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

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

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Abbreviations

CG comparative groups

cMPs comorbidity of mental disorders and chronic physical conditions

GP general practitioner

ICD International Classification of Diseases

MnoP mental disorders but no chronic physical condition

SHI statutory health insurance

TG target groups

1 Abstract

2 **Introduction** In 2017 in Germany, a structural reform of the outpatient psychotherapy
3 guideline has taken place as a reply to ongoing insufficient waiting times and access barriers
4 for specific patient groups. The reform includes new service elements, such as the
5 implementation of psychotherapeutic consultations, acute short-term psychotherapeutic
6 interventions, and relapse prophylaxis as well as the promotion of group therapies, the
7 facilitation of psychotherapists' availability, and the installation of appointment service centers.
8 The ES-RiP project is planned to thoroughly evaluate effects of the reform with a special focus
9 on patients with a comorbidity of mental disorders and chronic physical conditions (cMPs)
10 compared to patients with a mental disorder but no long-term physical condition (MnoP). The
11 project aims at evaluating (a) the extent to which the reform goals were achieved in the large
12 group of patients with cMPs, (b) the barriers that might be hindering the implementation of the
13 new guideline, and (c) the procedures required for further developing and improving outpatient
14 psychotherapy.

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

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

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

26 Strengths and limitations of this study

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

35 Introduction

36 In Germany, nearly 18 million people are affected by mental disorders every year [1].
37 Psychotherapy is the preferred treatment for these disorders and is commonly offered in
38 inpatient, day-care, or outpatient settings, with about 30 % of patients with mental disorders
39 attending outpatient psychotherapy [2]. In Germany, costs for these treatments are usually
40 covered by the respective health insurance schemes [3]. Which interventions are accepted
41 and financed is regulated by the psychotherapy guideline ('Psychotherapierichtlinie') (for
42 details on the German psychotherapeutic system see [3,4]).

43 In 2017, this guideline was reformed, and new elements like additional psychotherapeutic
44 consultation times, acute short-term psychotherapeutic interventions, and relapse prophylaxis
45 were implemented. Further, more group therapies were promoted, availability of
46 psychotherapists by telephone was facilitated, and appointment-service-points were set up to
47 convey psychotherapeutic consultations directly [5]. These measures were directed to improve
48 overall outpatient psychotherapeutic care by aiming to reduce long waiting times and help
49 overcome access barriers for outpatient treatment, especially for undersupplied groups. Of
50 those with mental disorders, about 46 % also suffer from at least one long-term physical
51 condition [6]. This is a serious healthcare problem as they are often in particular need of
52 treatment. Compared to patients with mental disorders but **no** chronic physical condition
53 (MnoP), patients with a **comorbidity** of mental disorders and chronic physical conditions
54 (cMPs) do not only have a significantly lower quality of life [7–9] as well as significantly
55 increased morbidity and mortality rates [10–12], they also require additional multidisciplinary
56 care [13] and cause significantly higher treatment costs [14–18]. In addition, if the mental
57 disorder remains untreated, the physical condition often deteriorates. Depression, for example,
58 may decrease adherence to treatment of the somatic disease, thus leading e.g. to a comatose
59 state in type 1 diabetes [19], or transplant rejection in organ recipients [20]. Despite the
60 increased need for care, patients with cMPs frequently experience poorer access to
61 psychotherapeutic offers, as they are more likely to be unable to attend treatments due to their
62 illness, or might cause additional work for psychotherapists in form of a need for intensive
63 interdisciplinary cooperation with physicians.

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

79 Since the introduction of the reform, preliminary evidence shows that the number of patients
80 having contact with a psychotherapist has increased and time to first contact has decreased,
81 but initiation of psychotherapy itself has become less [26,27]. This concurs with the results of
82 a survey with psychotherapists, in which more than half of them report that the reform has not
83 resulted in significant improvement of care for their patients [28]. However, besides these
84 general and short-term results no studies have been conducted on the extent to which the care
85 situation has changed for specific subgroups, like patients with cMPs. There are neither
86 objective analyses with routine data, nor are there any from the subjective perspectives of
87 GPs, psychotherapists, or patients with cMPs compared to patients MnoPs. In addition,
88 insights into the practical implementation of the new elements (e.g. psychotherapeutic
89 consultation times, acute short-term psychotherapeutic interventions, or relapse prophylaxis)
90 offered by the psychotherapists are currently lacking. Finally, it remains unclear whether the
91 new measures lowered waiting times and access barriers for patients at higher risk such as
92 patients with cMPs.

93 **Conceptual framework**

94 The ES-RiP evaluation concept of the reform of the psychotherapy guideline is based on the
95 theoretical 'Throughput-Model' by Schrappe and Pfaff [29] which describes relevant interacting
96 factors in the health care system and can be used to analyze the success of health care
97 interventions. The model differentiates four phases: In the 'input phase', a significant
98 organizational intervention like the reform of the psychotherapy guideline first meets up with
99 specific patient and provider groups. Following the input phase, the model describes the
100 transformation process of such a reform ('throughput phase'), the resulting treatment offers
101 ('output phase'), as well as the direct outcomes for patients and society ('outcome phase'). The
102 ES-RiP project specifically considers the various modifying factors by including different actors'
103 perspectives as well as different data sources in order to identify facilitating factors as well as
104 barriers for implementation. The success of the transformation process and the benefits of the
105 reform are reflected by societal relevant objective treatment parameters and patients'
106 subjective treatment results. Therefore, based on the Throughput-Model the ES-RiP approach
107 pursues an **outcome evaluation** (Throughput-Model: outcome) and a **process evaluation**
108 (Throughput-Model: throughput and output) while giving special attention to patients with cMPs.
109 Figure 1 offers an overview of the ES-RiP approach integrated in the Throughput-Model.

110 *Please insert figure 1 here*

111 **Aim**

112 The aim of the ES-RiP project is a comprehensive evaluation of the reform of the
113 psychotherapy guideline and its effects on patients with cMPs (= patients with combined
114 **mental disorders and long-term physical conditions**) compared to patients with MnoPs (=
115 patients with a **mental disorder but no long-term physical condition**). Considering pre- to post-
116 reform changes, a multi-level approach with an observational mixed-methods design will be
117 applied to investigate the following objectives:

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

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3 121 – Regarding the patients' perspectives, we will examine possible barriers and patient
4 122 satisfaction with waiting times and care in patients with cMPs and MoPs pre- and post-
5 123 reform.
6
7 124 – Regarding the service providers' perspective (GPs and psychotherapists), we will
8 125 assess reform-associated changes in the delivery and perception of psychotherapeutic
9 126 interventions.
10
11 127 – Regarding the payers' perspective, we will analyse health economic changes in terms
12 128 of direct and indirect costs.
13

14 129 **Methods and analysis**

15 130 **Study design**

16
17 131 The reform of the psychotherapy guideline is considered a complex intervention, and therefore,
18 132 its evaluation follows different methodological approaches [30]. A mixed-methods-design
19 133 (quantitative, qualitative) along with a multi-level approach (patients, service providers, payers)
20 134 combining several data sources (primary and secondary data) will be applied to evaluate the
21 135 reform from different perspectives. With respect to the underlying data sources, the overall
22 136 project is divided in four sub-studies (for more information on the respective data sources see
23 137 samples). The Throughput-Model offers the theoretical framework for this approach making it
24 138 possible to conduct an outcome-evaluation of the reform as well as an evaluation of the reform
25 139 process (figure 1 presents the integration of the ES-RiP approach into the Throughput-Model):

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28
29 140 (A) For the **outcome evaluation**, changes in waiting time for patients with cMPs and MnoPs
30 141 from pre- to post-reform will be compared. Analyses on the patients' perspective are based
31 142 on secondary SHI data from the BARMER company (sub-study I) and primary patient
32 143 reports (sub-study II).
33
34 144 (B) For the **process evaluation**, different perspectives of the service providers
35 145 (psychotherapists and GPs) will be examined. Evaluations are based on secondary SHI-
36 146 data from the National Association of Statutory Health Insurance Physicians (sub-study
37 147 III) as well as primary data from focus groups, surveys, interviews and observations (sub-
38 148 study IV).
39
40 149 (C) A **health economics evaluation** is supposed to reveal changes in the cost structure of
41 150 treatments pre- to post-reform. Analyses are based on accounting data of the health
42 151 insurance company BARMER (sub-study I).
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46 152
47 153 The multi-level approach including the respective data sources, major outcomes, and
48 154 corresponding sub-studies is presented in figure 2.

49 155
50 156 *Please insert figure 2 here*

51 157
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53 158 In addition, table 1 gives a detailed overview of the sub-studies and the respective data
54 159 sources, perspectives, types of evaluation, inclusion/exclusion criteria, outcomes, and
55 160 samples sizes.
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3 162 *Please insert table 1 here*
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7 164 **Sub-studies and Samples**

8 165 The realization of the ES-RiP project will take place in four sub-studies, which are determined
9 166 by different perspectives and use of distinct data sources:

10 167 Sub-study I): Based on routine data of the health insurance company BARMER (= BARMER
11 168 SHI-data), secondary analyses will be conducted to address the patients' and payers'
12 169 perspective. BARMER is a nationwide SHI company with over 8 million policyholders (> 10 %
13 170 of the German population). For research purposes, BARMER holds pseudonymized data on
14 171 nearly every aspect of health related services in a scientific Data Warehouse.

15 172 The two following target groups (TG) will be selected:

- 16 173 – (TG1) patients with cMPs (= patients with **combined mental disorders and long-term**
17 174 **physical conditions**) after the implementation of the reform (= post-reform).
18 175 – (TG2) patients with MnoPs (= patients with a **mental disorder but no long-term physical**
19 176 **condition**) after the implementation of the reform (= post-reform).

20 177 In order to evaluate the effects of the reform (pre-/post-reform) for these patient groups, two
21 178 comparative groups (CG) emerge:

- 22 179 – (CG1) a historical control group of patients with cMPs from the years before the
23 180 implementation of the reform (= pre-reform).
24 181 – (CG2) a historical control group of patients with MnoPs from the years before the
25 182 implementation of the reform (= pre-reform).

26 183 Sub-study II): A representative population-based phone-survey will be conducted to gather
27 184 subjective patient information (primary data). The survey will include a screening of
28 185 approximately 28,600 people to ensure participants will belong to one of the following three
29 186 groups:

- 30 187 – Group (A): n = 600 participants who wanted to see a psychotherapist but were unable
31 188 to achieve a psychotherapeutic face-to-face contact,
32 189 – Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention
33 190 pre-reform, and
34 191 – Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention
35 192 post-reform.

36 193 Sub-study III): Based on routine data from the National Association of Statutory Health
37 194 Insurance Physicians (= overall SHI-data), secondary analyses will be conducted to address
38 195 the service providers. The data cover all SHI insured persons in Germany (excluded are only
39 196 residents with private health insurance), which amounts roughly to 70 million individuals. In
40 197 contrast to the claims data of the BARMER, overall SHI-data are structured according to care
41 198 providers, not patients. This allows for analyses adjusted to existing resources. Sample
42 199 selection will be parallelized to study I) using diagnostic codes of the International Classification
43 200 of diseases 10th revision (ICD-10) to identify all patients with relevant somatic and mental
44 201 diagnoses (see below for detailed inclusion and exclusion criteria).

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3 202 Sub-study IV): To gather additional service provider information (subjective primary data),
4 203 focus groups, a nationwide survey, interviews as well as observations of psychotherapists will
5 204 be conducted in a sequential design.

7 205 – Focus groups: Four group discussions with $n = 10$ participants at a time, separately for
8 206 each profession (GPs and psychotherapists) to generate themes for the survey
9 207 questionnaire

11 208 – Surveys: GPs and psychotherapists (each $n = 1,200$) who were affected by the reform

13 209 – Interviews and observations on current practice post-reform: $n = 40$ psychotherapists will
14 210 be interviewed and $n = 10$ will be observed

16 211 **Sample Size Calculation**

18 212 For sub-studies I and III the full available routine data sets of the BARMER and the National
19 213 Association of Statutory Health Insurance Physicians will be used. This allows for sufficient
20 214 statistical power even to detect small effect sizes.

22 215 For sub-studies II and IV, sample sizes are based on number of cases in similar studies and
23 216 considerations on clinical relevance as well as empirically founded recommendations:

25 217 Sub-study II): For the population-based phone-survey, three target groups are to be
26 218 differentiated. The group most difficult to reach (group C) due to the shortness of the survey
27 219 period (2018 to 2019) was the basis for calculations. With a pre-planned sample size of
28 220 $n = 1,000$ (post-reform) we estimated the numbers needed to be contacted in the population-
29 221 based survey of patients. Given an incidence rate of 3.5 % new cases in the general population
30 222 of Germany who are in need of psychotherapy [31], this leads to $n = 28,571$ screenings
31 223 necessary to be performed for identifying them. Rounding up, we planned with $N = 28,600$
32 224 screenings to reach sufficient interviews for group C. Based on these considerations, the
33 225 estimated N for the other groups would result in $n = 2,286$ interviews (group B) and $n = 1,430$
34 226 interviews (group A), respectively.

36 227 Sub-study IV): We followed empirically based recommendations for sample sizes when using
37 228 qualitative methods [32,33]. For the quantitative surveys, we aimed at high precision of results
38 229 with at least 90 % confidence for estimates even when the two groups of psychotherapists
39 230 (medical and psychological psychotherapists) are analyzed separately. Therefore, $n = 1,200$
40 231 participating psychotherapists and general practitioners were determined sufficient. Based on
41 232 experiences from our own prior studies, we expected a participation rate of 30 %, and thus,
42 233 resulting in 4,000 invitation letters, each.

44 234 **Inclusion Criteria**

46 235 The following inclusion criteria will be applied for the subsequent sub-studies:

48 236 Sub-study I): Data on the total population of the BARMER will be included (accounting data
49 237 from 2009 to 2019).

51 238 Sub-Study II): Subjects with sufficient German language skills, cognitive proficiency, and
52 239 informed verbal consent to participate in the study will be included. Furthermore, the three
53 240 target groups of the patient sample will have to meet the following criteria:

54 241 – (A) participants who wanted to see a psychotherapist but were unable to achieve a
55 242 primary psychotherapeutic face-to-face contact,

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3 243 – (B) participants who had at least one psychotherapeutic intervention from the 1st quarter
4 244 of 2012 to the 1st quarter of 2017 (pre-reform), and
5
6 245 – (C) participants who had at least one psychotherapeutic intervention from the 1st
7 246 quarter of 2018 to the 4th quarter of 2019 (post-reform).
8

9 247 Sub-study III): Data from the full surveys of all persons insured with the National Association
10 248 of Statutory Health Insurance Physicians will be included (accounting data from 2015 to 2019).

11 249 Sub-study IV): Psychotherapists and GPs who will be included in the focus groups, interviews
12 250 (psychotherapists only), and surveys have to fulfill the following criteria:

- 13 251 – Psychotherapists: Entry in the medical register of the National Association of Statutory
14 252 Health Insurance Physicians under ‘psychological psychotherapists’ or ‘medical
15 253 psychotherapists’; treatment of adults; psychotherapeutic practice since at least 2015
16 254 (2 years prior to reform); informed consent.
17
18 255 – GPs: Entry in the medical register of the National Association of Statutory Health
19 256 Insurance Physicians under the group ‘general practitioner’ (internal or general
20 257 medicine); primary care work since at least 2015 (2 years prior to reform); informed
21 258 consent.
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26 259 **Exclusion Criteria**

27 260 For sub-studies I to III, participants will be excluded if they are < 18 or > 79 years old, and if
28 261 they have an organic, including symptomatic, mental disorder (ICD-10: F00-F09) or mental
29 262 retardation (ICD-10: F70-F79).
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32 263 **Data collection**

33 264 For sub-studies I) and III), secondary data will be obtained from the health insurance company
34 265 BARMER, and the National Association of Statutory Health Insurance Physicians. Primary
35 266 data will be collected for sub-studies II) and IV):
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37

38 267 Sub-study II): The representative population-based phone-survey will be conducted nationwide
39 268 from the last quarter of 2020 to the last quarter of 2021 (11 months). In order to accomplish
40 269 the defined sample sizes (group A: n = 600; group B; n = 1,000; group C: n = 1,000),
41 270 households will be contacted until these numbers are reached, or at least N = 28,600
42 271 households have been screened.
43
44

45 272 Sub-study IV): For the nationwide postal survey eligible participants (GPs and
46 273 psychotherapists) will be recruited from a random sample of GPs and psychotherapists listed
47 274 in the national SHI registries. The addresses will be supplied by the SHI. Relevant topics and
48 275 items for construction of the survey questionnaire are captured beforehand in the focus groups
49 276 [34] with other GPs and psychotherapists which will be recruited from cooperating institutions
50 277 of the consortium partners. The study participants for the interviews on practical
51 278 implementation of the new psychotherapeutic elements will be drawn from a group of
52 279 participants of the survey which have agreed on further participation. In a similar way, further
53 280 10 participants will be recruited for subsequent field observation in the psychotherapists’
54 281 practice.
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282 **Outcome Measures**

283 **Primary Outcomes**

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

288 **Secondary Outcomes**

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

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

295 Sub-Study III): Based on overall SHI-data, objective changes in care procedures will be
296 examined: frequency of psychotherapeutic offers (including the new psychotherapeutic
297 measures), spectrum of diagnoses, variability across psychotherapists, therapeutic settings,
298 therapy duration and therapy procedures as well as regional impacts.

299 Sub-study IV): Focus groups and surveys with GPs and psychotherapists will be conducted to
300 examine the process and effects of the reform from the perspective of the service providers.
301 Special attention will be given to the knowledge about the reform, perceived task shifts,
302 benefits and adverse effects, the cooperation between GPs and psychotherapists, referral
303 problems, as well as perceived differences for patients with cMPs compared to MnoPs in the
304 context of the reform. In addition, psychotherapists will be interviewed and their practices
305 observed to gain deeper insights on the implementation of the reform with regard to formal
306 aspects and content (indications, methods and techniques, networking, best practice
307 examples) as well as the organizational context

308 **Data analysis**

309 Sub-study I): Analysis of SHI-data is carried out according to 'Good Practice of Secondary
310 Data Analysis (GPS)' [35]. In order to test the first primary hypothesis regarding differences in
311 utilization of psychotherapeutic offers between the two target groups from pre to post reform,
312 different binary logistic regression analyses with contacts to psychotherapists (yes/no) as a
313 dependent variable will be conducted. The independent variable is TG (as in another model
314 the interaction term of TG and time before/after reform), while age, gender and regional supply
315 status will be included as control variables. The second primary hypothesis regarding a higher
316 reduction in waiting times for psychotherapy after the reform for MnoPs compared to cMPs will
317 be tested in linear regression models. Secondary outcomes will be analyzed in a descriptive
318 manner. We will report estimates with 95% confidence intervals and descriptive p-values.

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

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

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3 325 the reform: 2017; post-reform: 2018-2019). Subgroup analyses will be conducted for
4 326 physician/therapist group (medical or psychological psychotherapist), therapeutic settings
5 327 (individual therapy or group therapy), therapy duration (short-term therapy or long-term
6 328 therapy), therapy procedures (psychodynamic therapy or behavioral therapy), localization of
7 329 service provision (different regions in Germany) as well as coverage rate.

8
9 330 Sub-study IV): The analysis of service provider data will focus on the degree of implementation
10 331 of the new measures (additional psychotherapeutic consultation times, acute short-term
11 332 psychotherapeutic interventions, and relapse prophylaxis) and perceived effects on patients
12 333 with cMPs. Quantitative data from surveys will be analyzed on an overall level as well as for
13 334 the subgroups physicians and therapists (medical or psychological psychotherapist).
14 335 Qualitative data generated in the focus groups and interviews with GPs and psychotherapists
15 336 will be subjected to thematic analyses using the MAXQDA software.

19 337 **Patient and public involvement statement**

20 338 A representative of the German Working Group Self-Help Groups (Deutsche
21 339 Arbeitsgemeinschaft Selbsthilfegruppen [DAG SHG]) was involved as a member of a scientific
22 340 advisory board taking place at the very beginning of the project as well as its final stage to
23 341 discuss content, proceedings, and dissemination.

26 342 **Ethics and dissemination**

27 343 The study is registered at the German Clinical Trial Register (DRKS-ID: DRKS00020344), and
28 344 can also be found at <https://trialssearch.who.int/Trial2.aspx?TrialID=DRKS00020344>. Ethical
29 345 approval for the overall project was obtained from the Ethics Committee of the Justus Liebig
30 346 University Giessen and Marburg – Faculty of Medicine (approval number: AZ 107/20). Given
31 347 that the overall project is based on four sub-studies located in different parts of Germany, one
32 348 of the sub-studies collecting primary data required additional ethical approval. For sub-study
33 349 IV), approval was obtained from the Ethics Committee Heidelberg (approval number: S-
34 350 466/2020).

35 351 Analyses of secondary data will be based on pseudonymized (BARMER) and anonymized
36 352 (National Association of Statutory Health Insurance Physicians) datasets. The routine data
37 353 cannot be linked to any other insurance or service provider data. Hence, according to the 'Good
38 354 Practice of Secondary Data Analysis (GPS): guidelines and recommendations' [35] no ethics
39 355 approval and informed consent will be necessary .

40 356 Findings will be disseminated through national and international psychotherapy and health
41 357 services research journals and will be presented at relevant conferences and meetings.

48 358 **Discussion**

49 359 The ES-RiP project will provide novel and detailed information on current provision of
50 360 outpatient psychotherapeutic care and robust evidence on whether the structural reform is
51 361 associated with improved outcomes for specific subgroups.

52 362 To our knowledge, this project is the first aiming to analyze the psychotherapeutic care
53 363 situation of the large group of patients with cMPs embedded in an overarching evaluation of
54 364 the recent structural reform of outpatient psychotherapy. The focus on cMPs is important as it
55 365 has been shown that this subgroup was previously largely undersupplied even though they
56 366 have a high risk for adverse outcomes. A significant change in the provision of services for this

1
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3 367 target group would therefore be of high relevance not only for the individual patient but also for
4 368 society.

5
6 369 The investigation is based on different perspectives (patients, service providers, payers) and
7 370 methods (mixed-methods) to obtain a comprehensive outline of the reform effects. A special
8 371 focus will be on participatory process evaluation to assess determinants of implementation
9 372 success. With such a unique approach within one project, we will be able to better understand
10 373 the current challenges for patients with somatic and mental comorbidity in outpatient
11 374 psychotherapeutic care.

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14 375 Besides these strengths we are aware of some limitations of the project: Firstly, by using SHI
15 376 data, we cannot make any statements about patients with full private health insurance. Also,
16 377 routine data are known to capture diagnoses and time points with only a medium level of
17 378 accuracy. Therefore, the patients' perspective is an indispensable additional data source that
18 379 may be in turn biased due to the presence of a mental disorder itself. Hence, the third
19 380 perspective of health care providers is necessary to complete the picture by contextual
20 381 information.

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24 382 Based on these considerations, a major task of the project will therefore be the integration of
25 383 data from the various sub-studies, enabling cross-validation of results. Overall interpretation is
26 384 based on triangulation of the different perspectives and will involve discussions with various
27 385 stakeholders. Findings and insights are going to be utilized to identify procedures for further
28 386 development and improvement of the reform.

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30 387 Based on these findings, recommendations for future improvements of outpatient
31 388 psychotherapy for the seriously burdened group of patients with cMPs can be made.
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4 by last name): Borchers, Milena; Christoffer, Andrea; Filaloi Bouami, Soufiane; Friederich,
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7 Doering, Regina; Saam, Joachim; Schumacher, Catharina; Szardenings, Carsten;
8 Szecsenyi, Joachim; Werner, Samuel; Wild, Beate; Zara, Sandra;
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10
11 **Contributors:** HK drafted this manuscript. MH contributed to the writing of the manuscript.
12 The study's principal investigators JK, HCF, GH, TGG, JS, and BW designed the study and
13 obtained the funding. HK, JK, HCF, and MH obtained the ethics' approval. TGG and UM
14 contributed to the specific design of sub-study I and edited the manuscript. HK and JK
15 contributed to the specific design of sub-study II. JK supervised and edited the manuscript. GF
16 and AC contributed to the specific design of sub-study III and edited the manuscript. MH, HCF,
17 and JS contributed to the specific design of sub-study IV and edited the manuscript. All authors
18 read and approved the final manuscript.
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24
25

26 **Competing interests:** None declared.
27

28 **Ethics approval:** Ethical approval was obtained from the coordinating (Giessen) as well as
29 one local (Heidelberg) ethic committee, Justus Liebig University Giessen and Marburg –
30 Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-
31 466/2020).
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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
1 2 3 4 5 6 7 8 9 10 11 12 13 sub-study I	BARMER SHI-data – secondary data	patients payers	outcome evaluation health economic 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)	<ul style="list-style-type: none"> • 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 • health economic changes (direct treatment costs as well as indirect costs) 	available health insurance data from the BARMER company (approximately 8 million policyholders) available health insurance data from the BARMER company
14 15 16 17 18 19 20 21 22 23 24 25 26 sub-study II	population-based phone survey – primary data	patients	outcome evaluation	<p>sufficient German language skills; cognitive proficiency; informed verbal consent to study participation</p> <p>group (A) participants who wanted to see a psychotherapist but were unable to achieve a primary psychotherapeutic face-to-face contact</p> <p>group (B) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform)</p> <p>group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform)</p>	<ul style="list-style-type: none"> • 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
27 28 29 30 31 32 33 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)	<ul style="list-style-type: none"> • 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
34 35 36 37 38 39 40 41 42 43 44 45 46 sub-study IV	<p>psychotherapists: focus groups, survey, interviews & observations – primary data</p> <p>GPs: focus groups & survey – primary data</p>	service providers service providers	process evaluation process evaluation	<p>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</p> <p>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</p>	<ul style="list-style-type: none"> • 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 MnoP • formal aspects and content of new measures (methods and techniques, networking, best practice examples) 	<p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>interviews: N = 40</p> <p>survey: N = 1,200</p> <p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>survey: N = 1,200</p>

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

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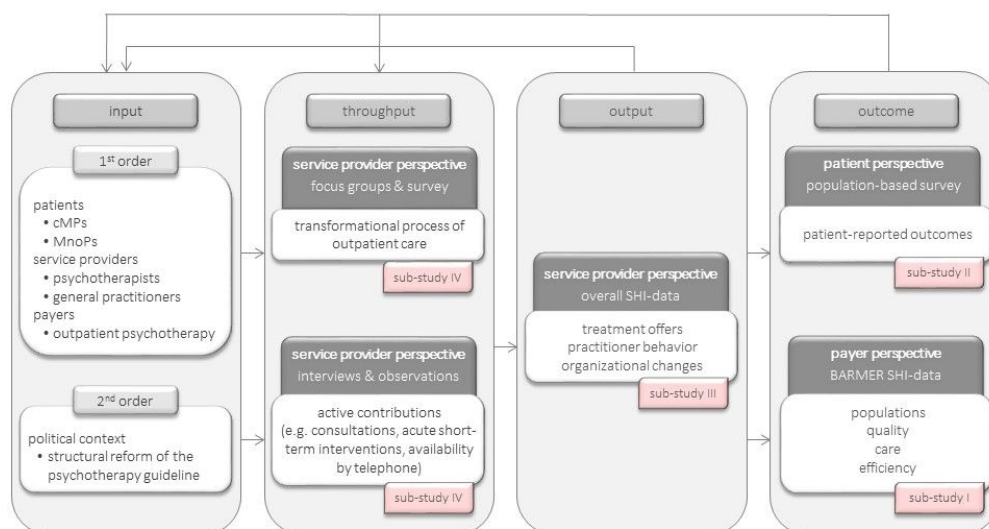


Figure 1: The ES-RiP approach embedded in the Throughput-Model

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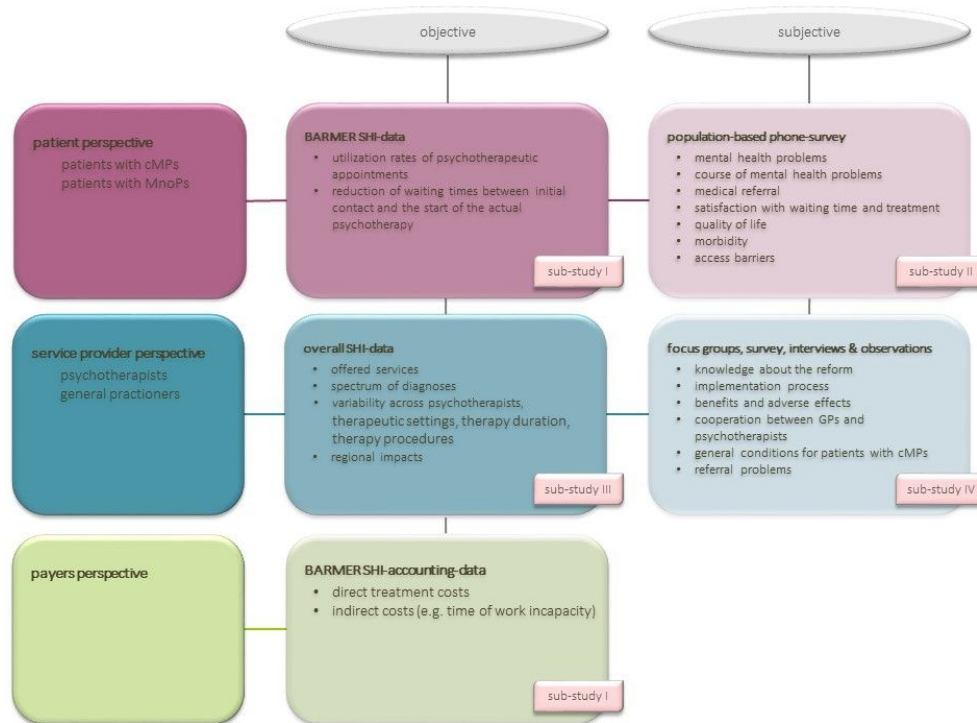


Figure 2: An overview of the three ES-RiP-perspectives (patients, service providers and payers) integrated in a multi-level approach, also including the respective data sources, major outcomes, and corresponding sub-studies

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BMJ Open

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

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

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26
27 Word count: 3956

Abbreviations

32 cMPs comorbidity of mental disorders and chronic physical conditions

33 GP general practitioner

34 ICD International Classification of Diseases

35 MnoP mental disorders but no chronic physical condition

36 SHI statutory health insurance

37 Abstract

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

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

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

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

63 Strengths and limitations of this study

- 64 • By applying the conceptual framework of the throughput model, this study will conduct
65 both outcome and process evaluation, and thus will allow for deeper insights and a
66 founded understanding of the results and possible limitations of the structural reform of
67 the psychotherapy guideline in 2017.
- 68 • Based on a mixed-methods design (quantitative and qualitative) along with a multilevel
69 approach (patients, service providers, and payers), the different perspectives and
70 various data sources (primary and secondary data) will be triangulated to evaluate the
71 reform.
- 72 • Analyses of statutory health insurance (SHI) data come with inherent limitations such as
73 possibly invalid diagnoses or clinically meaningless statistically significant results due to
74 the large number of included cases.
- 75 • Data from the representative population-based survey (substudy II) are based on
76 participants' self-reports and a broad retrospective inquiry period (starting from 2012);
77 therefore, the results will have to be interpreted with caution.

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4 79 rate in focus groups, surveys, interviews, and observations.
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- The validity of results on the provider perspective will highly depend on the participation rate in focus groups, surveys, interviews, and observations.

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80 Introduction

81 In Germany, nearly 18 million people are affected by mental disorders every year [1].
82 Psychotherapy is the preferred treatment for these disorders and is commonly offered in
83 inpatient, day-care, or outpatient settings, with approximately 30 % of patients with mental
84 disorders attending outpatient psychotherapy [2]. In Germany, costs for these treatments are
85 usually covered by the respective health insurance schemes [3]. Which interventions are
86 accepted and financed is regulated by the psychotherapy guideline ('Psychotherapierichtlinie');
87 for example, the type of psychotherapy (psychodynamic and cognitive behavioral
88 psychotherapy) or its duration (short- and long-term psychotherapy as well as the
89 corresponding probatory sessions) (for details on the German psychotherapeutic system see
90 [3,4]).

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

112 To improve access to psychotherapeutic care, it is important to understand the access routes
113 to outpatient psychotherapy in Germany. In terms of stepped care, GPs are of particular
114 importance for patients with mental disorders as they are usually the first and main contact
115 person [22]. Three-quarters of patients with mental disorders are treated exclusively by their
116 GP [23,24], indicating high barriers for referral to psychotherapy in primary care [25]. The
117 aforementioned difficulties in accessing a psychotherapist, long waiting times, and low flexibility
118 prior to the reform often caused reluctance among GPs to recommend psychotherapy to
119 patients [24]. Furthermore, patients either feared stigmatization should they attend
120 psychotherapy or did not have an appropriate understanding of what psychotherapy options
121 were available or of the routes of access to treatment [26]. In particular, for patients with cMPs
122 the diagnosis of a mental disorder is often challenging for the GP due to the symptomatic
123 overlap of mental disorders and physical diseases [27]. The new option of short-term
124 consultations and assessment sessions with a psychotherapist could help to overcome such

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3 125 diagnostic problems. Consequently, patients with cMPs should particularly benefit from the
4 126 reform due to the reduced waiting times and improved access to psychotherapy.

6 127 Since the introduction of the reform, preliminary evidence shows that the number of patients
7 128 having contact with a psychotherapist has increased and the time to first contact has
8 129 decreased, but initiation of psychotherapy itself has decreased [28,29]. This concurs with the
9 130 results of a survey of psychotherapists, in which more than half of them report that the reform
11 131 has not resulted in significant improvement of care for their patients [30]. However, other than
12 132 these general and short-term results, no studies have been conducted on the extent to which
14 133 the care situation has changed for specific subgroups, such as patients with cMPs. There are
15 134 nor objective analyses with routine data, nor are there any from the subjective perspectives of
16 135 GPs, psychotherapists, or patients with cMPs compared to patients with MnoPs. In addition,
17 136 insights into the practical implementation of the new elements (e.g. psychotherapeutic
19 137 consultation times, acute short-term psychotherapeutic interventions, or relapse prophylaxis)
20 138 offered by the psychotherapists are currently lacking. Finally, it remains unclear whether the
21 139 new measures actually shortened waiting times and reduced access barriers for patients at
22 140 higher risk, such as patients with cMPs.

24 141 **Conceptual framework**

26 142 The ES-RiP evaluation concept of the reform of the psychotherapy guideline is based on the
27 143 theoretical 'throughput model' by Schrappe and Pfaff [31] which describes relevant interacting
28 144 factors in the health care system and can be used to analyze the success of health care
29 145 interventions. The model differentiates four phases: In the 'input phase', a significant
30 146 organizational intervention such as the reform of the psychotherapy guideline first meets up
31 147 with specific patient and provider groups. Following the input phase, the model describes the
32 148 transformation process of such a reform ('throughput phase'), the resulting treatment offers
33 149 ('output phase'), and the direct outcomes for patients and society ('outcome phase'). The ES-
34 150 RiP project specifically considers the various modifying factors by including different
35 151 perspectives as well as different data sources to identify facilitating factors as well as barriers
36 152 for implementation. The success of the transformation process and the benefits of the reform
37 153 are reflected by societally relevant objective treatment parameters and patients' subjective
38 154 treatment results. Therefore, based on the throughput model the ES-RiP approach pursues an
39 155 **outcome evaluation** (throughput model: outcome) and a **process evaluation** (throughput
40 156 model: throughput and output) while giving special attention to patients with cMPs.

46 157 **Aim**

48 158 The aim of the ES-RiP project is a comprehensive evaluation of the reform of the
49 159 psychotherapy guideline and its effects on patients with cMPs compared to patients with
50 160 MnoPs. Considering pre- to post-reform changes, a multilevel approach which triangulates
51 161 different data-sources and mixed methods will be applied to investigate the following
52 162 objectives:

- 55 163 – Based on secondary data from the SHI company BARMER, we will test the hypotheses
56 164 that contacts with psychotherapists increased while waiting times for psychotherapy
57 165 decreased more in patients with cMPs compared to patients with MnoPs (substudy I).
- 59 166 – Regarding the patients' perspectives, we will examine their present health problems,
60 167 morbidity, medical referral, possible barriers for accessing psychotherapy, and patient

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3 168 satisfaction with waiting times and care among patients with cMPs and MoPs pre- and
4 169 post-reform (substudy II).Based on secondary data from the National Association of
5 170 Statutory Health Insurance Physicians, we will examine changes from the providers'
6 171 perspective in terms of offered services, the spectrum of diagnoses, variability across
7 172 psychotherapists, therapeutic settings, therapy duration, therapy procedures, and
8 173 regional impacts (substudy III).
9
10 174 – Regarding the service providers' perspective (GPs and psychotherapists), we will
11 175 assess reform-associated changes in the delivery and perception of psychotherapeutic
12 176 interventions (substudy IV).
13
14 177 – Regarding the payers' perspective, we will analyze health economic changes in terms
15 178 of direct and indirect costs of outpatient psychotherapy (substudy I).

179 **Methods and analysis**

180 **Study design**

181 The reform of the psychotherapy guideline is considered a complex intervention, and therefore,
182 its evaluation follows different methodological approaches [32]. A mixed-methods-design
183 (quantitative, qualitative) along with a multilevel approach (patients, service providers, payers)
184 triangulating several data sources (primary and secondary data) will be applied to evaluate the
185 reform from different perspectives. With respect to the underlying data sources, the overall
186 project is divided into four substudies (for more information on the respective data sources,
187 see 'substudies and samples'). The throughput model offers a theoretical framework for this
188 approach, making it possible to conduct an outcome evaluation of the reform as well as an
189 evaluation of the reform process:

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

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

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206 *Please insert figure 1 here*

208 **Substudies and Samples**

209 The ES-RiP project consists of a very complex evaluation scheme that is based on four
210 independent substudies whose results will be triangulated to answer the study aims from

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3 211 different perspectives and by using distinct data sources. We will use primary data collected
4 212 as part of the ES-RiP project from patients (substudy I) and providers (substudy IV). In addition,
5 213 our analyses will be based on routine data collected by the health insurance company
6 214 BARMER (= BARMER SHI data) as well as the SHI data from the National Association of
7 215 Statutory Health Insurance Physicians. In Germany, both data sources are considered SHI
8 216 data. BARMER SHI data include only those also insured with BARMER, allowing for analyses
9 217 from patients' and payers' perspectives. SHI data from the National Association of Statutory
10 218 Health Insurance Physicians (= overall SHI data) are structured according to care providers
11 219 and include data of all those insured with the SHI in Germany (including BARMER data but
12 220 also data from other health insurance companies). For example, BARMER SHI data allow for
13 221 analyses regarding the proportion of patients diagnosed with depression. We thereby might
14 222 analyze whether a person has actually made use of psychotherapy. Overall SHI data, however,
15 223 will only allow for analyses of those persons treated by, e.g., a psychotherapist, and therefore,
16 224 offering information on only those persons diagnosed with, e.g., depression who are already
17 225 in psychotherapy. We provide detailed information regarding the samples from the four
18 226 substudies (see also Table 1; note that the year of the reform (2017) will be considered a
19 227 transition period):

20 228 Substudy I: Based on the BARMER SHI data, analyses will be conducted to address the
21 229 patients' and payers' perspectives. BARMER is a nationwide SHI company with over 8 million
22 230 policyholders (> 10 % of the German population). For research purposes, BARMER holds
23 231 pseudonymized data on nearly every aspect of health related services in a scientific data
24 232 warehouse. To evaluate the effects of the reform, we will compare patients with cMPs to
25 233 patients with MnoPs pre-reform (2009-2016) to post-reform (2018-2019).

26 234 Substudy II): A representative population-based phone survey of patients with cMPs as well
27 235 as patients with MnoPs will be conducted to gather subjective patient information. The survey
28 236 will include a screening of approximately 28,600 people to ensure that the participants will
29 237 belong to one of the following three groups:

- 30 238 – Group (A): n = 600 participants who wanted to see a psychotherapist but were unable
31 239 to achieve psychotherapeutic face-to-face contact pre- or post-reform,
32 240 – Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention
33 241 from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform), and
34 242 – Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention
35 243 from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform).

36 244 Substudy III): Based on overall SHI data, we will analyze data from the providers' perspective.
37 245 The data cover all SHI insured persons in Germany (only residents with private health
38 246 insurance are excluded), which amounts to approximately 70 million individuals. Sample
39 247 selection will be aligned to substudy I) using diagnostic codes of the International Classification
40 248 of Diseases 10th revision (ICD-10) to identify all patients with relevant somatic and mental
41 249 diagnoses (see below for the detailed inclusion and exclusion criteria). We will compare
42 250 patients with cMPs to patients with MnoPs pre-reform (20015-2016) to post-reform (2018-
43 251 2019).

44 252 Substudy IV): To gather additional service provider information on the treatment of patients
45 253 with cMPs and patients with MnoPs, focus groups, a nationwide survey, interviews and

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3 254 observations of psychotherapists will be conducted using a sequential four-stage (qualitative-
4 255 quantitative-qualitative-qualitative) design [33].

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6 256 – Focus groups: Four group discussions with $n = 10$ participants at a time, separately for
7 257 each profession (GPs and psychotherapists), will be used to generate themes for the
8 258 survey questionnaire.

9
10 259 – Surveys: GPs and psychotherapists (each $n = 1,200$) who were affected by the reform.

11
12 260 – Interviews and observations on current practice post-reform: $n = 40$ psychotherapists will
13 261 be interviewed and $n = 10$ will be observed.

14
15 262 In 2021 and therefore 4 years after the reform, providers will be asked about the extent of
16 263 perceived differences in the care of patients with cMPs and with MnoPs before and after the
17 264 reform.

18
19 265 Table 1 gives a detailed overview of the substudies and the respective data sources,
20 266 perspectives, types of evaluation, inclusion/exclusion criteria, outcomes, and sample sizes,
21 267 while Figure 2 offers an overview of the ES-RiP approach integrated into the throughput model.

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26 269 *Please insert Table 1 here*

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30 271 *Please insert Figure 2 here*

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33 273 **Sample Size Calculation**

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35 274 For substudies I and III, the full available routine data sets of the BARMER and the National
36 275 Association of Statutory Health Insurance Physicians will be used. This allows for sufficient
37 276 statistical power to detect even small effect sizes.

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39 277 For substudies II and IV, sample sizes are based on number of cases in similar studies and
40 278 considerations on clinical relevance as well as empirically founded recommendations [25,34]:

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42 279 Substudy II): For the population-based phone survey, three target groups are to be
43 280 differentiated. The group most difficult to reach (Group C) due to the shortness of the survey
44 281 period (2018 to 2019) was the basis for the calculations. With a preplanned sample size of
45 282 $n = 1,000$ (post-reform) we estimated the numbers needed to be contacted in the population-
46 283 based survey of patients. Given an incidence of 3.5 % new cases in the general population of
47 284 Germany who are in need of psychotherapy [35], this leads to $n = 28,571$ screenings
48 285 necessary to be performed for identifying them. Rounding up, we planned for $N = 28,600$
49 286 screenings to reach sufficient interviews for Group C. Based on these considerations, the
50 287 estimated N for the other groups would result in $n = 2,286$ interviews (Group B) and $n = 1,430$
51 288 interviews (Group A), respectively.

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55 289 Substudy IV): We followed empirically based recommendations for sample sizes when using
56 290 qualitative methods [36,37]. For the quantitative surveys, we aimed at high precision of the
57 291 results with at least 90 % confidence for estimates even when the two groups of
58 292 psychotherapists (medical and psychological psychotherapists) were analyzed separately.
59 293 Therefore, $n = 1,200$ participating psychotherapists and general practitioners were determined

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3 294 to be sufficient. Based on experiences from our own prior studies, we expected a participation
4 295 rate of 30 %, thus, resulting in 4,000 invitation letters each.

6 296 **Inclusion and Exclusion Criteria**

8 297 For substudies I to III, we will only include participants who are 18 to 79 years old. We will
9 298 exclude participants if they have an organic, including symptomatic, mental disorder (ICD-10:
10 299 F00-F09) or mental retardation (ICD-10: F70-F79).

12 300 The following specific inclusion and exclusion criteria will be applied for the subsequent
13 301 substudies:

15 302 Substudy I): We will include persons with specified mental disorders diagnosed in 2015, 2016,
16 303 2018 and 2019 and exclude persons with contact with a psychotherapist within the 2 preceding
18 304 years.

19 305 Substudy II): We will include participants with sufficient German language skills, cognitive
20 306 proficiency, and informed verbal consent to participate in the study. Furthermore, participants
22 307 will be screened to fulfill the requirements of belonging to either Group A (no face-2-face
23 308 contact), Group B (psychotherapy pre-reform), or Group C (psychotherapy post-reform) (for
24 309 further details, see Substudies and Samples).

26 310 Substudy IV): Psychotherapists and GPs who will be included in the focus groups, interviews
27 311 (psychotherapists only), and surveys have to fulfill the following criteria:

- 29 312 – Psychotherapists: Entry in the medical register of the National Association of Statutory
30 313 Health Insurance Physicians under 'psychological psychotherapists' or 'medical
31 314 psychotherapists'; treatment of adults; psychotherapeutic practice since at least 2015
32 315 (2 years prior to reform); informed consent.
- 34 316 – GPs: Entry in the medical register of the National Association of Statutory Health
35 317 Insurance Physicians under the group 'general practitioner' (internal or general
36 318 medicine); primary care work since at least 2015 (2 years prior to reform); informed
37 319 consent.

40 320 **Data collection**

41 321 For substudies I) and III), secondary data will be obtained from the health insurance company
42 322 BARMER and the National Association of Statutory Health Insurance Physicians. For
43 323 substudies II) and IV), we will collect the following primary data:

46 324 Substudy II): The representative population-based phone survey will be conducted nationwide
47 325 from the last quarter of 2020 to the last quarter of 2021 (11 months) in the form of a structured
48 326 interview that also includes open questions. Data will be collected by the independent
49 327 demography research institute USUMA Berlin. Interviews will be administered by trained
50 328 interviewers. Within 258 predefined regions households will be selected by a random route
51 329 procedure. In households with multiple persons, one person will be randomly selected using
52 330 the Kish-Selection Grid. To accomplish the defined sample sizes (Group A: n = 600; Group B;
53 331 n = 1,000; Group C: n = 1,000), households will be contacted until these numbers are reached,
54 332 or at least N = 28,600 households have been screened.

58 333 Substudy IV): In the first phase of substudy IV (last quarter of 2020), we will conduct focus
59 334 groups to derive relevant topics and items for the construction of the survey questionnaire
60 335 separately for GPs and psychotherapists along a semi-standardized moderation guide [38].

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3 336 Participants will be recruited from cooperating institutions of the consortium. For the second
4 337 phase (second and third quarter of 2021), we will conduct a nationwide postal survey. Here,
5 338 eligible participants (GPs and psychotherapists) will be recruited from a random sample of GPs
6 339 and psychotherapists listed in the national SHI registries. The addresses will be supplied by
7 340 the SHI. In the third phase (last quarter of 2021), study participants for semi-guided interviews
8 341 regarding the practical implementation of the new psychotherapeutic elements will be drawn
9 342 from a group of participants in the survey who have agreed to further participation. In a similar
10 343 way and to supplement the interviews, 10 more participants will be recruited for subsequent
11 344 focused non-participant observations of psychotherapists in their practice (first quarter of 2022)
12 345 [39,40].

16 346 **Outcome Measures**

17 347 **Primary Outcomes**

18 348 Based on the BARMER SHI data (substudy I), pre- to post-reform changes in 1) contact rates
19 349 with psychotherapists and 2) waiting time between primary contact and initiation of
20 350 psychotherapeutic treatment in the two subgroups of patients a) with cMPs and b) MnoPs will
21 351 be assessed.

22 352 **Secondary Outcomes**

23 353 Substudy I): In addition to the primary outcomes, BARMER SHI data will also comprise health
24 354 economic parameters such as direct treatment costs and indirect costs, e.g., sick leave days.

25 355 Substudy II): The phone survey will gather data on subjective patient outcomes regarding
26 356 experiences within the psychotherapeutic system. The phone survey will address health
27 357 problems, the course of the health problems, medical referral, satisfaction with the waiting time
28 358 and treatment, quality of life, morbidity, and access barriers.

29 359 Substudy III): Based on the overall SHI data, changes in the care procedures will be examined:
30 360 frequency of psychotherapeutic offers (including the new psychotherapeutic measures),
31 361 spectrum of diagnoses, variability across psychotherapists, therapeutic settings, therapy
32 362 duration and therapy procedures as well as regional impacts.

33 363 Substudy IV): Focus groups and surveys with GPs and psychotherapists will be conducted to
34 364 examine the process and effects of the reform from the perspective of the service providers.
35 365 Special attention will be given to knowledge about the reform, perceived task shifts, benefits
36 366 and adverse effects, cooperation between GPs and psychotherapists, referral problems, and
37 367 perceived differences for patients with cMPs compared to MnoPs in the context of the reform.
38 368 In addition, psychotherapists will be interviewed and their practices observed to gain deeper
39 369 insights into the implementation of the reform with regard to formal aspects and content
40 370 (indications, methods and techniques, networking, best practice examples) as well as the
41 371 organizational context.

42 372 **Data analysis**

43 373 Substudy I): Analysis of BARMER SHI data is carried out according to 'Good Practice of
44 374 Secondary Data Analysis (GPS)' [41]. To test the first primary hypothesis regarding differences
45 375 in the utilization of psychotherapeutic offers between patients with cMPs and MnoPs from pre-
46 376 to post-reform, different binary logistic regression analyses will be conducted with contacts to
47 377 psychotherapists (yes/no) as a dependent variable. The independent variables are cMPs and
48 378 MnoPs (as in another model the interaction term of cMPs/MnoPs and time pre-/post-reform),

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3 379 while age, gender and regional supply status will be included as control variables. The second
4 380 primary hypothesis regarding a higher reduction in waiting times for psychotherapy after the
5 381 reform for MnoPs compared to cMPs will be tested in linear regression models. Secondary
6 382 outcomes will be analyzed in a descriptive manner. We will report estimates with 95%
7 383 confidence intervals and descriptive *p* value.

8
9 384 Substudy II): Descriptive analyses of the patient reported outcomes (phone survey) will focus
10 385 on differences between cMPs and MnoPs regarding the three Groups A to C.

11
12 386 Substudy III): Descriptive analyses of the overall SHI data will compare the care situation for
13 387 the patient groups of interest (cMPs vs. MnoPs) in different periods (pre-reform: 2015-2016;
14 388 year of the reform: 2017; post-reform: 2018-2019). Subgroup analyses will be conducted for
15 389 the physician/therapist group (medical or psychological psychotherapist), therapeutic settings
16 390 (individual therapy or group therapy), therapy duration (short-term therapy or long-term
17 391 therapy), therapy procedures (e.g., psychodynamic therapy or behavioral therapy), localization
18 392 of service provision (different regions in Germany) and coverage rate.

19
20 393 Substudy IV): Descriptive analyses of service provider data will focus on the degree of
21 394 implementation of the new measures (additional psychotherapeutic consultation times, acute
22 395 short-term psychotherapeutic interventions, and relapse prophylaxis) and perceived effects on
23 396 patients with cMPs. Quantitative data from surveys will be analyzed on an overall level as well
24 397 as for subgroups of physicians and therapists (medical or psychological psychotherapist).
25 398 Qualitative data generated in the focus groups and interviews with GPs and psychotherapists
26 399 will be subjected to thematic analyses using MAXQDA software. Observation notes will be
27 400 analyzed to complement the interviews, particularly in terms of contrary evidence and context.

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33 402 **Patient and public involvement statement**

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35 403 A representative of the German Working Group Self-Help Groups (Deutsche
36 404 Arbeitsgemeinschaft Selbsthilfegruppen [DAG SHG]) has been involved as a member of a
37 405 scientific advisory board taking place at the very beginning of the project as well as its final
38 406 stage. The planned study design, proceedings, and addressed content will be discussed at a
39 407 very early stage (three months after the project has started) with the advisory board including
40 408 the patient representative. Near the end of the project, when the results are ready, we will
41 409 discuss our findings, proceedings, and strategies for dissemination with the advisory board
42 410 (again including the same patient representative) to gain their input regarding our possible
43 411 conclusions.

44 412 **Ethics and dissemination**

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46
47 413 This study is registered at the German Clinical Trial Register (DRKS-ID: DRKS00020344; 23.
48 414 July 2020) and can also be found at
49 415 <https://trialssearch.who.int/Trial2.aspx?TrialID=DRKS00020344>. Ethical approval for the overall
50 416 project was obtained from the Ethics Committee of the Justus Liebig University Giessen and
51 417 Marburg – Faculty of Medicine (approval number: AZ 107/20; 6th October 2020). Given that
52 418 the overall project is based on four substudies located in different parts of Germany, one of the
53 419 substudies collecting primary data required additional ethical approval. For substudy IV),
54 420 approval was obtained from the Ethics Committee Heidelberg (approval number: S-466/2020).
55 421 With regard to SHI data, the approval for the overall study sufficed, and no additional approval
56 422 was needed. Analyses of secondary data will be based on pseudonymized (BARMER) and
57 423 anonymized (National Association of Statutory Health Insurance Physicians) datasets. The

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3 424 secondary data can be linked neither to each other nor to the primary data collected in this
4 425 study. Hence, according to the 'Good Practice of Secondary Data Analysis (GPS): guidelines
5 426 and recommendations' [41], no additional ethics approval or informed consent is necessary.

7 427 The patient survey will be conducted in accordance with the Declaration of Helsinki and will
8 428 fulfill the ethical guidelines of the International Code of Marketing and Social Research Practice
9 429 of the International Chamber of Commerce and the European Society of Opinion and
11 430 Marketing Research.

13 431 Findings will be disseminated through national and international psychotherapy and health
14 432 services research journals and will be presented at relevant conferences and meetings.

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For peer review only

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11 **Contributors:** HK drafted this manuscript. MH contributed to the writing of the manuscript.
12 The study's principal investigators JK, HCF, GH, TGG, JS, and BW designed the study and
13 obtained the funding. HK, JK, HCF, and MH obtained the ethics' approval. TGG and UM
14 contributed to the specific design of substudy I and edited the manuscript. HK and JK
15 contributed to the specific design of substudy II. JK supervised and edited the manuscript. GF
16 and AC contributed to the specific design of substudy III and edited the manuscript. MH, HCF,
17 and JS contributed to the specific design of substudy IV and edited the manuscript. All authors
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21

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27

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30 Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-
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Table 1: Overview of the most important characteristics of the respective substudies

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	data source	perspective	evaluation	inclusion & exclusion criteria	outcomes	sample size
1 2 3 4 5 6 7 8 9 10 11 12 13 substudy I	BARMER SHI data	patients payers	outcome evaluation health economic 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)	<ul style="list-style-type: none"> 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 health economic changes (direct treatment costs as well as indirect costs) 	available health insurance data from the BARMER company (approximately 8 million policyholders) available health insurance data from the BARMER company
14 15 16 17 18 19 20 21 22 23 24 25 26 substudy II	population-based phone survey	patients	outcome evaluation	<p>sufficient German language skills; cognitive proficiency; informed verbal consent to study participation</p> <p>group (A) participants who wanted to see a psychotherapist but were unable to achieve a primary psychotherapeutic face-to-face contact</p> <p>group (B) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform)</p> <p>group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform)</p>	<ul style="list-style-type: none"> 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
27 28 29 30 31 32 33 34 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)	<ul style="list-style-type: none"> 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)
35 36 37 38 39 40 41 42 43 44 45 46 substudy IV	<p>psychotherapists: focus groups, survey, interviews & observations</p> <p>GPs: focus groups & survey</p>	service providers service providers	process evaluation process evaluation	<p>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</p> <p>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</p>	<ul style="list-style-type: none"> 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 MnOP formal aspects and content of new measures (methods and techniques, networking, best practice examples) 	<p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>interviews: N = 40</p> <p>survey: N = 1,200</p> <p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>survey: N = 1,200</p>

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

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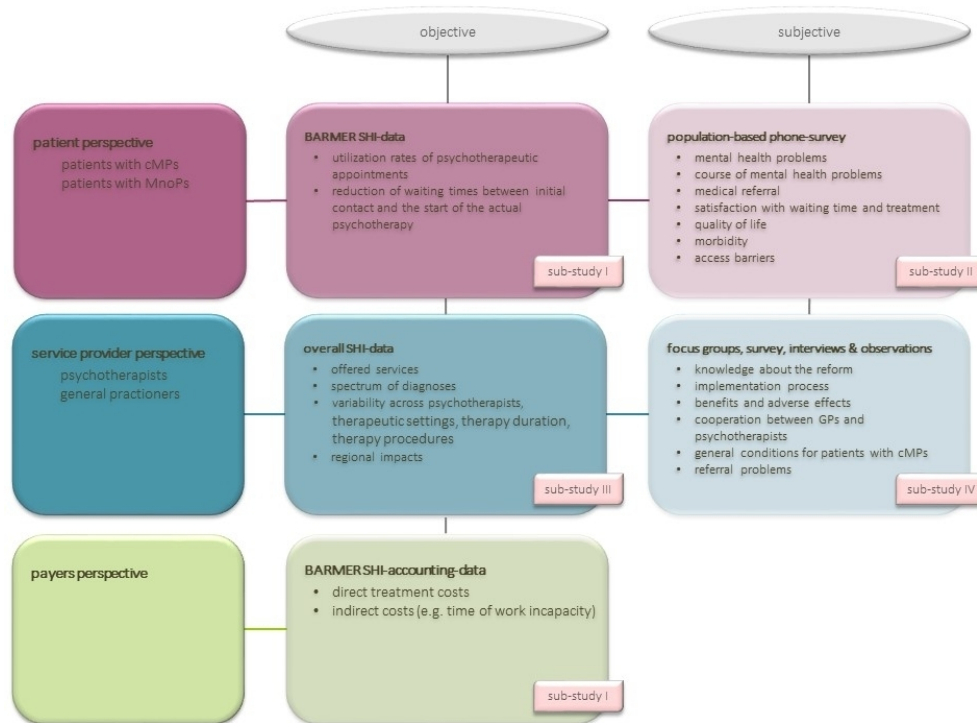


Figure 1: The ES-RiP approach embedded in the Throughput-Model

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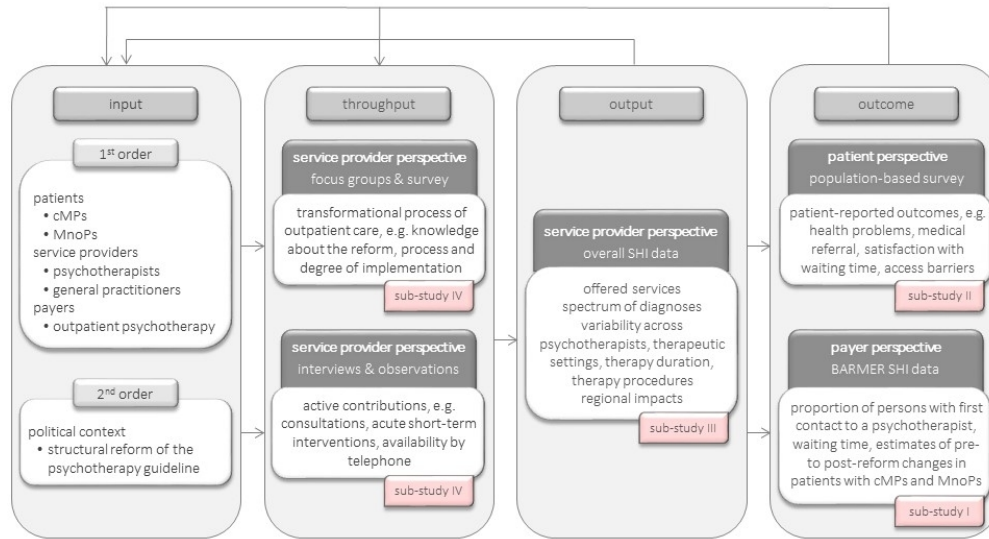


Figure 2: An overview of the three ES-RiP-perspectives (patients, service providers and payers) integrated in a multi-level approach, also including the respective data sources, major outcomes, and corresponding substudies

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BMJ Open

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

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

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26
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Abbreviations

32 cMPs comorbidity of mental disorders and chronic physical conditions

33 GP general practitioner

34 ICD International Classification of Diseases

35 MnoP mental disorders but no chronic physical condition

36 SHI statutory health insurance

37 Abstract

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

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

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

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

63 Strengths and limitations of this study

- 64 • By applying the conceptual framework of the throughput model, this study will conduct
65 both outcome and process evaluation, and thus will allow for deeper insights and a
66 founded understanding of the results and possible limitations of the structural reform of
67 the psychotherapy guideline in 2017.
- 68 • Based on a mixed-methods design (quantitative and qualitative) along with a multilevel
69 approach (patients, service providers, and payers), the different perspectives and
70 various data sources (primary and secondary data) will be triangulated to evaluate the
71 reform.
- 72 • Analyses of statutory health insurance (SHI) data come with inherent limitations such as
73 possibly invalid diagnoses or clinically meaningless statistically significant results due to
74 the large number of included cases.
- 75 • Data from the representative population-based survey (substudy II) are based on
76 participants' self-reports and a broad retrospective inquiry period (starting from 2012);
77 therefore, the results will have to be interpreted with caution.

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3 78 • The validity of results on the provider perspective will highly depend on the participation
4 79 rate in focus groups, surveys, interviews, and observations.
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80 Introduction

81 In Germany, nearly 18 million people are affected by mental disorders every year [1].
82 Psychotherapy is the preferred treatment for these disorders and is commonly offered in
83 inpatient, day-care, or outpatient settings, with approximately 30 % of patients with mental
84 disorders attending outpatient psychotherapy [2]. In Germany, costs for these treatments are
85 usually covered by the respective health insurance schemes [3]. Which interventions are
86 accepted and financed is regulated by the psychotherapy guideline ('Psychotherapierichtlinie');
87 for example, the type of psychotherapy (psychodynamic and cognitive behavioural
88 psychotherapy) or its duration (short- and long-term psychotherapy as well as the
89 corresponding probatory sessions) (for details on the German psychotherapeutic system see
90 [3,4]).

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

112 To improve access to psychotherapeutic care, it is important to understand the access routes
113 to outpatient psychotherapy in Germany. In terms of stepped care, GPs are of particular
114 importance for patients with mental disorders as they are usually the first and main contact
115 person [22]. Three-quarters of patients with mental disorders are treated exclusively by their
116 GP [23,24], indicating high barriers for referral to psychotherapy in primary care [25]. The
117 aforementioned difficulties in accessing a psychotherapist, long waiting times, and low
118 flexibility prior to the reform often caused reluctance among GPs to recommend psychotherapy
119 to patients [24]. Furthermore, patients either feared stigmatisation should they attend
120 psychotherapy or did not have an appropriate understanding of what psychotherapy options
121 were available or of the routes of access to treatment [26]. In particular, for patients with cMPs
122 the diagnosis of a mental disorder is often challenging for the GP due to the symptomatic
123 overlap of mental disorders and physical diseases [27]. The new option of short-term
124 consultations and assessment sessions with a psychotherapist could help to overcome such

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3 125 diagnostic problems. Consequently, patients with cMPs should particularly benefit from the
4 126 reform due to the reduced waiting times and improved access to psychotherapy.

6 127 Since the introduction of the reform, preliminary evidence shows that the number of patients
7 128 having contact with a psychotherapist has increased and the time to first contact has
8 129 decreased, but initiation of psychotherapy itself has decreased [28,29]. This concurs with the
9 130 results of a survey of psychotherapists, in which more than half of them report that the reform
11 131 has not resulted in significant improvement of care for their patients [30]. However, other than
12 132 these general and short-term results, no studies have been conducted on the extent to which
14 133 the care situation has changed for specific subgroups, such as patients with cMPs. There are
15 134 nor objective analyses with routine data, nor are there any from the subjective perspectives of
16 135 GPs, psychotherapists, or patients with cMPs compared to patients with MnoPs. In addition,
17 136 insights into the practical implementation of the new elements (e.g. psychotherapeutic
19 137 consultation times, acute short-term psychotherapeutic interventions, or relapse prophylaxis)
20 138 offered by the psychotherapists are currently lacking. Finally, it remains unclear whether the
21 139 new measures actually shortened waiting times and reduced access barriers for patients at
22 140 higher risk, such as patients with cMPs.

24 141 **Conceptual framework**

26 142 The ES-RiP evaluation concept of the reform of the psychotherapy guideline is based on the
27 143 theoretical 'throughput model' by Schrappe and Pfaff [31] which describes relevant interacting
28 144 factors in the health care system and can be used to analyse the success of health care
29 145 interventions. The model differentiates four phases: In the 'input phase', a significant
30 146 organisational intervention such as the reform of the psychotherapy guideline first meets up
31 147 with specific patient and provider groups. Following the input phase, the model describes the
32 148 transformation process of such a reform ('throughput phase'), the resulting treatment offers
33 149 ('output phase'), and the direct outcomes for patients and society ('outcome phase'). The ES-
34 150 RiP project specifically considers the various modifying factors by including different
35 151 perspectives as well as different data sources to identify facilitating factors as well as barriers
36 152 for implementation. The success of the transformation process and the benefits of the reform
37 153 are reflected by societally relevant objective treatment parameters and patients' subjective
38 154 treatment results. Therefore, based on the throughput model the ES-RiP approach pursues an
39 155 **outcome evaluation** (throughput model: outcome) and a **process evaluation** (throughput
40 156 model: throughput and output) while giving special attention to patients with cMPs.

46 157 **Aim**

48 158 The aim of the ES-RiP project is a comprehensive evaluation of the reform of the
49 159 psychotherapy guideline and its effects on patients with cMPs compared to patients with
50 160 MnoPs. Considering pre- to post-reform changes, a multilevel approach which triangulates
51 161 different data-sources and mixed methods will be applied to investigate the following
52 162 objectives:

- 55 163 – Based on secondary data from the statutory health insurance (SHI) company BARMER,
56 164 we will test the hypotheses that contacts with psychotherapists increased while waiting
57 165 times for psychotherapy decreased more in patients with cMPs compared to patients
58 166 with MnoPs (substudy I).

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3 167 – Regarding the patients' perspectives, we will examine their present health problems,
4 168 morbidity, medical referral, possible barriers for accessing psychotherapy, and patient
5 169 satisfaction with waiting times and care among patients with cMPs and MoPs pre- and
6 170 post-reform (substudy II). Based on secondary data from the National Association of
7 171 Statutory Health Insurance Physicians, we will examine changes from the providers'
8 172 perspective in terms of offered services, the spectrum of diagnoses, variability across
9 173 psychotherapists (e.g. medical or psychological psychotherapists), therapeutic settings,
10 174 therapy duration, therapy procedures, and regional impacts (substudy III).
- 11 175 – Regarding the service providers' perspective (GPs and psychotherapists), we will
12 176 assess reform-associated changes in the delivery and perception of psychotherapeutic
13 177 interventions (substudy IV).
- 14 178 – Regarding the payers' perspective, we will analyse health economic changes in terms
15 179 of direct and indirect costs of outpatient psychotherapy (substudy I).

180 **Methods and analysis**

181 **Study design**

182 The reform of the psychotherapy guideline is considered a complex intervention, and therefore,
183 its evaluation follows different methodological approaches [32, 33]. A sequential QUANT-qual
184 mixed-methods-design along with a multilevel approach (patients, service providers, payers)
185 triangulating several data sources (primary and secondary data) will be applied to evaluate the
186 reform from different perspectives. With respect to the underlying data sources, the overall
187 project is divided into four substudies (for more information on the respective data sources,
188 see 'substudies and samples'). The throughput model offers a theoretical framework for this
189 approach, making it possible to conduct an outcome evaluation (which is the primary objective
190 of the ES-RiP project) of the reform as well as an evaluation of the reform process:

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

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

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207 *Please insert figure 1 here*
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209 **Substudies and Samples**

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

220 SHI data from the National Association of Statutory Health Insurance Physicians (= overall SHI
221 data) are structured according to care providers and include data of all those insured with the
222 SHI in Germany (including BARMER data but also data from other health insurance
223 companies). For example, BARMER SHI data allow for analyses regarding the proportion of
224 patients diagnosed with depression. We thereby might analyse whether a person has actually
225 made use of psychotherapy. Overall SHI data, however, will only allow for analyses of those
226 persons treated by, e.g., a psychotherapist, and therefore, offering information on only those
227 persons diagnosed with, e.g., depression who are already in psychotherapy. We provide
228 detailed information regarding the samples from the four substudies (see also Table 1; note
229 that the year of the reform (2017) will be considered a transition period):

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

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

- 240 – Group (A): n = 600 participants who wanted to see a psychotherapist but were unable
241 to achieve psychotherapeutic face-to-face contact pre- or post-reform,
- 242 – Group (B): n = 1,000 participants who had at least one psychotherapeutic intervention
243 from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform), and
- 244 – Group (C): n = 1,000 participants who had at least one psychotherapeutic intervention
245 from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform).

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

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

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

262 In 2021 and therefore 4 years after the reform, providers will be asked about the extent of
263 perceived differences in the care of patients with cMPs and with MnoPs before and after the
264 reform.

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

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269 *Please insert Table 1 here*

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271 *Please insert Figure 2 here*

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273 **Sample Size Calculation**

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

277 For substudies II and IV, sample sizes are based on number of cases in similar studies and
278 considerations on clinical relevance as well as empirically founded recommendations [25,34]:

279 Substudy II): For the population-based phone survey, three target groups are to be
280 differentiated. The group most difficult to reach (Group C) due to the shortness of the survey
281 period (2018 to 2019) was the basis for the calculations. With a preplanned sample size of
282 $n = 1,000$ (post-reform) we estimated the numbers needed to be contacted in the population-
283 based survey of patients. Given an incidence of 3.5 % new cases in the general population of
284 Germany who are in need of psychotherapy [35], this leads to $n = 28,571$ screenings
285 necessary to be performed for identifying them. Rounding up, we planned for $N = 28,600$
286 screenings to reach sufficient interviews for Group C. Based on these considerations, the
287 estimated N for the other groups would result in $n = 2,286$ interviews (Group B) and $n = 1,430$
288 interviews (Group A), respectively.

289 Substudy IV): We followed empirically based recommendations for sample sizes when using
290 qualitative methods [36,37]. For the quantitative surveys, we aimed at high precision of the
291 results with at least 90 % confidence for estimates even when the two groups of
292 psychotherapists (medical and psychological psychotherapists) were analysed separately.

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3 293 Therefore, n = 1,200 participating psychotherapists and general practitioners were determined
4 294 to be sufficient. Based on experiences from our own prior studies, we expected a participation
5 295 rate of 30 %, thus, resulting in 4,000 invitation letters each.

7 296 **Inclusion and Exclusion Criteria**

9 297 For substudies I to III, we will only include participants who are 18 to 79 years old. We will
10 298 exclude participants if they have an organic, including symptomatic, mental disorder (ICD-10:
11 299 F00-F09) or mental retardation (ICD-10: F70-F79).

13 300 The following specific inclusion and exclusion criteria will be applied for the subsequent
14 301 substudies:

16 302 Substudy I): We will include persons with specified mental disorders diagnosed in 2015, 2016,
17 303 2018 or 2019 and exclude persons with contact with a psychotherapist within the 2 preceding
18 304 years.

20 305 Substudy II): We will include participants with sufficient German language skills, cognitive
21 306 proficiency, and informed verbal consent to participate in the study. Furthermore, participants
22 307 will be screened to fulfil the requirements of belonging to either Group A (no face-2-face
23 308 contact), Group B (psychotherapy pre-reform), or Group C (psychotherapy post-reform) (for
24 309 further details, see Substudies and Samples).

26 310 Substudy IV): Psychotherapists and GPs who will be included in the focus groups, interviews
27 311 (psychotherapists only), and surveys have to fulfil the following criteria:

- 30 312 – Psychotherapists: Entry in the medical register of the National Association of Statutory
31 313 Health Insurance Physicians under 'psychological psychotherapists' or 'medical
32 314 psychotherapists'; treatment of adults; psychotherapeutic practice since at least 2015
33 315 (2 years prior to reform); informed consent.
- 35 316 – GPs: Entry in the medical register of the National Association of Statutory Health
36 317 Insurance Physicians under the group 'general practitioner' (internal or general
37 318 medicine); primary care work since at least 2015 (2 years prior to reform); informed
38 319 consent.

41 320 **Data collection**

42 321 For substudies I) and III), secondary data will be obtained from the health insurance company
43 322 BARMER and the National Association of Statutory Health Insurance Physicians. For
44 323 substudies II) and IV), we will collect the following primary data:

46 324 Substudy II): The representative population-based phone survey will be conducted nationwide
47 325 from the last quarter of 2020 to the last quarter of 2021 (11 months) in the form of a structured
48 326 interview that also includes open questions. The interview was developed based on the works
49 327 of Albani and colleagues [25] and will comprise a screening as well as five respective topics:
50 328 psychotherapy, medication, somatic diseases, sociodemographic data, and dual-frame.
51 329 Patients with diabetes will additionally be asked about diabetes-related distress.

53 330 Data will be collected by the independent demography research institute USUMA Berlin.
54 331 Interviews will be administered by trained interviewers. Within 258 predefined regions
55 332 households will be selected by a random route procedure. In households with multiple persons,
56 333 one person will be randomly selected using the Kish-Selection Grid. To accomplish the defined
57 334 sample sizes (Group A: n = 600; Group B; n = 1,000; Group C: n = 1,000), households will be

335 contacted until these numbers are reached, or at least N = 28,600 households have been
336 screened.

337 Substudy IV): In the first phase of substudy IV (last quarter of 2020), we will conduct focus
338 groups to derive relevant topics and items for the construction of the survey questionnaire
339 separately for GPs and psychotherapists along a semi-standardised moderation guide [38].
340 Participants will be recruited from cooperating institutions of the consortium. For the second
341 phase (second and third quarter of 2021), we will conduct a nationwide postal survey. Here,
342 eligible participants (GPs and psychotherapists) will be recruited from a random sample of GPs
343 and psychotherapists listed in the national SHI registries. The addresses will be supplied by
344 the SHI. In the third phase (last quarter of 2021), study participants for semi-guided interviews
345 regarding the practical implementation of the new psychotherapeutic elements will be drawn
346 from a group of participants in the survey who have agreed to further participation. In a similar
347 way and to supplement the interviews, 10 more participants will be recruited for subsequent
348 focused non-participant observations of psychotherapists in their practice (first quarter of 2022)
349 [39,40].

350 **Outcome Measures**

351 ***Primary Outcomes***

352 Based on the BARMER SHI data (substudy I), pre- to post-reform changes in 1) contact rates
353 with psychotherapists and 2) waiting time between primary contact and initiation of
354 psychotherapeutic treatment in the two subgroups of patients a) with cMPs and b) MnoPs will
355 be assessed.

356 ***Secondary Outcomes***

357 Substudy I): In addition to the primary outcomes, BARMER SHI data will also comprise health
358 economic parameters such as direct treatment costs and indirect costs, e.g., sick leave days.

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

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

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

376 Data analysis

377 Substudy I): Analysis of BARMER SHI data is carried out according to 'Good Practice of
378 Secondary Data Analysis (GPS)' [41]. To test the first primary hypothesis regarding differences
379 in the utilisation of psychotherapeutic offers between patients with cMPs and MnoPs from pre-
380 to post-reform, different binary logistic regression analyses will be conducted with contacts to
381 psychotherapists (yes/no) as a dependent variable. The independent variables are cMPs and
382 MnoPs (as in another model the interaction term of cMPs/MnoPs and time pre-/post-reform),
383 while age, gender and regional supply status will be included as control variables. The second
384 primary hypothesis regarding a higher reduction in waiting times for psychotherapy after the
385 reform for MnoPs compared to cMPs will be tested in linear regression models. Secondary
386 outcomes will be analysed in a descriptive manner. We will report estimates with 95%
387 confidence intervals and descriptive *p* value.

388 Substudy II): Descriptive analyses of the patient reported outcomes (phone survey) will focus
389 on differences between cMPs and MnoPs regarding the three Groups A to C.

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

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

405

406 Patient and public involvement statement

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

416 Ethics and dissemination

417 This study is registered at the German Clinical Trial Register (DRKS-ID: DRKS00020344; 23.
418 July 2020) and can also be found at
419 <https://trialsearch.who.int/Trial2.aspx?TrialID=DRKS00020344>. Ethical approval for the overall

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3 420 project was obtained from the Ethics Committee of the Justus Liebig University Giessen and
4 421 Marburg – Faculty of Medicine (approval number: AZ 107/20; 6th October 2020). Given that
5 422 the overall project is based on four substudies located in different parts of Germany, one of the
6 423 substudies collecting primary data required additional ethical approval. For substudy IV,
7 424 approval was obtained from the Ethics Committee Heidelberg (approval number: S-466/2020).
8 425 With regard to SHI data, the approval for the overall study sufficed, and no additional approval
9 426 was needed. Analyses of secondary data will be based on pseudonymised (BARMER) and
10 427 anonymised (National Association of Statutory Health Insurance Physicians) datasets. The
11 428 secondary data can be linked neither to each other nor to the primary data collected in this
12 429 study. Hence, according to the ‘Good Practice of Secondary Data Analysis (GPS): guidelines
13 430 and recommendations’ [41], no additional ethics approval or informed consent is necessary.

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17 431 The patient survey will be conducted in accordance with the Declaration of Helsinki and will
18 432 fulfil the ethical guidelines of the International Code of Marketing and Social Research Practice
19 433 of the International Chamber of Commerce and the European Society of Opinion and
20 434 Marketing Research.

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23 435 Findings will be disseminated through national and international psychotherapy and health
24 436 services research journals and will be presented at relevant conferences and meetings.

437

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3 **Collaborators:** The ES-RiP-Consortium study group includes (organised alphabetically
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7 Doering, Regina; Saam, Joachim; Schumacher, Catharina; Szardenings, Carsten;
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11 **Contributors:** HK drafted this manuscript. MH contributed to the writing of the manuscript.
12 The study's principal investigators JK, HCF, GH, TGG, JS, and BW designed the study and
13 obtained the funding. HK, JK, HCF, and MH obtained the ethics' approval. TGG and UM
14 contributed to the specific design of substudy I and edited the manuscript. HK and JK
15 contributed to the specific design of substudy II. JK supervised and edited the manuscript. GF
16 and AC contributed to the specific design of substudy III and edited the manuscript. MH, HCF,
17 and JS contributed to the specific design of substudy IV and edited the manuscript. All authors
18 read and approved the final manuscript.
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30 Faculty of Medicine (approval number: AZ 107/20) and Heidelberg (approval number: S-
31 466/2020).
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Table 1: Overview of the most important characteristics of the respective substudies

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	data source	perspective	evaluation	inclusion & exclusion criteria	outcomes	sample size
1 2 3 4 5 6 7 8 9 10 11 12 13 substudy I	BARMER SHI data	patients payers	outcome evaluation health economic 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)	<ul style="list-style-type: none"> • 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 • health economic changes (direct treatment costs as well as indirect costs) 	available health insurance data from the BARMER company (approximately 8 million policyholders) available health insurance data from the BARMER company
14 15 16 17 18 19 20 21 22 23 24 25 26 substudy II	population-based phone survey	patients	outcome evaluation	<p>sufficient German language skills; cognitive proficiency; informed verbal consent to study participation</p> <p>group (A) participants who wanted to see a psychotherapist but were unable to achieve a primary psychotherapeutic face-to-face contact</p> <p>group (B) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2012 to the 1st quarter of 2017 (pre-reform)</p> <p>group (C) participants who had at least one psychotherapeutic intervention from the 1st quarter of 2018 to the 4th quarter of 2019 (post-reform)</p>	<ul style="list-style-type: none"> • 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
27 28 29 30 31 32 33 34 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)	<ul style="list-style-type: none"> • 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)
35 36 37 38 39 40 41 42 43 44 45 46 substudy IV	<p>psychotherapists: focus groups, survey, interviews & observations</p> <p>GPs: focus groups & survey</p>	service providers service providers	process evaluation process evaluation	<p>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</p> <p>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</p>	<ul style="list-style-type: none"> • 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 MnOP • formal aspects and content of new measures (methods and techniques, networking, best practice examples) 	<p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>interviews: N = 40</p> <p>survey: N = 1,200</p> <p>focus groups: N = 40 (4 groups with n = 10 participants)</p> <p>survey: N = 1,200</p>

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5 Figure 1: An overview of the three ES-RiP-perspectives (patients, service providers and payers)
6 integrated in a multi-level approach, also including the respective data sources, major outcomes, and
7 corresponding substudies
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3 Figure 2: The ES-RiP approach embedded in the Throughput-Model
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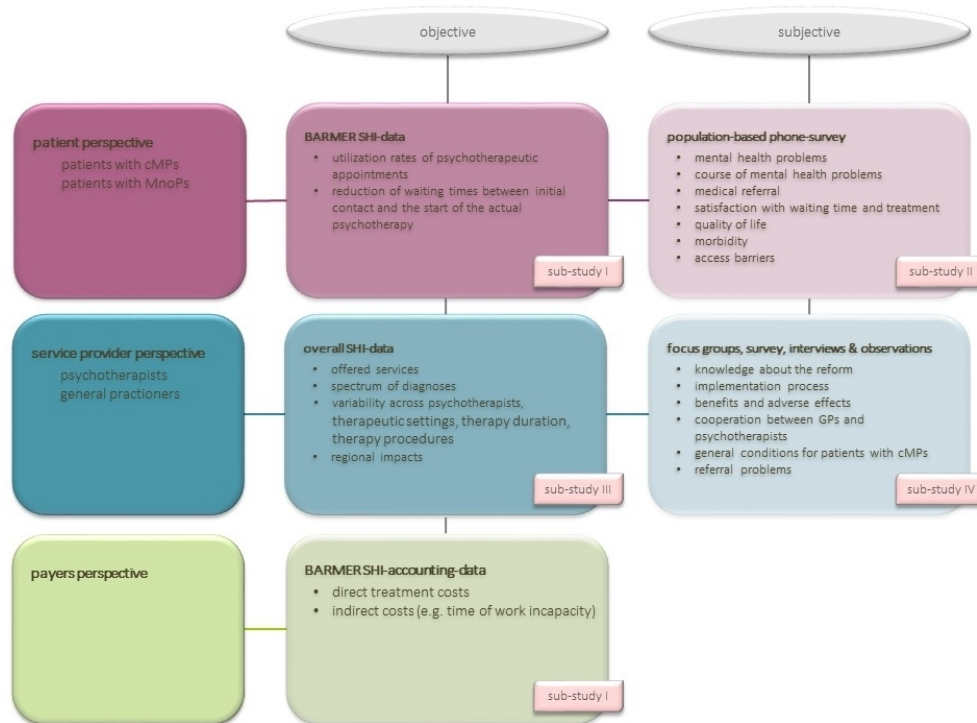


Figure 1: The ES-RiP approach embedded in the Throughput-Model

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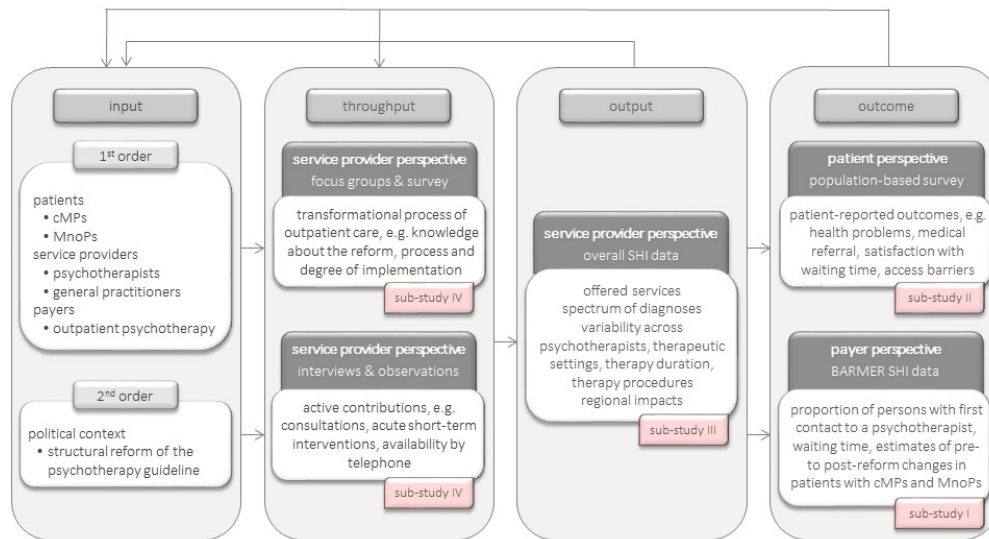


Figure 2: An overview of the three ES-RiP-perspectives (patients, service providers and payers) integrated in a multi-level approach, also including the respective data sources, major outcomes, and corresponding substudies

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