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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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057298
Article Type:	Protocol
Date Submitted by the Author:	11-Sep-2021

Complete List of Authors:	Kampling, Hanna; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Kruse, Johannes; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Friederich, Hans-Christoph; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Heuft, Gereon; University Hospital Munster, Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Christoffer, Andrea; University Hospital Munster, 3Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Grobe, Thomas; AQUA, Institute for Applied Quality improvement and Research in Health Care GmbH Marschall, Ursula; BARMER, Institute for Health System Research, Department Medicine and health services research Szecsenyi, Joachim; University Hospital Heidelberg, Department of General Practice and Health Services Research Wild, Beate; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Hartmann, Mechthild ; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics

Keywords:	MENTAL HEALTH, PRIMARY CARE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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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

Kampling H[1], Kruse J[1], Friederich H-C[2], Heuft G[3], Christoffer A[3], Grobe TG[4], Marschall U[5], Szecsenyi J[6], Wild B[2], Hartmann M[2] & the ES-RiP-Consortium

[1]Clinic for Psychosomatic Medicine and Psychotherapy, Medical Center, Justus Liebig University Giessen and Marburg

[2]Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg

[3]Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health, University Hospital Muenster

[4]aQua – Institute for Applied Quality improvement and Research in Health Care GmbH

[5]BARMER Institute for Health System Research, Department Medicine and health services research

[6]Department of General Practice and Health Services Research, University Hospital Heidelberg, Heidelberg, Germany

Corresponding author:
Dr. phil. Hanna Kampling
Department of Psychosomatic Medicine and Psychotherapy
Justus Liebig University Giessen
Ludwigstraße 76, 35390 Gießen, Germany
Phone: +49 641 99 45646
Email: hanna.kampling@psycho.med.uni-giessen.de

Word count: 3956

Abbreviations

CG	comparative groups
cMPs	**c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s**
GP	general practitioner
ICD	International Classification of Diseases
MnoP	**m**ental disorders but **no** chronic **p**hysical condition
SHI	statutory health insurance
TG	target groups

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Abstract

Introduction In 2017 in Germany, a structural reform of the outpatient psychotherapy guideline has taken place as a reply to ongoing insufficient waiting times and access barriers for specific patient groups. The reform includes new service elements, such as the implementation of 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 centers. The ES-RiP project is planned to thoroughly evaluate effects of the reform with a special focus on patients with a comorbidity of mental disorders and chronic physical conditions (cMPs) compared to patients with a mental disorder but no long-term physical condition (MnoP). The project aims at evaluating (a) the extent to which the reform goals were achieved in the large group of patients with cMPs, (b) the barriers that might be hindering 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 multi-level approach (patients, service providers, payers) combining 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 as well as one local ethic 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.

Trial registration The study was registered at the German Clinical Trial Register (DRKS) and can be found at https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00020344.

Strengths and limitations of this study

- Comprehensive multi-level approach with mixed-methods design to study effects of the outpatient psychotherapy reform in 2017
- Integration of process and outcome evaluation to gather an understanding of the results and possible limitations of the structural reform
- representative population-based surveys combined with analyses of objective SHI-data
- multi-perspective evaluation of the structural reform with integration of results
- further prospective longitudinal assessments may be necessary to inform on long-term effects for patients

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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 about 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 details on the German psychotherapeutic system see [3,4]).

In 2017, this guideline was reformed, and new elements like additional psychotherapeutic consultation times, acute short-term psychotherapeutic interventions, and relapse prophylaxis were implemented. Further, more group therapies were promoted, availability of psychotherapists by telephone was facilitated, and appointment-service-points were set up to convey psychotherapeutic consultations directly [5]. These measures were directed to improve overall outpatient psychotherapeutic care by aiming to reduce long waiting times and help overcome access barriers for outpatient treatment, especially for undersupplied groups. Of those with mental disorders, about 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 to patients with **m**ental disorders but **no** chronic **p**hysical condition (MnoP), patients with a **c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s** (cMPs) do not only have a significantly lower quality of life [7–9] as well as significantly increased morbidity and mortality rates [10–12], they also require additional multidisciplinary care [13] and cause significantly higher treatment costs [14–18]. In addition, if the mental disorder remains untreated, the physical condition often deteriorates. Depression, for example, may decrease adherence to treatment of the somatic disease, thus leading e.g. to a comatose state in type 1 diabetes [19], or transplant rejection in organ recipients [20]. Despite the increased need for care, patients with cMPs frequently experience poorer access to psychotherapeutic offers, as they are more likely to be unable to attend treatments due to their illness, or might cause additional work for psychotherapists in form of a need for intensive interdisciplinary cooperation with physicians.

In order to improve access to psychotherapeutic care, it is important to understand the access routes to outpatient psychotherapy in Germany. In terms of stepped care, general practitioners (GPs) are of particular importance for patients with mental disorders as they are usually the first and main contact person [21]. Three-quarters of patients with mental disorders are treated exclusively by their GP [22,23], indicating high barriers for referral to psychotherapy in primary care [24]. The aforementioned difficulties to reach the psychotherapists, long waiting times, and low flexibility prior to the reform often caused reluctances among GPs to recommend psychotherapy to patients. Furthermore, fear of stigmatization or insufficient knowledge about psychotherapeutic offers and access routes were frequent obstacles on patients' level. In particular, for patients with cMPs diagnosis of a mental disorder is often challenging for the GP due to the symptomatic overlap of mental disorders and physical diseases [25]. The new option of short-term consultation and assessment sessions with a psychotherapist could help to overcome such diagnostic problems. Consequently, patients with cMPs should particularly benefit from the reform by means of reduced waiting times and improved access to psychotherapy.

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Since the introduction of the reform, preliminary evidence shows that the number of patients having contact with a psychotherapist has increased and time to first contact has decreased, but initiation of psychotherapy itself has become less [26,27]. This concurs with the results of a survey with psychotherapists, in which more than half of them report that the reform has not resulted in significant improvement of care for their patients [28]. However, besides these general and short-term results no studies have been conducted on the extent to which the care situation has changed for specific subgroups, like patients with cMPs. There are neither objective analyses with routine data, nor are there any from the subjective perspectives of GPs, psychotherapists, or patients with cMPs compared to patients MnoPs. In addition, insights into the practical implementation of the new elements (e.g. 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 lowered waiting times and 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 [29] which describes relevant interacting factors in the health care system and can be used to analyze the success of health care interventions. The model differentiates four phases: In the 'input phase', a significant organizational intervention like 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'), as well as the direct outcomes for patients and society ('outcome phase'). The ES-RiP project specifically considers the various modifying factors by including different actors' perspectives as well as different data sources in order 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 societal 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. Figure 1 offers an overview of the ES-RiP approach integrated in the Throughput-Model.

Please insert figure 1 here

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 (= patients with **c**ombined **m**ental disorders and long-term **p**hysical conditions) compared to patients with MnoPs (= patients with a **m**ental disorder but **no** long-term **p**hysical condition). Considering pre- to post-reform changes, a multi-level approach with an observational mixed-methods design will be applied to investigate the following objectives:

- Based on statutory health insurance (SHI) data, we will test the hypotheses that contacts to psychotherapists are increased and waiting times for psychotherapy are decreased more in patients with cMPs compared to patients with MnoPs.

- Regarding the patients' perspectives, we will examine possible barriers and patient satisfaction with waiting times and care in patients with cMPs and MoPs pre- and post-reform.
- Regarding the service providers' perspective (GPs and psychotherapists), we will assess reform-associated changes in the delivery and perception of psychotherapeutic interventions.
- Regarding the payers' perspective, we will analyse health economic changes in terms of direct and indirect costs.

Methods and analysis

Study design

The reform of the psychotherapy guideline is considered a complex intervention, and therefore, its evaluation follows different methodological approaches [30]. A mixed-methods-design (quantitative, qualitative) along with a multi-level approach (patients, service providers, payers) combining 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 in four sub-studies (for more information on the respective data sources see samples). The Throughput-Model offers the theoretical framework for this approach making it possible to conduct an outcome-evaluation of the reform as well as an evaluation of the reform process (figure 1 presents the integration of the ES-RiP approach into the Throughput-Model):

(A) For the **outcome evaluation**, changes in waiting time for patients with cMPs and MnoPs from pre- to post-reform will be compared. Analyses on the patients' perspective are based on secondary SHI data from the BARMER company (sub-study I) and primary patient reports (sub-study II).

(B) For the **process evaluation**, different perspectives of the service providers (psychotherapists and GPs) will be examined. Evaluations are based on secondary SHI-data from the National Association of Statutory Health Insurance Physicians (sub-study III) as well as primary data from focus groups, surveys, interviews and observations (sub-study IV).

(C) A **health economics evaluation** is supposed to reveal changes in the cost structure of treatments pre- to post-reform. Analyses are based on accounting data of the health insurance company BARMER (sub-study I).

The multi-level approach including the respective data sources, major outcomes, and corresponding sub-studies is presented in figure 2.

Please insert figure 2 here

In addition, table 1 gives a detailed overview of the sub-studies and the respective data sources, perspectives, types of evaluation, inclusion/exclusion criteria, outcomes, and samples sizes.

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Please insert table 1 here

Sub-studies and Samples

The realization of the ES-RiP project will take place in four sub-studies, which are determined by different perspectives and use of distinct data sources:

Sub-study I): Based on routine data of the health insurance company BARMER (= BARMER SHI-data), secondary analyses will be conducted to address the patients' and payers' perspective. BARMER is a nationwide SHI company with over 8 million policyholders (> 10 % of the German population). For research purposes, BARMER holds pseudonymized data on nearly every aspect of health related services in a scientific Data Warehouse.

The two following target groups (TG) will be selected:

- (TG1) patients with cMPs (= patients with **c**ombined **m**ental disorders and long-term **p**hysical conditions) after the implementation of the reform (= post-reform).
- (TG2) patients with MnoPs (= patients with a **m**ental disorder but **no** long-term **p**hysical condition) after the implementation of the reform (= post-reform).

In order to evaluate the effects of the reform (pre-/post-reform) for these patient groups, two comparative groups (CG) emerge:

- (CG1) a historical control group of patients with cMPs from the years before the implementation of the reform (= pre-reform).
- (CG2) a historical control group of patients with MnoPs from the years before the implementation of the reform (= pre-reform).

Sub-study II): A representative population-based phone-survey will be conducted to gather subjective patient information (primary data). The survey will include a screening of approximately 28,600 people to ensure 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 a psychotherapeutic face-to-face contact,
- Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention pre-reform, and
- Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention post-reform.

Sub-study III): Based on routine data from the National Association of Statutory Health Insurance Physicians (= overall SHI-data), secondary analyses will be conducted to address the service providers. The data cover all SHI insured persons in Germany (excluded are only residents with private health insurance), which amounts roughly to 70 million individuals. In contrast to the claims data of the BARMER, overall SHI-data are structured according to care providers, not patients. This allows for analyses adjusted to existing resources. Sample selection will be parallelized to study 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 detailed inclusion and exclusion criteria).

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Sub-study IV): To gather additional service provider information (subjective primary data), focus groups, a nationwide survey, interviews as well as observations of psychotherapists will be conducted in a sequential design.

- Focus groups: Four group discussions with n = 10 participants at a time, separately for each profession (GPs and psychotherapists) to generate themes for the survey questionnaire
- Surveys: GPs and psychotherapists (each n = 1,200) who were affected by the reform
- Interviews and observations on current practice post-reform: n = 40 psychotherapists will be interviewed and n = 10 will be observed

Sample Size Calculation

For sub-studies 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 even to detect small effect sizes.

For sub-studies 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:

Sub-study 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 to 2019) was the basis for calculations. With a pre-planned sample size of n = 1,000 (post-reform) we estimated the numbers needed to be contacted in the population-based survey of patients. Given an incidence rate of 3.5 % new cases in the general population of Germany who are in need of psychotherapy [31], this leads to n = 28,571 screenings necessary to be performed for identifying them. Rounding up, we planned with 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 = 2,286 interviews (group B) and n = 1,430 interviews (group A), respectively.

Sub-study IV): We followed empirically based recommendations for sample sizes when using qualitative methods [32,33]. For the quantitative surveys, we aimed at high precision of results with at least 90 % confidence for estimates even when the two groups of psychotherapists (medical and psychological psychotherapists) are analyzed separately. Therefore, n = 1,200 participating psychotherapists and general practitioners were determined sufficient. Based on experiences from our own prior studies, we expected a participation rate of 30 %, and thus, resulting in 4,000 invitation letters, each.

Inclusion Criteria

The following inclusion criteria will be applied for the subsequent sub-studies:

Sub-study I): Data on the total population of the BARMER will be included (accounting data from 2009 to 2019).

Sub-Study II): Subjects with sufficient German language skills, cognitive proficiency, and informed verbal consent to participate in the study will be included. Furthermore, the three target groups of the patient sample will have to meet the following criteria:

- (A) participants who wanted to see a psychotherapist but were unable to achieve a primary psychotherapeutic face-to-face contact,

- (B) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform), and
- (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform).

Sub-study III): Data from the full surveys of all persons insured with the National Association of Statutory Health Insurance Physicians will be included (accounting data from 2015 to 2019).

Sub-study IV): Psychotherapists and GPs who will be included in the focus groups, interviews (psychotherapists only), and surveys have to fulfill 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 'general practitioner' (internal or general medicine); primary care work since at least 2015 (2 years prior to reform); informed consent.

Exclusion Criteria

For sub-studies I to III, participants will be excluded if they are < 18 or > 79 years old, and if they have an organic, including symptomatic, mental disorder (ICD-10: F00-F09) or mental retardation (ICD-10: F70-F79).

Data collection

For sub-studies I) and III), secondary data will be obtained from the health insurance company BARMER, and the National Association of Statutory Health Insurance Physicians. Primary data will be collected for sub-studies II) and IV):

Sub-study 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 order to accomplish the defined sample sizes (group A: n = 600; group B; n = 1,000; group C: n = 1,000), households will be contacted until these numbers are reached, or at least N = 28,600 households have been screened.

Sub-study IV): For the nationwide postal survey 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. Relevant topics and items for construction of the survey questionnaire are captured beforehand in the focus groups [34] with other GPs and psychotherapists which will be recruited from cooperating institutions of the consortium partners. The study participants for the interviews on practical implementation of the new psychotherapeutic elements will be drawn from a group of participants of the survey which have agreed on further participation. In a similar way, further 10 participants will be recruited for subsequent field observation in the psychotherapists' practice.

Outcome Measures

Primary Outcomes

Pre- to post-reform changes of 1) contact rates with psychotherapists and 2) waiting time between primary contact and initiation of psychotherapeutic treatment in patients with mental disorders in the two subgroups of patients a) with and b) without long-term physical conditions, assessed by the BARMER SHI-data (sub-study I).

Secondary Outcomes

Sub-study I): In addition to the primary outcomes, BARMER SHI-data will also comprise health economic parameters like direct treatment costs and indirect costs, e.g. sick leave days.

Sub-study 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 health problems, medical referral, satisfaction with waiting time and treatment, quality of life, morbidity, and access barriers.

Sub-Study III): Based on overall SHI-data, objective changes in 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.

Sub-study 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 the knowledge about the reform, perceived task shifts, benefits and adverse effects, the cooperation between GPs and psychotherapists, referral problems, as well as perceived differences for patients with cMPs compared to MnoPs in the context of the reform. In addition, psychotherapists will be interviewed and their practices observed to gain deeper insights on the implementation of the reform with regard to formal aspects and content (indications, methods and techniques, networking, best practice examples) as well as the organizational context

Data analysis

Sub-study I): Analysis of SHI-data is carried out according to ‘Good Practice of Secondary Data Analysis (GPS)’ [35]. In order to test the first primary hypothesis regarding differences in utilization of psychotherapeutic offers between the two target groups from pre to post reform, different binary logistic regression analyses with contacts to psychotherapists (yes/no) as a dependent variable will be conducted. The independent variable is TG (as in another model the interaction term of TG and time before/after 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 to cMPs will be tested in linear regression models. Secondary outcomes will be analyzed in a descriptive manner. We will report estimates with 95% confidence intervals and descriptive p-values.

Sub-study II): Analysis of the patient reported outcomes (phone-survey) will focus on differences between cMPs and MnoPs regarding the three groups (A: wish for psychotherapy but no face-to-face contact with a psychotherapist, B: face-to-face contact with a psychotherapist pre-reform, and C: face-to-face contact with a psychotherapist post-reform).

Sub-study III): Analysis of the overall SHI-data will compare the care situation for the patient groups of interest (cMPs vs. MnoPs) in different time periods (pre-reform: 2015-2016; year of

the reform: 2017; post-reform: 2018-2019). Subgroup analyses will be conducted for 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 (psychodynamic therapy or behavioral therapy), localization of service provision (different regions in Germany) as well as coverage rate.

Sub-study IV): The analysis 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 analyzed on an overall level as well as for the subgroups 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 the MAXQDA software.

Patient and public involvement statement

A representative of the German Working Group Self-Help Groups (Deutsche Arbeitsgemeinschaft Selbsthilfegruppen [DAG SHG]) was involved as a member of a scientific advisory board taking place at the very beginning of the project as well as its final stage to discuss content, proceedings, and dissemination.

Ethics and dissemination

The study is registered at the German Clinical Trial Register (DRKS-ID: DRKS00020344), 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). Given that the overall project is based on four sub-studies located in different parts of Germany, one of the sub-studies collecting primary data required additional ethical approval. For sub-study IV), approval was obtained from the Ethics Committee Heidelberg (approval number: S-466/2020).

Analyses of secondary data will be based on pseudonymized (BARMER) and anonymized (National Association of Statutory Health Insurance Physicians) datasets. The routine data cannot be linked to any other insurance or service provider data. Hence, according to the 'Good Practice of Secondary Data Analysis (GPS): guidelines and recommendations' [35] no ethics approval and informed consent will be necessary .

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

Discussion

The ES-RiP project will provide novel and detailed information on current provision of outpatient psychotherapeutic care and robust evidence on whether the structural reform is associated with improved outcomes for specific subgroups.

To our knowledge, this project is the first aiming to analyze the psychotherapeutic care situation of the large group of patients with cMPs embedded in an overarching evaluation of the recent structural reform of outpatient psychotherapy. The focus on cMPs is important as it has been shown that this subgroup was previously largely undersupplied even though they have a high risk for adverse outcomes. A significant change in the provision of services for this

target group would therefore be of high relevance not only for the individual patient but also for society.

The investigation is based on different perspectives (patients, service providers, payers) and methods (mixed-methods) to obtain a comprehensive outline of the reform effects. A special focus will be on participatory process evaluation to assess determinants of implementation success. With such a unique approach within one project, we will be able to better understand the current challenges for patients with somatic and mental comorbidity in outpatient psychotherapeutic care.

Besides these strengths we are aware of some limitations of the project: Firstly, by using SHI data, we cannot make any statements about patients with full private health insurance. Also, routine data are known to capture diagnoses and time points with only a medium level of accuracy. Therefore, the patients' perspective is an indispensable additional data source that may be in turn biased due to the presence of a mental disorder itself. Hence, the third perspective of health care providers is necessary to complete the picture by contextual information.

Based on these considerations, a major task of the project will therefore be the integration of data from the various sub-studies, enabling cross-validation of results. Overall interpretation is based on triangulation of the different perspectives and will involve discussions with various stakeholders. Findings and insights are going to be utilized to identify procedures for further development and improvement of the reform.

Based on these findings, recommendations for future improvements of outpatient psychotherapy for the seriously burdened group of patients with cMPs can be made.

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Collaborators: The ES-RiP-Consortium study group includes (organised alphabetically by last name): Borchers, Milena; Christoffer, Andrea; Filaloi Bouami, Soufiane; Friederich, Hans-Christoph; Grobe, Thomas G.; Hartmann, Mechthild; Hegelow, Martin; Heuft, Gereon; Kampling, Hanna; Koch, Raphael; Kruse, Johannes; Leikeim, Lisa; Marschall, Ursula; Poß-Doering, Regina; Saam, Joachim; Schumacher, Catharina; Szardenings, Carsten; Szecsenyi, Joachim; Werner, Samuel; Wild, Beate; Zara, Sandra;

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

Funding: The Innovation Fund of the Federal Joint Committee of Germany grant number 01VSF19004 supported this work.

Competing interests: None declared.

Ethics approval: Ethical approval was obtained from the coordinating (Giessen) as well as one local (Heidelberg) ethic committee, Justus Liebig University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-466/2020).

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Table 1: Overview of the most important characteristics of the respective sub-studies

	data source	perspective	evaluation	inclusion & exclusion criteria	outcomes	sample size
sub-study I	BARMER SHI-data – secondary data	patients	outcome evaluation	18 to 79 years old insured persons with specified mental disorders within the years 2015, 2016, 2018 and 2019; exclusion of persons with contact to 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 to a psychotherapist within one year • waiting time between first contact and start of a regular psychotherapy • estimates of pre- 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
sub-study II	population-based phone survey – primary data	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 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform) group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform)	• health problems • the course of health problems • medical referral • satisfaction with waiting time and treatment • quality of life • morbidity • presentation and frequency of access barriers	28,600 phone contacts incl. screenings, thereof 2,600 phone interviews: group (A) n = 600 group (B) n = 1,000 group (C) n = 1,000
sub-study III	overall SHI-data – secondary data	service providers	process evaluation	time span from 2015 to 2019; included treated patients: age range < 18 to > 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
sub-study IV	psychotherapists: focus groups, survey, interviews & observations – primary data	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 to 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 = 1,200
	GPs: focus groups & survey – primary data	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 = 1,200

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Figure 1: The ES-RiP approach embedded in the Throughput-Model

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Figure 2: 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 sub-studie

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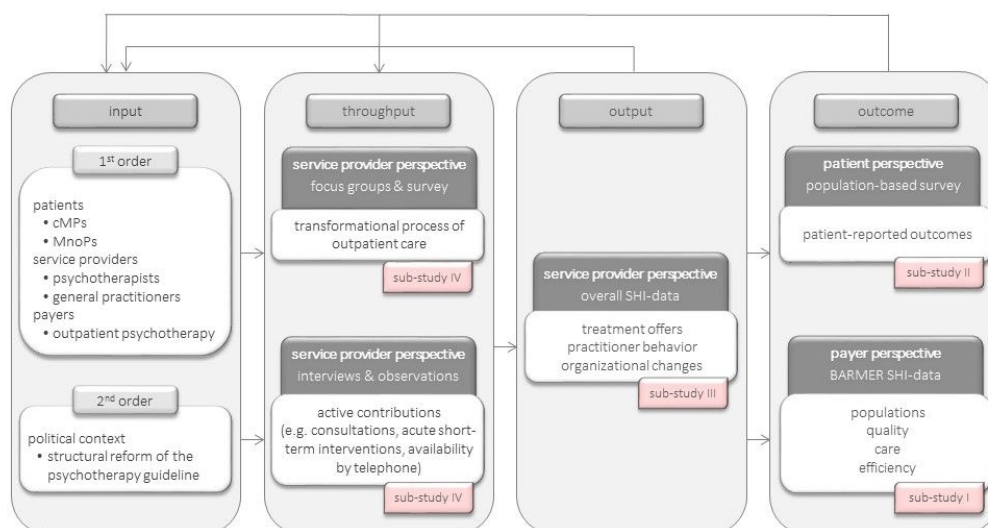

Figure 1: The ES-RiP approach embedded in the Throughput-Model

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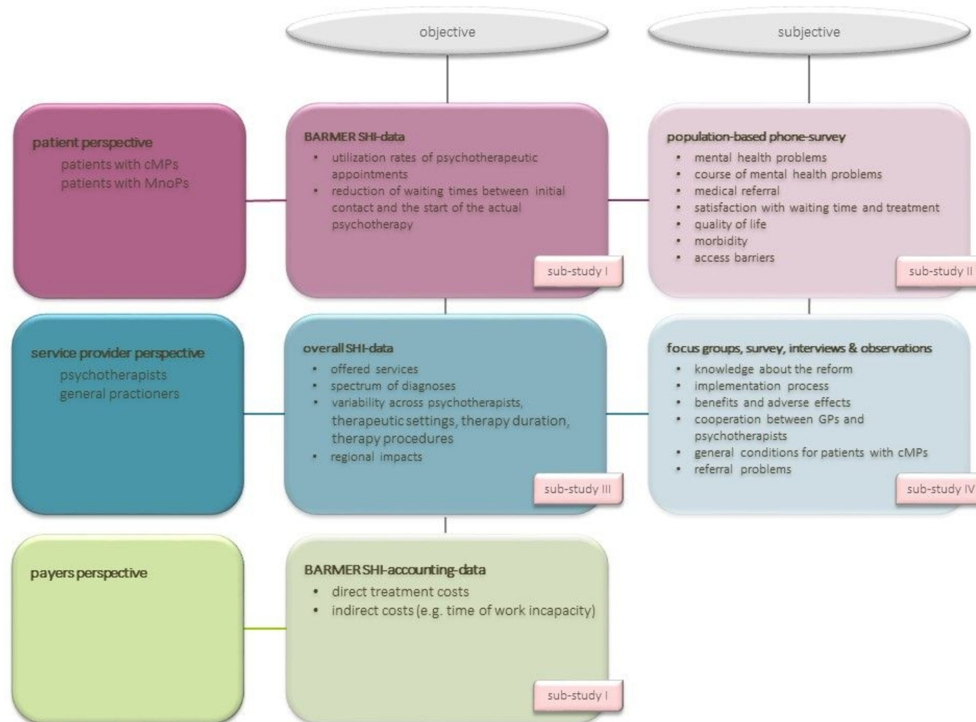

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Evaluating effects of the structural reform of outpatient psychotherapy for patients with mental disorders in Germany – comparing patients with and without comorbid chronic physical condition: rationale and study protocol of the ES-RiP project

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057298.R1
Article Type:	Protocol
Date Submitted by the Author:	14-Apr-2022

Complete List of Authors:	Kampling, Hanna; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Kruse, Johannes; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Friederich, Hans-Christoph; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Heuft, Gereon; University Hospital Munster, Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Christoffer, Andrea; University Hospital Munster, 3Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Grobe, Thomas; AQUA, Institute for Applied Quality improvement and Research in Health Care GmbH Marschall, Ursula; BARMER, Institute for Health System Research, Department Medicine and health services research Szecsenyi, Joachim; University Hospital Heidelberg, Department of General Practice and Health Services Research Wild, Beate; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Hartmann, Mechthild ; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics

Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research, Mental health
Keywords:	MENTAL HEALTH, PRIMARY CARE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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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

Kampling H[1], Kruse J[1], Friederich H-C[2], Heuft G[3], Christoffer A[3], Grobe TG[4], Marschall U[5], Szecsenyi J[6], Wild B[2], Hartmann M[2] & the ES-RiP-Consortium

[1]Clinic for Psychosomatic Medicine and Psychotherapy, Medical Center, Justus Liebig University Giessen and Marburg

[2]Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg

[3]Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health, University Hospital Muenster

[4]aQua – Institute for Applied Quality improvement and Research in Health Care GmbH

[5]BARMER Institute for Health System Research, Department Medicine and health services research

[6]Department of General Practice and Health Services Research, University Hospital Heidelberg, Heidelberg, Germany

Corresponding author:
Dr. phil. Hanna Kampling
Department of Psychosomatic Medicine and Psychotherapy
Justus Liebig University Giessen
Ludwigstraße 76, 35392 Gießen, Germany
Phone: +49 641 99 45646
Email: hanna.kampling@psycho.med.uni-giessen.de

Word count: 3956

Abbreviations

cMPs	**c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s**
GP	general practitioner
ICD	International Classification of Diseases
MnoP	**m**ental disorders but **no** chronic **p**hysical condition
SHI	statutory health insurance

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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 (e.g. 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 centers. 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 to 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 to 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.

Trial registration This study was registered at the German Clinical Trial Register (DRKS) and can be found at https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00020344.

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 (SHI) 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.

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78 • The validity of results on the provider perspective will highly depend on the participation
79 rate in focus groups, surveys, interviews, and observations.

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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 behavioral psychotherapy) or its duration (short- 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 directed to improve overall outpatient psychotherapeutic care by aiming to reduce long waiting times and help overcome access barriers (e.g. general practitioners’ (GP) 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 health care problem as they are often in particular need of treatment. Compared to patients with **m**ental disorders but **no** chronic **p**hysical condition (MnoP), patients with a **c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s** (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 the physical condition often deteriorates. Depression, for example, may decrease adherence to treatment of the somatic disease, thus leading e.g. to more hypoglycemic 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 aforementioned difficulties in accessinga 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 stigmatization 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 [27]. The new option of short-term consultations and assessment sessions with a psychotherapist could help to overcome such

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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 [28,29]. 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 improvement of care for their patients [30]. 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 nor objective analyses with routine data, nor are there any from the subjective perspectives of GPs, psychotherapists, or patients with cMPs compared to patients with MnoPs. In addition, insights into the practical implementation of the new elements (e.g. 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 [31] which describes relevant interacting factors in the health care system and can be used to analyze the success of health care interventions. The model differentiates four phases: In the 'input phase', a significant organizational 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 to patients with MnoPs. Considering pre- 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 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 to 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

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satisfaction with waiting times and care among patients with cMPs and MoPs pre- 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, 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 analyze 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 [32]. 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. With respect to the underlying data sources, the overall project is divided into four substudies (for more information on the respective data sources, see 'substudies and samples'). The throughput model offers a theoretical framework for this approach, making it possible to conduct an outcome evaluation of the reform as well as an evaluation of the reform process:

(A) For the **outcome evaluation**, changes in the waiting time for patients with cMPs and MnoPs from pre- 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).

(B) 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, interviews, and observations (substudy IV).

(C) A **health economics evaluation** is intended to reveal changes in the cost structure of treatments pre- 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.

Please insert figure 1 here

Substudies and Samples

The ES-RiP project 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 I) 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 include only those also insured with BARMER, 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 analyze whether a person has actually made use of psychotherapy. Overall SHI data, however, will only allow for analyses of those persons treated by, e.g., a psychotherapist, and therefore, offering information on only those persons diagnosed with, e.g., depression who are already in psychotherapy. We provide detailed information regarding the samples from the four substudies (see also 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 pseudonymized 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- or post-reform,
- Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform), and
- Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform).

Substudy III): Based on overall SHI data, we will analyze 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 (20015-2016) 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 using a sequential four-stage (qualitative-quantitative-qualitative-qualitative) design [33].

- 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 = 1,200) who were affected by the reform.
- Interviews and observations on current practice post-reform: 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 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.

Please insert Table 1 here

Please insert Figure 2 here

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 [25,34]:

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 to 2019) was the basis for the calculations. With a preplanned sample size of n = 1,000 (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 [35], 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 = 2,286 interviews (Group B) and n = 1,430 interviews (Group A), respectively.

Substudy IV): We followed empirically based recommendations for sample sizes when using qualitative methods [36,37]. 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 analyzed separately. Therefore, n = 1,200 participating psychotherapists and general practitioners were determined

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to be sufficient. Based on experiences from our own prior studies, we expected a participation rate of 30 %, thus, resulting in 4,000 invitation letters each.

Inclusion and Exclusion Criteria

For substudies I to III, we will only include participants who are 18 to 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 in2015, 2016, 2018 and 2019 and exclude persons with contact with a psychotherapist within the 2 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 fulfill 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 Substudies and Samples).

Substudy IV): Psychotherapists and GPs who will be included in the focus groups, interviews (psychotherapists only), and surveys have to fulfill 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 ‘general practitioner’ (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. 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 = 1,000; Group C: n = 1,000), 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-standardized moderation guide [38].

Participants will be recruited from cooperating institutions of the consortium. For the second phase (second and third quarter 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) [39,40].

Outcome Measures

Primary Outcomes

Based on the BARMER SHI data (substudy I), pre- to post-reform changes in 1) contact rates with psychotherapists and 2) waiting time between primary contact and initiation of psychotherapeutic treatment in the two subgroups of patients a) with cMPs and b) 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, e.g., 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 to 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 organizational context.

Data analysis

Substudy I): Analysis of BARMER SHI data is carried out according to 'Good Practice of Secondary Data Analysis (GPS)' [41]. To test the first primary hypothesis regarding differences in the utilization of psychotherapeutic offers between patients with cMPs and MnoPs from pre- 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-/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 to cMPs will be tested in linear regression models. Secondary outcomes will be analyzed in a descriptive manner. We will report estimates with 95% confidence intervals and descriptive *p* value.

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 (e.g., psychodynamic therapy or behavioral therapy), localization 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 analyzed 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 analyzed 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 [DAG SHG]) 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 (three 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 (DRKS-ID: DRKS00020344; 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; 6th 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 pseudonymized (BARMER) and anonymized (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' [41], no additional ethics approval or informed consent is necessary.

The patient survey will be conducted in accordance with the Declaration of Helsinki and will fulfill 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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Collaborators: The ES-RiP-Consortium study group includes (organised alphabetically by last name): Borchers, Milena; Christoffer, Andrea; Filaloi Bouami, Soufiane; Friederich, Hans-Christoph; Grobe, Thomas G.; Hartmann, Mechthild; Hegelow, Martin; Heuft, Gereon; Kampling, Hanna; Koch, Raphael; Kruse, Johannes; Leikeim, Lisa; Marschall, Ursula; Poß-Doering, Regina; Saam, Joachim; Schumacher, Catharina; Szardenings, Carsten; Szecsenyi, Joachim; Werner, Samuel; Wild, Beate; Zara, Sandra;

Contributors: HK drafted this manuscript. MH contributed to the writing of the manuscript. The study's principal investigators JK, HCF, GH, TGG, JS, and BW designed the study and obtained the funding. HK, JK, HCF, 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, HCF, and JS contributed to the specific design of substudy IV and edited the manuscript. All authors read and approved the final manuscript.

Funding: The Innovation Fund of the Federal Joint Committee of Germany grant number 01VSF19004 supported this work.

Competing interests: None declared.

Ethics approval: Ethical approval was obtained from the coordinating (Giessen) as well as one local (Heidelberg) ethic committee, Justus Liebig University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-466/2020).

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

	data source	perspective	evaluation	inclusion & exclusion criteria	outcomes	sample size
substudy I	BARMER SHI data	patients	outcome evaluation	18 to 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 one year • waiting time between first contact and start of a regular psychotherapy • estimates of pre- 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 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform) group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th 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 2,600 phone interviews: group (A) n = 600 group (B) n = 1,000 group (C) n = 1,000
substudy III	overall SHI data	service providers	process evaluation	from 2015 to 2019; included treated patients: age range 18 to 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 & 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 to 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 = 1,200
	GPs: focus groups & 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 = 1,200

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5 Figure 1: The ES-RiP approach embedded in the Throughput-Model
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Figure 2: 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

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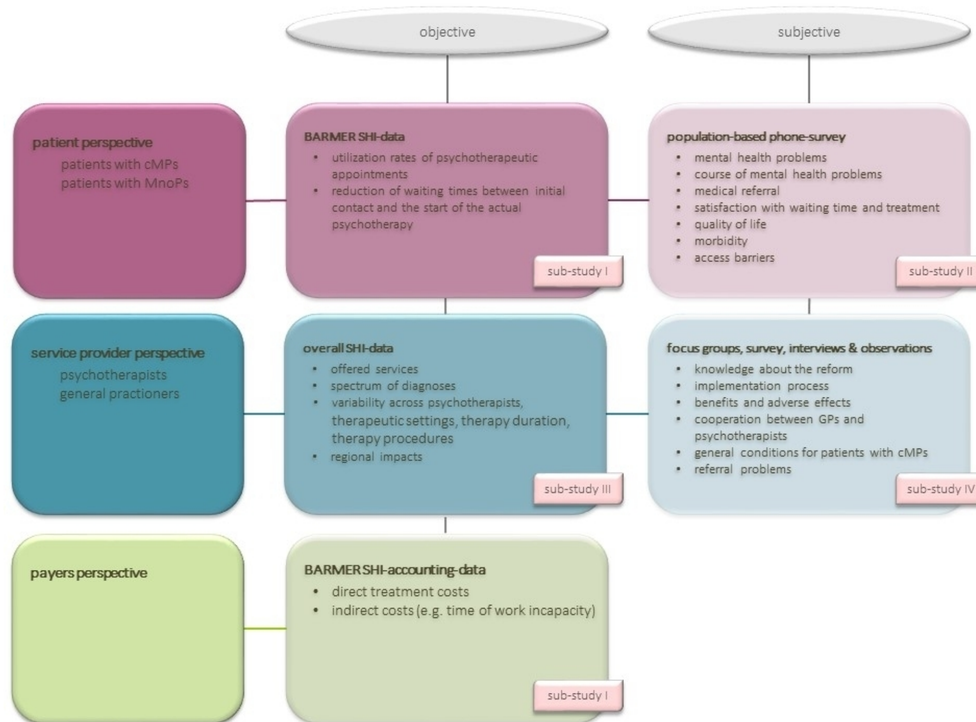

Figure 1: The ES-RiP approach embedded in the Throughput-Model

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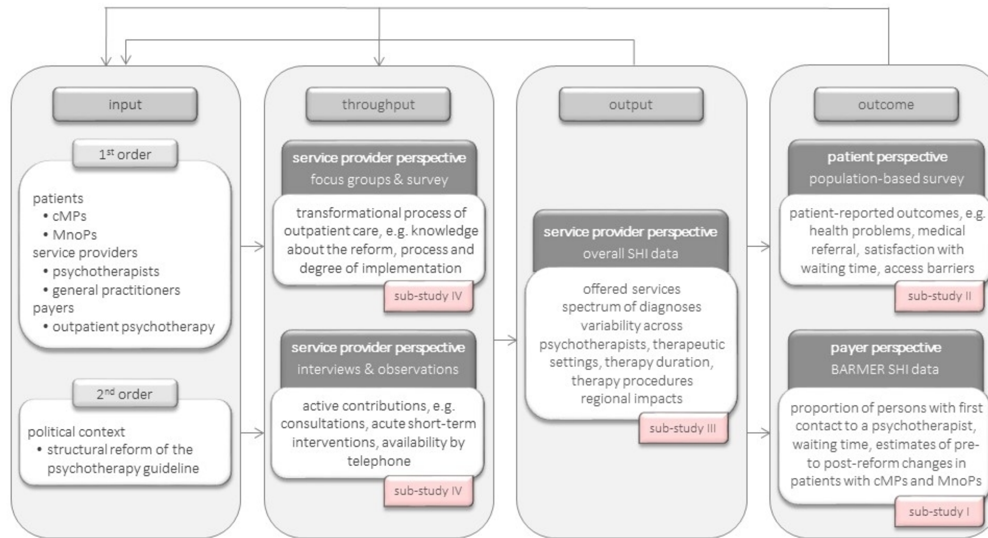

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Evaluating effects of the structural reform of outpatient psychotherapy for patients with mental disorders in Germany – comparing patients with and without comorbid chronic physical condition: rationale and study protocol of the ES-RiP project

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057298.R2
Article Type:	Protocol
Date Submitted by the Author:	08-Jul-2022
Complete List of Authors:	Kampling, Hanna; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Kruse, Johannes; Justus Liebig University Giessen Faculty of Medicine, Department of Psychosomatic Medicine and Psychotherapy Friederich, Hans-Christoph; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Heuft, Gereon; University Hospital Munster, Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Christoffer, Andrea; University Hospital Munster, 3Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health Grobe, Thomas; AQUA, Institute for Applied Quality improvement and Research in Health Care GmbH Marschall, Ursula; BARMER, Institute for Health System Research, Department Medicine and health services research Szecsenyi, Joachim; University Hospital Heidelberg, Department of General Practice and Health Services Research Wild, Beate; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics Hartmann, Mechthild ; University Hospital Heidelberg, Department of General Internal Medicine and Psychosomatics
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research, Mental health
Keywords:	MENTAL HEALTH, PRIMARY CARE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, QUALITATIVE RESEARCH, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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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

Kampling H[1], Kruse J[1], Friederich H-C[2], Heuft G[3], Christoffer A[3], Grobe TG[4], Marschall U[5], Szecsenyi J[6], Wild B[2], Hartmann M[2] & the ES-RiP-Consortium

[1]Clinic for Psychosomatic Medicine and Psychotherapy, Medical Center, Justus Liebig University Giessen and Marburg

[2]Department of General Internal Medicine and Psychosomatics, University Hospital Heidelberg

[3]Section of Psychosomatic Medicine and Psychotherapy, Clinic for Mental Health, University Hospital Muenster

[4]aQua – Institute for Applied Quality improvement and Research in Health Care GmbH

[5]BARMER Institute for Health System Research, Department Medicine and health services research

[6]Department of General Practice and Health Services Research, University Hospital Heidelberg, Heidelberg, Germany

Corresponding author:
Dr. phil. Hanna Kampling
Department of Psychosomatic Medicine and Psychotherapy
Justus Liebig University Giessen
Ludwigstraße 76, 35392 Gießen, Germany
Phone: +49 641 99 45646
Email: hanna.kampling@psycho.med.uni-giessen.de

Word count: 4143

Abbreviations

cMPs	**c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s**
GP	general practitioner
ICD	International Classification of Diseases
MnoP	**m**ental disorders but **no** chronic **p**hysical condition
SHI	statutory health insurance

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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 (e.g. 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 to 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 to 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.

Trial registration This study was registered at the German Clinical Trial Register (DRKS) and can be found at https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00020344.

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 (SHI) 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.

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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- 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 (e.g. general practitioners' (GP) 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 health care problem as they are often in particular need of treatment. Compared to patients with **m**ental disorders but **no** chronic **p**hysical condition (MnoP), patients with a **c**omorbidity of **m**ental disorders and chronic **p**hysical condition**s** (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 e.g. 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 aforementioned 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 [27]. The new option of short-term consultations and assessment sessions with a psychotherapist could help to overcome such

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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 [28,29]. 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 improvement of care for their patients [30]. 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 nor objective analyses with routine data, nor are there any from the subjective perspectives of GPs, psychotherapists, or patients with cMPs compared to patients with MnoPs. In addition, insights into the practical implementation of the new elements (e.g. 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 [31] which describes relevant interacting factors in the health care system and can be used to analyse the success of health care 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 to patients with MnoPs. Considering pre- 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 to patients with MnoPs (substudy I).

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- 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- 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 (e.g. 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 [32, 33]. 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 'substudies and samples'). 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:

(A) For the **outcome evaluation**, changes in the waiting time for patients with cMPs and MnoPs from pre- 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).

(B) 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, interviews, and observations (substudy IV).

(C) A **health economics evaluation** is intended to reveal changes in the cost structure of treatments pre- 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.

Please insert figure 1 here

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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, e.g., a psychotherapist, and therefore, offering information on only those persons diagnosed with, e.g., depression who are already in psychotherapy. We provide detailed information regarding the samples from the four substudies (see also 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- or post-reform,
- Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform), and
- Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th 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 = 1,200) who were affected by the reform.
- Interviews and observations on current practice post-reform: 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 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.

Please insert Table 1 here

Please insert Figure 2 here

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 [25,34]:

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 to 2019) was the basis for the calculations. With a preplanned sample size of n = 1,000 (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 [35], 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 = 2,286 interviews (Group B) and n = 1,430 interviews (Group A), respectively.

Substudy IV): We followed empirically based recommendations for sample sizes when using qualitative methods [36,37]. 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 = 1,200 participating psychotherapists and general practitioners were determined to be sufficient. Based on experiences from our own prior studies, we expected a participation rate of 30 %, thus, resulting in 4,000 invitation letters each.

Inclusion and Exclusion Criteria

For substudies I to III, we will only include participants who are 18 to 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 2 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 Substudies and Samples).

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 ‘general practitioner’ (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 = 1,000; Group C: n = 1,000), 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 [38]. Participants will be recruited from cooperating institutions of the consortium. For the second phase (second and third quarter 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) [39,40].

Outcome Measures

Primary Outcomes

Based on the BARMER SHI data (substudy I), pre- to post-reform changes in 1) contact rates with psychotherapists and 2) waiting time between primary contact and initiation of psychotherapeutic treatment in the two subgroups of patients a) with cMPs and b) 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, e.g., 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 to 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): Analysis of BARMER SHI data is carried out according to 'Good Practice of Secondary Data Analysis (GPS)' [41]. To test the first primary hypothesis regarding differences in the utilisation of psychotherapeutic offers between patients with cMPs and MnoPs from pre- 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-/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 to cMPs will be tested in linear regression models. Secondary outcomes will be analysed in a descriptive manner. We will report estimates with 95% confidence intervals and descriptive p value.

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 (e.g., psychodynamic therapy or 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 [DAG SHG]) 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 (three 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 (DRKS-ID: DRKS00020344; 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; 6th 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' [41], 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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Collaborators: The ES-RiP-Consortium study group includes (organised alphabetically by last name): Borchers, Milena; Christoffer, Andrea; Filaloi Bouami, Soufiane; Friederich, Hans-Christoph; Grobe, Thomas G.; Hartmann, Mechthild; Hegelow, Martin; Heuft, Gereon; Kampling, Hanna; Koch, Raphael; Kruse, Johannes; Leikeim, Lisa; Marschall, Ursula; Poß-Doering, Regina; Saam, Joachim; Schumacher, Catharina; Szardenings, Carsten; Szecsenyi, Joachim; Werner, Samuel; Wild, Beate; Zara, Sandra;

Contributors: HK drafted this manuscript. MH contributed to the writing of the manuscript. The study's principal investigators JK, HCF, GH, TGG, JS, and BW designed the study and obtained the funding. HK, JK, HCF, 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, HCF, and JS contributed to the specific design of substudy IV and edited the manuscript. All authors read and approved the final manuscript.

Funding: The Innovation Fund of the Federal Joint Committee of Germany grant number 01VSF19004 supported this work.

Competing interests: None declared.

Ethics approval: Ethical approval was obtained from the coordinating (Giessen) as well as one local (Heidelberg) ethic committee, Justus Liebig University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-466/2020).

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

	data source	perspective	evaluation	inclusion & exclusion criteria	outcomes	sample size
substudy I	BARMER SHI data	patients	outcome evaluation	18 to 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 one year • waiting time between first contact and start of a regular psychotherapy • estimates of pre- 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 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform) group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th 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 2,600 phone interviews: group (A) n = 600 group (B) n = 1,000 group (C) n = 1,000
substudy III	overall SHI data	service providers	process evaluation	from 2015 to 2019; included treated patients: age range 18 to 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 & 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 to 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 = 1,200
	GPs: focus groups & 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 = 1,200

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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

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Figure 2: The ES-RiP approach embedded in the Throughput-Model

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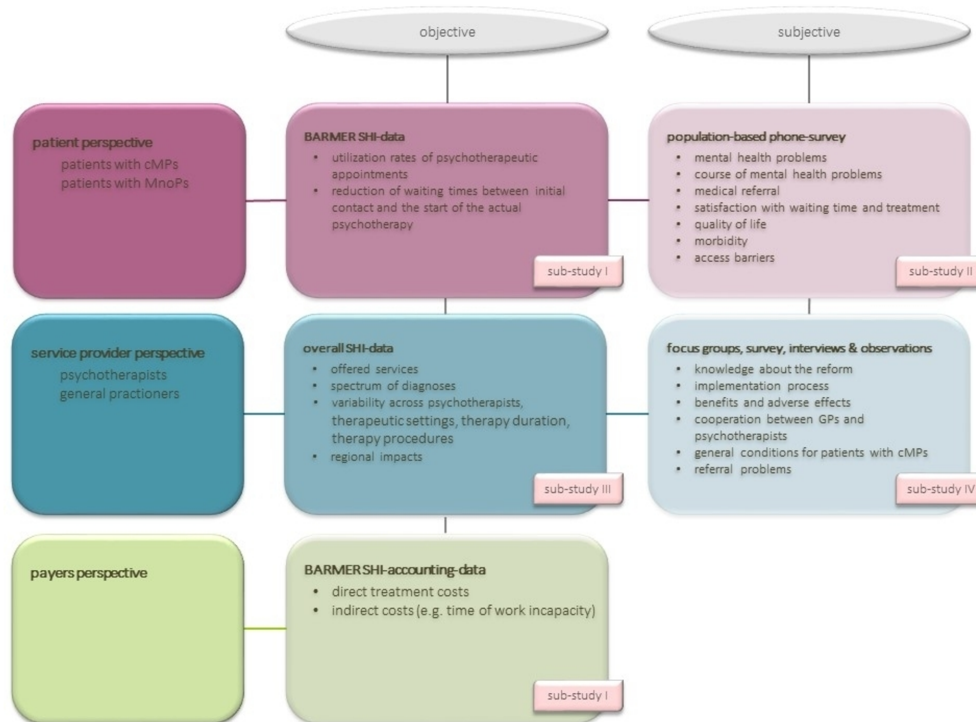

Figure 1: The ES-RiP approach embedded in the Throughput-Model

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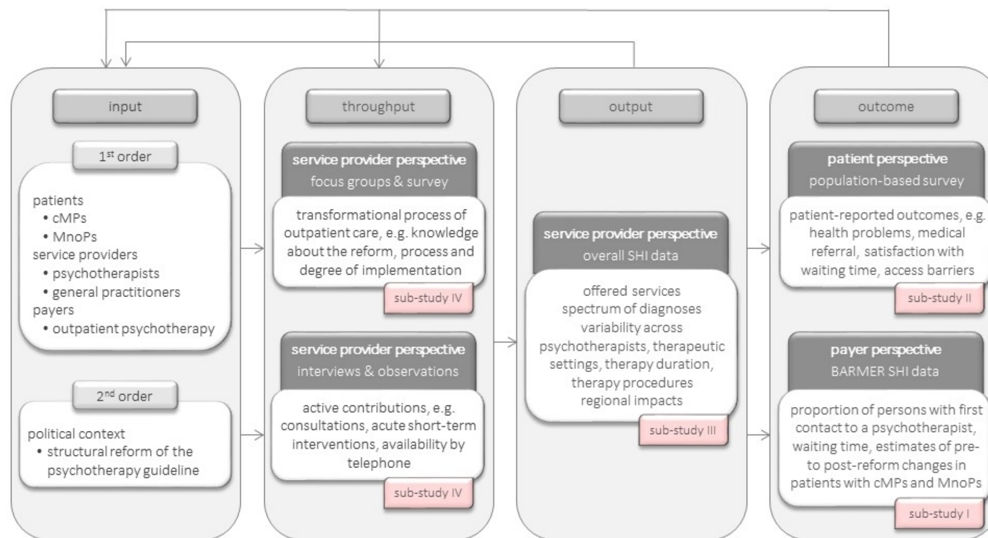

Figure 2: An overview of the three ES-RiP-perspectives (patients, service providers and payers) integrated in a multi-level approach, also including the respective data sources, major outcomes, and corresponding substudies

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