudies I and III, secondary data will be obtained from the health insurance company BARMER and the National Association of Statutory Health Insurance Physicians. For substudies II and IV, we will collect the following primary data:

Substudy II: the representative population-based phone survey will be conducted nationwide from the last quarter of 2020 to the last quarter of 2021 (11 months) in the form of a structured interview that also includes open questions. The interview was developed based on the works of Albani and colleagues[25] and will comprise a screening as well as five respective topics: psychotherapy, medication, somatic diseases, sociodemographic data and dual-frame. Patients with diabetes will additionally be asked about diabetes-related distress.

Data will be collected by the independent demography research institute USUMA Berlin. Interviews will be administered by trained interviewers. Within 258 predefined regions households will be selected by a random route procedure. In households with multiple persons, one person will be randomly selected using the Kish-Selection Grid. To accomplish the defined sample sizes (group A: n=600; group B; n=1000; group C: n=1000), households will be contacted until these numbers are reached, or at least N=28 600 households have been screened.

Substudy IV: in the first phase of substudy IV (last quarter of 2020), we will conduct focus groups to derive relevant topics and items for the construction of the survey questionnaire separately for GPs and psychotherapists along a semi-standardised moderation guide.[37] Participants will be recruited from cooperating institutions of the consortium. For the second phase (second and third quarters of 2021), we will conduct a nationwide postal survey. Here, eligible participants (GPs and psychotherapists) will be recruited from a random sample of GPs and psychotherapists listed in the national SHI registries. The addresses will be supplied by the SHI. In the third phase (last quarter of 2021), study participants for semi-guided interviews regarding the practical implementation of the new psychotherapeutic elements will be drawn from a group of participants in the survey who have agreed to further participation. In a similar way and to supplement the interviews, 10 more participants will be recruited for subsequent focused non-participant observations of psychotherapists in their practice (first quarter of 2022).[38 39]

Outcome measures

Primary outcomes

Based on the BARMER SHI data (substudy I), pre-reform to post-reform changes in (a) contact rates with psychotherapists and (b) waiting time between primary contact and initiation of psychotherapeutic treatment in the two subgroups of patients (i) with cMPs and (ii) MnoPs will be assessed.

Secondary outcomes

Substudy I: in addition to the primary outcomes, BARMER SHI data will also comprise health economic parameters such as direct treatment costs and indirect costs, for example, sick leave days.

Substudy II: the phone survey will gather data on subjective patient outcomes regarding experiences within the psychotherapeutic system. The phone survey will address health problems, the course of the health problems, medical referral, satisfaction with the waiting time and treatment, quality of life, morbidity and access barriers.

Substudy III: based on the overall SHI data, changes in the care procedures will be examined: frequency of psychotherapeutic offers (including the new psychotherapeutic measures), spectrum of diagnoses, variability across psychotherapists, therapeutic settings, therapy duration and therapy procedures as well as regional impacts.

Substudy IV: focus groups and surveys with GPs and psychotherapists will be conducted to examine the process and effects of the reform from the perspective of the service providers. Special attention will be given to knowledge about the reform, perceived task shifts, benefits and adverse effects, cooperation between GPs and psychotherapists, referral problems, and perceived differences for patients with cMPs compared with MnoPs in the context of the reform. In addition, psychotherapists will be interviewed and their practices observed to gain deeper insights into the implementation of the reform with regard to formal aspects and content (indications, methods and techniques, networking, best practice examples) as well as the organisational context.

Data analysis

Substudy I: analyses of BARMER SHI data is carried out according to 'Good Practice of Secondary Data Analysis (GPS)'.[40] To test the first primary hypothesis regarding differences in the usage of psychotherapeutic offers between patients with cMPs and MnoPs from pre-reform to post-reform, different binary logistic regression analyses will be conducted with contacts to psychotherapists (yes/no) as a dependent variable. The independent variables are cMPs and MnoPs (as in another model the interaction term of cMPs/MnoPs and time pre-reform/post-reform), while age, gender and regional supply status will be included as control variables. The second primary hypothesis regarding a higher reduction in waiting times for psychotherapy after the reform for MnoPs compared with cMPs will be tested in linear regression models. Secondary outcomes will be analysed in a descriptive manner. We will report estimates with 95%-CIs and descriptive p-values.

Substudy II: descriptive analyses of the patient-reported outcomes (phone survey) will focus on differences

between cMPs and MnoPs regarding the three groups A to C.

Substudy III: descriptive analyses of the overall SHI data will compare the care situation for the patient groups of interest (cMPs vs MnoPs) in different periods (pre-reform: 2015–2016; year of the reform: 2017; post-reform: 2018–2019). Subgroup analyses will be conducted for the physician/therapist group (medical or psychological psychotherapist), therapeutic settings (individual therapy or group therapy), therapy duration (short-term therapy or long-term therapy), therapy procedures (eg, psychodynamic therapy or cognitive behavioural therapy), localisation of service provision (different regions in Germany) and coverage rate.

Substudy IV: descriptive analyses of service provider data will focus on the degree of implementation of the new measures (additional psychotherapeutic consultation times, acute short-term psychotherapeutic interventions and relapse prophylaxis) and perceived effects on patients with cMPs. Quantitative data from surveys will be analysed on an overall level as well as for subgroups of physicians and therapists (medical or psychological psychotherapist). Qualitative data generated in the focus groups and interviews with GPs and psychotherapists will be subjected to thematic analyses using MAXQDA software. Observation notes will be analysed to complement the interviews, particularly in terms of contrary evidence and context.

Patient and public involvement statement

A representative of the German Working Group Self-Help Groups (Deutsche Arbeitsgemeinschaft Selbsthilfegruppen) has been involved as a member of a scientific advisory board taking place at the very beginning of the project as well as its final stage. The planned study design, proceedings and addressed content will be discussed at a very early stage (3 months after the project has started) with the advisory board including the patient representative. Near the end of the project, when the results are ready, we will discuss our findings, proceedings and strategies for dissemination with the advisory board (again including the same patient representative) to gain their input regarding our possible conclusions.

ETHICS AND DISSEMINATION

This study is registered at the German Clinical Trial Register (23 July 2020) and can also be found at https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00020344. Ethical approval for the overall project was obtained from the Ethics Committee of the Justus Liebig University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20; 6 October 2020). Given that the overall project is based on four substudies located in different parts of Germany, one of the substudies collecting primary data required additional ethical approval. For substudy IV, approval was obtained from the Ethics Committee Heidelberg (approval number: S-466/2020). With regard to SHI data, the approval for the overall study sufficed, and no additional approval was needed. Analyses of secondary data will be based on pseudonymised (BARMER) and anonymised (National Association of Statutory Health Insurance Physicians) datasets. The secondary data can be linked neither to each other nor to the primary data collected in this study. Hence, according to the 'Good Practice of Secondary Data Analysis (GPS): guidelines and recommendations',[40] no additional ethics approval or informed consent is necessary.

The patient survey will be conducted in accordance with the Declaration of Helsinki and will fulfil the ethical guidelines of the International Code of Marketing and Social Research Practice of the International Chamber of Commerce and the European Society of Opinion and Marketing Research.

Findings will be disseminated through national and international psychotherapy and health services research journals and will be presented at relevant conferences and meetings.

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Contributors HK drafted this manuscript. MH contributed to the writing of the manuscript. The study's principal investigators JK, H-CF, GH, TGG, JS and BW designed the study and obtained the funding. HK, JK, H-CF and MH obtained the ethics approval. TGG and UM contributed to the specific design of substudy I and edited the manuscript. HK and JK contributed to the specific design of substudy II. JK supervised and edited the manuscript. GF and AC contributed to the specific design of substudy III and edited the manuscript. MH, H-CF and JS contributed to the specific design of substudy IV and edited the manuscript. All authors read and approved the final manuscript.

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