BMJ Open

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-036021
Article Type:	Protocol
Date Submitted by the Author:	26-Nov-2019

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Keywords:	Adult psychiatry < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Original article

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

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Running title: Study protocol for RECOVER randomized controlled trial
Word count text body: 5.428
Word count abstract: 422
For publication in: BMJ Open (Impact 2.413)

ABSTRACT

Introduction

Health care systems around the world are looking for solutions to the growing problem of mental disorders. RECOVER is the synonym for an evidence-based, stepped and cross-sectoral coordinated care service model for mental disorders. RECOVER implements a cross-sectoral network with managed care, comprehensive psychological, somatic and social diagnostics, crisis resolution and a general structure of four severity levels, each with assigned evidence-based therapy models (e.g. assertive community treatment) and therapies (e.g. psychotherapy). Development, implementation, evaluation and transfer are funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020.

Methods and analysis

The trial is conducted in accordance to the SPIRIT Statement. The study aims to compare the RECOVER model with treatment as usual (TAU). Following questions are examined: Does RECOVER reduce mental health care costs compared to TAU? Does RECOVER improve patient relevant outcomes? Is RECOVER cost-effective compared to TAU? A total sample of 890 patients with mental disorders will be assessed at baseline and individually randomized into RECOVER or TAU. Follow-up assessments are conducted after 6 and 12 months. As primary outcomes, cost reduction, improvement in symptoms, daily functioning and quality of life as well as cost-effectiveness-ratios will be measured. In addition, several secondary outcomes will be assessed. Primary and secondary outcomes are evaluated according to the intention-to-treat principle. Mixed linear or logistic regression models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. The evaluation of therapy utilization and productivity losses is done with difference-in-difference regressions.

Ethics and dissemination

Ethical approval from the Ethics committee of the Hamburg Medical Association has been obtained (PV5672). The results will be disseminated to service users and their families via the media, to healthcare professionals via professional training and meetings and to researchers via conferences and publications.

Key words

Stepped care, coordinated care, mental disorders, severe mental illness, e-mental-health

Trial registration number and registry name

ClinicalTrials.gov (NCT03459664), Recover

Protocol version

26.11.2019 (Version 1.0)

STRENGHTS AND LIMITATIONS

- One of the first studies assessing an evidence-based, stepped and cross-sectoral coordinated care service model for all main common and severe mental disorders. It implements a cross-sectoral care network with managed care, a comprehensive psychological, somatic and social initial diagnosis, crisis resolution for all patients in acute crises and four severity levels (from mild to severe mental illness), each with assigned evidence-based therapy models and therapies. The model integrates service providers from all sectors including clinics, outpatient centers in clinics, private psychiatrists, psychologists and general practitioners and services of clinical and vocational rehabilitation.
- Fidelity and integrity of the RECOVER service model was established by 12 standard operating procedure (SOP) manuals for all core components.
- The study provides a unique opportunity to evaluate the impact of such a stepped care service model on health care costs, of cost-effectiveness and on patients' outcomes with respect to symptoms, functioning, quality of life and satisfaction with care.
- The RECOVER project was initially supported by 4 and now 19 health insurance funds, which represent a high proportion (about 80%) of all insured persons.
- The incentives for integrating the network partners were developed with the respective associations and chambers. However, there are no established incentives in the German health care system that promote binding participation. In this respect, network management was and is a central task.

BACKGROUND AND RATIONALE

About 30 % of the German population are affected by a mental disorder per year [1], relevant losses of the functional level have about 20 % of patients. [1,2] This means that approximately 15 million people in Germany are affected by a relevant mental disorder every year. The Organization for Economic Cooperation and Development (OECD) [3,4] has calculated that the share of direct and indirect costs for mental disorders in Germany in the gross domestic product was 4.8% in 2015, approximately 146 billion €.

These costs are also caused by structural problems of the German health care system for mental disorders. [3,5,6] The Organization for Economic Cooperation and Development (OECD[3]), the Advisory Councils on Health Care [5] and Macroeconomic Development [6], professional societies (German Society of Psychiatry, Psychotherapy and Neurology; DGPPN [7]), health insurances (DAK-Gesundheit [8], BARMER [9]) as well as patient and family associations (BapK [10]) criticize the fragmented structures and services, the lack of trans-sectoral coordination, permeability and cooperation, inefficient use of funds due to overuse and underuse as well as strong regional discrepancies. In addition, there are problems with access to care, inadequate standardization in diagnostics and indications, long waiting times for psychotherapy, misdistribution in outpatient psychotherapy to the detriment of severe mental illnesses (SMI) and the lack of implementation of assertive treatment models for short-term acute treatment and for long-term treatment of patients with SMI. Furthermore, the digitalization of the care system and the use of E-Mental-Health has not yet been implemented. [6]

Like many other countries, Germany has responded to these structural deficits with a largely non-systematic increase in quantity of care. Since 2005, almost all indicators of the health care system have shown an increase: number of hospitals (especially clinics for psychosomatic medicine), inpatient and day-clinic treatment places, number of psychiatric outpatient departments and treated cases, number of psychotherapists in private practice, etc. [11] In contrast to almost all other European countries, which have often promoted the development of the community psychiatry, even inpatient treatment places have risen (+14% in Germany vs -17% other European countries).[12] In other health care systems such an increase has not led to a reduced prevalence of common mental disorders. [13] Accordingly, many experts and associations like the OECD recommend an improvement in quality of care and the implementation of evidence-based structures and interventions.[3,13]

Accordingly, the Advisory Councils on Health Care [5] and Macroeconomic Development [6] as well as professional associations [7] in Germany call for the *"introduction of stepped, needs-based, person-centered, cross-sector and setting-spanning care"* and the *"introduction of digital health including the use of e-mental-health solutions in all sectors of the health care system".* However, when implementing such an evidence-based, stepped and coordinated care service model, including e-mental-health, some evidence-based principles must be taken into account. [14,15]

(1) Stepped care models exist for certain mental disorders (e.g. for major depression [16-18], anxiety disorders[17], personality disorders [19,20] or psychosis [21]) or so-called "service models",[14,15,22] in which evidence-based therapy models and therapies are logically linked in one evidence-based stepped care model. The inter- and trans-sectoral treatment processes are based on components of managed and coordinated care. Service models work cross-sectoral in a network of service providers that jointly cover the entire spectrum of care, including inpatient, day-care, outpatient and rehabilitative care. [14]

(2) Stepped care is a system of treatment delivery and monitoring in which the most effective and resource-saving treatment is the first treatment option. [14] Coordinated (or collaborative) care refers to care that is coordinated between service providers across sectors and disciplines and is also referred to as integrated care. Stepped and coordinated care has four main principles: (a) Service providers work together and coordinate across sector boundaries; (b) Interventions depend on the severity of the disease, the most effective and resource-saving treatment is always initiated first; (c) As many treatment models and therapies as possible are evidence-based and demonstrably effective, effective therapies are more efficient and (d) an up- or downgrading takes place according to pre-defined rules (e.g. disease progression). [22]

(3) Severity levels are based on epidemiology with respect to the severity distribution of 20% of patients with relevant functional deficits: (a) 9-12% have a mild severity, (b) 4-6% a moderate severity and (c) 1-2% a moderate to severe severity. [2] These diseases mostly belong to the so-called Common Mental Disorder (henceforth CMD), i.e. mental diseases with a comparatively high prevalence, but a low risk for the development of a severe mental illness (e.g. unipolar depression, anxiety disorders). The remaining 1-2% of the 20% of patients suffer from a so-called severe mental illness (SMI). [2,23,24] The definition of SMI comprises (a) the diagnosis of a mental disorder and (b) a functional level that is consistently and severely impaired by the disorder. [22,23] The highest risk for SMI is in schizophrenia (90% will develop an SMI), followed by schizophrenia spectrum disorders (60%), bipolar I disorder and unipolar severe depression with psychotic symptoms (both 40%) and personality disorders (30%; especially the emotionally unstable personality disorder [23]). Relative to 100%, 60% of all SMI are psychotic disorders. [24]

(4) Regarding the integration of evidence-based therapy models and guidelines therapies into the model, the OECD Report of 2014 [3] systematizes evidence-based interventions for patients with CMD and SMI. With regard to CMD, these are psychotherapy, e-mental-health and work(re)integration. For patients with SMI it is short-term crisis resolution, early intervention services and assertive community treatment as well as psychotherapy, e-mental-health and work (re)integration (e.g. supported employment) and peer support.

(5) In principle, the approach is to achieve improved care without increasing resources. [14-21] To this end, various cost approaches could be integrated: (a) outpatient care before inpatient or day-clinic care, (b) stepped outpatient care, (c) care for mild (or moderate) mental disorders primarily by e-mental-health

instead of face to face psychotherapy, (d) stepped psychotherapy (e.g. group or short-term psychotherapy before long-term), (e) outreach crisis resolution to prevent or shorten inpatient or day-clinic care, (f) assertive community treatment for people with SMI to prevent and shorten inpatient or day-clinic care, (g) rapid access to supported employment to reduce days with inability to work and (h) access to evidence-based care with better recovery and less consecutive costs.

Objectives

This article reports on the development, implementation and evaluation of the RECOVER care model. Efficiency and effectiveness of the RECOVER care model are evaluated from 2017 to the end of 2020 in a prospective, monocentric, randomized controlled trial (RCT). In addition, the RECOVER model will be transferred to the Centre for Mental Health of the Hospital Itzehoe, starting from 1.1.2020, where it will be examined in an accompanying quality assurance study. This article reports on the study protocol for the RECOVER RCT. The trial is conducted in accordance to the SPIRIT Statement for reporting parallel group randomized trials.[40] The primary hypotheses include that RECOVER leads to cost savings compared to standard care within the 1-year treatment period, that RECOVER leads to greater benefits in terms of improving the patient's state of health, and that RECOVER has a better efficiency (cost-effectiveness) than standard care.

Trial design and conceptual framework: RECOVER model

The so-called RECOVER model was developed on the basis of these structural, therapeutic and cost-saving approaches. RECOVER is the synonym for an evidence-based, stepped and coordinated care service model for mental disorders. Development, implementation and evaluation are funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020 (funding code: 01NVF16018).

The RECOVER model was developed by a consortium of representatives from Hamburg, Itzehoe and Germany including the Hamburg Health Authority, Hamburg patient and family associations, the Hamburg Chambers and Associations of Physicians, General Practitioners and Psychotherapists, the behavioural therapy centre "*Behavioural Therapy Falkenried clinics GmbH"* and the work integration centre "*ARINET GmbH"*, the German expert associations of adult and child and youth psychiatry and psychotherapy (DGPPN, DGKJP), the Centre for Psychosocial Medicine of the Hospital Itzehoe and the University Hospital Hamburg-Eppendorf (UKE) as consortium leader with 9 departments and institutes. The accompanying research is carried out by three independent institutes for health economics, health care research and medical epidemiology and biometrics. The application and execution of studies within the Innovation Fund is tied to the participation of health insurances. The RECOVER was initially supported by 4 health insurances including BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg and HEK. Since the introduction of the model in January 2018 the network is constantly growing to by now over 270 participating institutions, registered physicians, general practitioners, psychotherapists and staff. In addition, 13 further health insurances joined the RECOVER model. In 2018, the German Society for Psychiatry, Psychotherapy

and Neurology awarded the RECOVER model as the reference model for sustainable psychiatry in the future in Germany. [7]

RECOVER combines three approaches: [14,15] Firstly, managed and coordinated care across sectors within a sectoral partner network. Secondly, stepped care within four severity levels from mild mental disorders (level 1) to severe mental disorders (level 4) with associated treatment packages, always with the proviso that the most effective resource-saving interventions are used first. Thirdly, as many interventions as possible are evidence-based, because evidence-based interventions are more efficient and thus save resources.

The RECOVER service model consists of 9 innovative care components, which are described in more detail in the following section. Each care component has been documented in a standard operating procedure (SOP) manual (e.g. seeswww.recover-hamburg.de). [25-27]

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(1) Improvement of managed and coordinated care

The UKE has established a Competence Centre for Integrated Mental Health Care. This centre has the task of improving the management and coordination of all cross-sectoral forms of care. This includes, for example, the involvement of institutions and clinicians through cooperation agreements, the establishment of a sectoral care network, care management (i.e. case management, allocation of therapy appointments, documentation), training and quality assurance. Access to care is improved by immediate appointments mostly within three to five days and the possibility of 24h crisis intervention. Information on access to care is available from all cooperation partners and can be accessed by patients and their relatives via the publicly accessible website. In addition, the centre is the operator of a new E-Mental-Health platform (eRECOVER; see www.erecover.de; see 6), which was developed within the framework of RECOVER. An online outpatient clinic for digital therapy has been integrated. [26]

(2) Improvement of diagnostics and crisis resolution

The improvement of diagnostics and crisis intervention is achieved through the implementation of a Crisis Resolution Team (so-called AID & CARE Team). AID stands for **A**mbulance for **I**ndication and **D**iagnostics, CARE for **C**risis **A**nd **RE**solution. It is a specialized, multi-professional and interdisciplinary team of physicians, psychologists, nursing staff, social workers and recovery counsellors from adult psychiatry, child and youth psychiatry, psychosomatics, medical psychology, general practice, sexual medicine and forensic psychiatry as well as a network partner for supported employment. The tasks include standardised interdisciplinary biological, psychological and social initial diagnostics, indication and treatment planning, cross-sector outreach crisis intervention and managed care (implementation of the cross-sector treatment plan). The team works with an electronic board (called AID & CARE Board), in which all patients are

discussed twice a day, especially those in crisis resolution treatment. The team assigns patients to one of four severity levels and the corresponding treatment plan is implemented by the Competence Centre in cooperation within the care network. The CARE treatment can be used again at any time during the entire therapy period. [26]

(3) Improvement of care for people with severe mental illness

Improvement of care for people with SMI is supported by the integration of Therapeutic Assertive Community Treatment (TACT) for severe psychotic disorders including schizophrenia spectrum disorders (F2) and bipolar I disorder (F31), severe unipolar depression with psychotic features and severe borderline personality disorders (F60.3). [27] These indications were chosen because these diagnoses have the highest risk for the development of SMI and account for about 80% of all patients with SMI. [24] This so-called "Hamburg integrated care model" has been financed since 2007 as §140 SGB V Integrated care contract by 5 health insurances and was included into the RECOVER model for people in severity level 4. [28-31] Currently, there are four TACT teams: two for multiple-episode patients with severe psychoses, one team for adolescents and young adults with a first-episode psychosis and one team for patients with borderline personality disorders. Each team is responsible for around 80-100 patients in a 1:15-1:25 clinician-patient ratio with 24h/365days emergency interventions. The TACT teams have extensive expertise and are multidisciplinary including psychiatrists, psychologists, nurses, social workers and peers, ≥ 80% are psychiatrists and psychologists. The Hamburg model was examined in three major evaluations with regard to effectiveness and efficiency. These studies showed a good efficacy regarding symptoms, functional level, quality of life, remission and recovery [28-31] with high efficiency. [32]

(4) Integration of general practice

People with mental disorders, especially those with SMI, display a high morbidity and mortality risk. [30,33] Various models have attempted to improve coordination between primary care and psychiatry with unclear success. [30] One of the most recommended models is the so-called Reverse Integrated Care model (RIC), in which primary health care providers are co-located in the mental health setting. [30] In RECOVER, this is achieved by integrating general practitioners into the AID & CARE team. They are responsible for all somatic assessments, the organisation of further examinations and therapies in the network and the establishment, management and training of a network of general practitioners.

(5) Integration and increased flexibility of psychotherapy

Due to the long waiting times for usual psychotherapy of 5 months [34] on average and the preference of patients with mild and moderate mental illness [35], RECOVER has developed various incentives for psychotherapists together with the Psychotherapists' Chamber in Hamburg. The objectives are to shorten waiting times, to take over patients with higher degrees of severity through joint treatment with the Crisis Resolution team and case manager, and more frequent use of stepped and flexible psychotherapy. The incentives include for example the waiver of the application procedure, which is now supported by all

health insurances, the increase in short-term and group psychotherapies, the possibility of utilisation of the Crisis Resolution Team at any time and treating crises together on an outpatient basis as well as the qualification of staff through certified, free further training courses, case conferences and quality circles. In the future, psychotherapists in private practice can also use the E-Mental-Health platform eRECOVER.

(6) Integration of E-Mental-Health

Despite its great potential and meanwhile also evidence [36-38], E-Mental-Health is hardly integrated into the German health care system, it is not part of the standard care and is currently used by less than 1% of all clinics as well as outpatient clinicians and psychotherapists. Within RECOVER, E-Mental-Health is integrated into the stepped care model. The E-Mental-Health platform eRECOVER (see www.erecover.de) provides digital diagnostics and therapy for all severity levels. In level 1, this is the first intervention before face-to-face psychotherapy. In other levels it accompanies other interventions. Within eRECOVER, the following variants of digital therapy can be performed: (a) digital self-help programs, (b) guided digital therapy, (c) blended digital therapy. In the future, video individual therapy and video group therapy will be added.

(7) Integration of Supported Employment

Individual Placement and Support (IPS) is a further development of Supported Employment (SE). It includes training and work (re)integration with reintegration or integration on the first (paid) training or labour market with promotion of the sustainability of the intervention through job coaching. [35] The basis of this intervention is that 95% of all days of incapacity for work in Germany are generated by patients with CMD and that these patients in particular do not have access to evidence-based work (re)integration. Accordingly, a partnership was initiated with a provider of SE (ARINET GmbH) which offers the following interventions: (a) systematic screening and examination of occupational perspectives, (b) for patients with incapacity to work, measures such as job coaching or clarification assistance for early employability with initial counselling, in-company further training, training on the job and support on the job at the workplace, (c) advice and support for taking a vocational rehabilitation measure. Supported Employment offers counselling for people who are unable to work, clarification of prerequisites or integration and placement in the existing labour market. The know-how is passed on to network partners and gradually a cooperation network with employers is established.

(8) Integration of culture- and language-sensitive care for migrants and refugees

The integration of cultural aspects in the therapy of mental disorder is becoming increasingly important. A number of measures have been implemented to improve integration: Within the AID & CARE team, specially trained employees work who in turn instruct other employees and provide further education in regard to cross-cultural competencies. In addition, culturally sensitive diagnostics has been implemented. A manual is to ensure quality standards for culturally sensitive care.

(9) Participation of peers and relatives and implementation of peer support

The aim is to improve the empowerment and participation of patients and their families in the organisation, treatment and research. The goals are to be achieved by representing patient and family associations on the RECOVER advisory board and by peer support in all major clinical units (crisis resolution team and assertive community treatment teams). In addition, the goals of the project and the accompanying research were coordinated with a special committee of patients and relatives.

Improvement of evidence-based treatment is achieved by assigning evidence-based treatment models and therapies to the four severity levels (levels 1-4) as shown in the 9 innovative care components. Regardless of severity, all patients will have access to managed and coordinated care, diagnostics and crisis resolution, social work, supported employment and peer support. Depending on the degree of severity, patients in levels 1-4 receive the following treatment packages:

a) **Level 1:** mild severity (mostly CMD): counselling, active waiting, self-help, guided digital therapy, social work, supported employment and peer support.

b) **Level 2:** moderate severity (mostly CMD): Coordinated standard care with stepped individual and/or group psychotherapy (≤ 12h), digital therapy, social work, supported employment and peer support.

c) **Level 3:** moderate to severe severity (mostly CMD): coordinated standard care plus case management with tiered individual and/or group psychotherapy (> 12h to long term), digital therapy, social work, supported employment and peer support.

d) **Level 4:** Severe mental illness (1-2%, SMI): Therapeutic assertive community treatment (TACT) including 24h crisis resolution and individual and/or group psychotherapy, digital therapy, social work, supported employment and peer support.

METHODS AND ANALYSIS

Study design

The RECOVER study is a prospective, monocentric, randomized controlled trial (RCT) conducted in the catchment area of the University Medical Center Hamburg-Eppendorf, Germany.

Changes of trial design

In addition to the 4 health insurance funds, another 15 health insurance funds have joined the model, which has not resulted in any changes of the study design.

Study setting

The study takes place within the catchment area of the University Medical Center Hamburg-Eppendorf, Hamburg, Germany from January 2018 to December 2020. The Department of Psychiatry and Psychotherapy covers a sector of approximately 330.000 inhabitants. The sector comprises about 20 psychiatric institutions and about 100 registered specialists in psychiatry and psychotherapy, general practice and psychosomatics and about 200 registered psychological psychotherapists. The RCT is conducted by three independent institutions: the Department of Medical Psychology (UKE), the Department of Health Economics (UKE) and the Department of Biostatistics (UKE). As part of the study implementation, the research institutions also have the task of monitoring the data.

Inclusion criteria

Eligible participants are people at the age of ≥16 years, insured with one of the 19 health insurances involved and living in the catchment area of the UKE (8km radius) when they suffer from at least one relevant mental disorder according to the International statistical classification of diseases and related health problems - 10th revision, German Modification [41]: schizophrenic spectrum disorders (ICD-10: F20, F22, F23, F25), bipolar disorder (ICD-10: F31), major depression (ICD-10: F32, F33), anxiety disorder (ICD-10: F40, F41), obsessive-compulsive disorder (ICD-10: F42), post-traumatic stress disorder (ICD-10: F43.1), adjustment disorder (ICD-10: F43.2), somatoform disorders (ICD-10: F45), eating disorder (ICD-10: F50), personality disorder (ICD-10: F60, F61) or attention deficit hyperactivity disorder (ICD-10: F90).

Exclusion criteria

Subjects are excluded from the study when fulfilling the criteria for organic mental disorders (ICD-10: F00-09); with a main diagnosis of addiction disorders (ICD-10: F10-19) (comorbid addiction disorders do not lead to exclusion), with severe or moderate mental retardation (pre-diagnosed ICD-10: F72/F73), with insufficient knowledge of German, with impairment of vision and/or hearing not to be corrected.

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Interventions

Upon inclusion in the study, all participants receive a detailed psychological assessment. This consists of standardized procedures regarding the main diagnosis, comorbid disorders, social problem areas, functional level and quality of life (see table 2). On the basis of combined criteria consisting of severity of the disease and functional level, the classification into the 4 severity levels is carried out (see table 1). Subsequently, the randomization and thus the allocation to the intervention and control group takes place. With regard to the comparison of structures and interventions between intervention and control groups, table 2 compares all essential care components (see table 2).

RECOVER (Intervention Group, IG)

Patients assigned to the RECOVER model are first admitted to the center and registered in the IT file. The patient is then automatically assigned to a case manager of the AID & CARE team. On the basis of the preceding standardized diagnostics, the case manager carries out a re-evaluation of the psychosocial diagnostics, transfers the data to the AID board and calls in a social worker for social problems. As a standard, each patient receives somatic diagnostics from the general practitioner. Subsequently, the patient is discussed in the twice-daily multi-professional and interdisciplinary meetings and a treatment plan is drawn up. In acute crises, the patient is admitted to the CARE treatment. In contrast to standard care, the treatment plan is organized in the network for the patient. The case manager always remains the patient's primary contact person, even when referrals are made to the network. If another acute crisis occurs, the patient can be treated again with CARE at any time.

Treatment-As-Usual (Control Group, CG)

The control group receives standard care that is possible in the sector of the University Hospital Hamburg-Eppendorf. This includes the use of full and day-clinic inpatient treatment within the Clinic for Psychiatry and Psychotherapy of the UKE and the Clinic for Child and Adolescent Psychiatry of the UKE, the treatment in the Psychiatric Outpatient Clinic of the UKE, the use of therapy from specialists in general practice and psychiatry as well as psychological psychotherapists and treatment at institutions of assisted living and rehabilitation of mental illnesses.

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Outcomes and hypotheses

Primary outcomes

1) 12 months treatment in RECOVER compared to TAU result in a reduction of a) costs of care by the health insurance (SHI) system, b) costs of care by other payers, c) costs due to loss of productivity (indirect costs). RECOVER is cost-saving compared to TAU.
2) 12 months treatment in RECOVER compared to TAU is associated with a) improved disease remission and response, b) reduced symptoms and illness severity, c) improved functioning and d) improved health-related quality of life. These measures will be linearly transformed and added up to one measure "psycho-functional level".
3) 12 months treatment in RECOVER compared to TAU lead to a gain in quality-adjusted life years (QALYs) across all patients, with simultaneously unchanged or reduced direct (SHI perspective) or direct and indirect (societal perspective) costs.

Secondary outcomes

12 months treatment in RECOVER compared to TAU leads to the following secondary outcomes: 1) a reduction of inpatient and day-care admissions and inpatient and day-care days, 2) a reduction days with inability to work, 3) a lower service disengagement rate, 4) a reduction of waiting time until start of application psychotherapy, 5) a higher percentage of patients with SMI with group and individual psychotherapy, 6) a higher use of digital therapy, and 7) a higher use of peer support.

Changes to trial outcomes after trial commenced

None

Sample size

The sample size is based on a power calculation to detect a statistically significant difference between the intervention and control group of a small to medium effect size (Cohen's f of 0.175) after 12 months (t12)). 234 study participants in total (117 in each group) are required given a statistical power of at least 80% (with a type-1 error rate of 5% in a 2-sided test and 10% explained variance by the baseline value). The sample size is increased to 384 to include interactions of the interventions with a small to medium effect size (Cohen's f of 0.175) with the originally planned six stratified severity level. Diagnostics is performed centrally. After the individual randomisation of each study participant, the therapy in RECOVER and in TAU takes place in approximately 50 clusters with approximately 21 participants each. To take this cluster effect into account, an intra-class correlation (ICC) = .05 is assumed. So we obtain a design effect of 2.0 for the primary, continuous outcome, which leads to a total number of 890 patients that have to be included (dropout rate of about 30% is included).

Assignment of interventions

Single blinded study (outcomes assessor): Individuals who evaluate the outcomes of interest will remain blinded regarding a participant's condition (RECOVER/TAU) over the course of the study. The individual stratified randomization (i.e. four severity levels) will be conducted after baseline assessment and communicated to the participant by a person that is not the outcome assessor. We have used the procedure “ralloc” (STATA-SE 14) with variable block sizes within each stratum. During follow-up assessments after 6 and 12 month the outcome assessor will remain blinded regarding a participant's condition.

Data collection, management, and analysis

Data will be collected before intervention (t0) after 6 (t6) and 12 months (t12). The following instruments are used: Diagnostic and Statistical Manual of Mental disorders (DSM-V) (structured clinical interview (SKID I and II [42]), psychiatric use of care services (FIMPsy questionnaire[43]), general use of health services (FIMA questionnaire[44]), disease remission or responses (HEALTH-49[45]; CGI[46]). Moreover, the use of additional, study specific health services like the use of digital therapy is assessed in a questionnaire. The severity of the symptoms is also measured for the different diagnostic groups (diagnosis-specific). Further

questionnaires measure everyday function level (observer rated: GAF [47]), health-related quality of life (EQ-5D-5L [48], SF-12 [49], ReQOL [50]), and QALYs (based on EQ-5D-5L index[48]). Various risk parameters and comorbid diseases are recorded across all diagnoses. If applicable, relatives will be interviewed (questionnaire and interview). The collected health data are enriched with secondary data obtained from external data owner (e.g. inpatient performance data, outpatient medical performance data, etc.). After 12 months (at t12), this data is requested from the health insurance companies for the past 36 months. A monetary valuation is then performed according to standardized monetary valuation rates.[51,52] For more details, see table 3.

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The primary and secondary outcomes are evaluated according to the intention-to-treat principles. For the primary outcome psycho-functional level, the change from baseline to 12 months follow-up will be analyzed by calculating a linear mixed model with group (RECOVER, TAU), severity level and interaction between group and severity level as fixed effects, cluster as random effect and the baseline value of psycho-functional level as a covariate. Disease remission and response to treatment are analyzed using mixed logistic regression. Remission is assumed if a predefined cut-off value is achieved at follow-up (e.g. PHQ-9≤5). Response to treatment is assumed if a patient has improved by 50% of the initial symptoms. Changes in disease symptoms, everyday function level and HQOL are analyzed using mixed linear regression models. The evaluation of the primary outcome direct and indirect costs during the 12 month follow-up is done by using multiple difference-in-difference regressions. We assume that the intervention is cost saving, if the negative difference in costs is statistically significant ($p<0.05$). Results are interpreted as cost neutral, if the difference in costs is negative and not statistically significant (intervention is less expensive) or if the difference in costs is positive with a p-value >0.5 (intervention is more expensive). In this case, we assume that the intervention is not increasing costs. All models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. Adjusted means and odds ratios, respectively, with their 95% confidence intervals and p-values will be reported. The two-sided type I error will be set at .05. Interim analyses are not planned. Cost-effectiveness will be analyzed by incremental cost-effectiveness ratios (ICER). Cost-effectiveness acceptability curves based on net benefit regressions will be used to evaluate uncertainty of the ICER. A detailed statistical analysis plan will be prepared and finalized before the code is broken. Results will be reported according to the SPIRIT guidelines. Only the analysis of primary outcomes will be considered in a confirmatory manner. For sensitivity analyses, missing values are replaced by multiple imputations and per-protocol analyses are performed.

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Secondary outcomes are examined with multivariate methods (logistic regression, difference-in-difference regression). The secondary outcomes will be evaluated according to the scale level with mixed linear or logistic regression models. For the analysis of inhibiting and promoting factors for the overall treatment model and an effective and efficient implementation of RECOVER in clinical routine, qualitative methods are used. The results of the study will be evaluated using descriptive and inferential statistical analyses of sociodemographic and diagnostic data. The predictive value of different factors will be tested by logistic regression.

DISCUSSION

Health systems around the world are looking for efficient solutions to the growing problem of mental health care and its funding. In Germany, the Advisory Councils on Health Care and Macroeconomic Development as well as professional associations call for the introduction of stepped, integrated and coordinated care. RECOVER is the acronym for such an evidence-based, stepped and cross-sectoral coordinated care service model for all main common and severe mental disorders. RECOVER implements a cross-sectoral care network with managed care, a comprehensive psychological, somatic and social initial diagnosis, crisis resolution for all patients in acute crises and four severity levels (from mild to severe mental illness), each with assigned evidence-based therapy models and therapies. The RECOVER study will be able to answer important questions regarding costs, efficiency and effectiveness of the model. In addition, it evaluates the transfer of the model to another region in Germany.

Successful confirmation of the efficiency and effectiveness of the RECOVER model can make theoretical, clinical and societal contributions. First, the findings will generate new knowledge about stepped care service models, effective integrated therapy models and therapies as well as efficient care processes. Specifically, the integration of e-mental health will help to increase acceptance and use of digital diagnostics and therapy. Second, the proof of effectiveness and efficiency creates all the prerequisites to transfer the model into standard care. How this can be achieved is already the subject of intensive cooperation between the developers of the RECOVER model and the participating health insurance funds. Third, the proof of effectiveness and efficiency, the accompanying research and experience with the transfer of the model as well as the 12 quality assurance manuals create optimal prerequisites for the further transfer of the model or essential individual therapy models into other German regions.

ETHICS AND DISSEMINATION

The written consent of all participants will be obtained and they will receive a detailed explanation of the study objectives, the voluntary nature of their participation, their right to withdraw their participation and the risks and benefits of the study.

RECOVER is a care model that should not cause any physical or psychological harm to participants. In the event of an unforeseen problem or if the participant experiences inconvenience or anxiety while filling out the questionnaire or answering the questions in the interview, the researcher will report this to the head of data collection. The researchers will help the participants to get additional support from experts. Participants can also choose not to answer the questions or stop the interview. Participants are asked to sign two copies of the informed consent form, one to be given to the participants and the other to be returned to the principal investigator of this study for recording purposes. The consent forms will be kept separate from the data. All data collected, without personal names, will be stored in the locked cabinet of the principal investigator (PI), while all digital or electronic records will be password-protected and kept in the PI computer for 5 years. Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

The current RCT and process evaluation will improve our understanding of the impact of RECOVER on the results of service users, especially as far as they are concerned:

1) Demonstrate the benefits and unintended consequences of recovery-oriented, strength-based services for people with mental illness.
2) Highlight the key therapeutic ingredients of RECOVER and how they affect SMCM outcomes.
3) Review how you can best use RECOVER in Germany.

Post trial care of the study participants is ensured by the possibility of further treatment in the standard care.

Our disimination policy aims at several important target groups. To share our knowledge with service users and their families, PI and the team will work with the local community and media. Healthcare professionals will benefit from the study's contribution to staff training and expert interviews. We will share our findings with researchers at home and abroad through conference presentations and publications in peer-reviewed journals. Our results are also disseminated through seminars organized by the PI Department and RECOVER websites.

OTHER INFORMATION

Registration

Ethics committee of the Hamburg Medical Association (PV5672).

Registration number with ClinicalTrials.gov (NCT03459664).

Protocol

The full trial protocol can be accessed through ClinicalTrials.gov

Funding

Development, implementation and testing are funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020. When the GKV-VSG came into force in July 2015, the G-BA was given the task of promoting new forms of health care and health care research with the overriding aim of further developing the quality of SHI care via the newly introduced §§ 92a and b SGB V. The G-BA is responsible for the development of new forms of health care and health care research with the aim of improving the quality of SHI care. To this end, the Federal Government has set up an innovation fund which will provide annual funding of 300 million euros between 2016 and 2019. The funder had no role in study design, data collection and analysis, writing of the report, and decision to submit the study protocol for publication.

Steering committee

The RECOVER study was coordinated, monitored and accompanied by a steering committee. The steering committee included study directors, study coordinators, representatives of the Hamburg Ministry of Health and Consumer Protection, representatives of the three independent scientific research institutions, representatives of the University Hospital and the Itzehoe Hospital (for the transfer), representatives of the participating health insurance funds, representatives of the Hamburg Chamber of Psychotherapists and Medical Association as well as representatives of the Hamburg patient and family associations.

Data statement section

Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

Acknowledgement

We thank all employees and partners of the RECOVER project who are not mentioned. In particular, we would like to thank the partners of the participating health insurances and their representatives: BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg, HEK, IKK Classic, BKK Mobil Oil, BKK Salzgitter, BKK Public, BKK RWE, BKK Linde, BKK Technoform, BKK Verbund Plus, Energie BKK, Heimat BKK, TUI BKK, Salus BKK, VIACTIV Krankenkasse, WMF Betriebskrankenkasse.

Authors contributions

All authors have fulfilled authorship criteria according to following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of interests

1) Conflicts of interest regarding the present research project

All authors: None

2) Conflicts of interest in general

Martin Lambert: consultant or speaker fees AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH, Sanovi Aventis, Trommsdorff GmbH & Co. KG
Anne Karow: consultant or speaker fees from AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH
Jürgen Gallinat: speaker fees from Lundbeck GmbH, Otsuka Pharma GmbH, Janssen Cilag GmbH
Daniel Lüdecke: speaker fees Janssen Cilag GmbH
Vivien Kraft: none
Anja Rohenkohl: none
Romy Schröter: none
Constanze Finter: none
Anna-Katharina Siem: none
Lisa Tlach: none
Nathalie Werkle: none
Susann Bargel: none
Gunda Ohm: none
Martin Hoff: none
Helmut Peter: none
Martin Scherer: none
Claudia Mews: none
Susanne Pruskil: none
Johannes Lüke: none
Martin Härter: none
Jörg Dirmaier: none
Michael Schulte-Markwort: none
Bernd Löwe: none
Peer Briken: none
Heike Peper: none
Michael Schweiger: none
Mike Mösko: none
Thomas Bock: honoraria from Astra Zeneca
Martin Wittzack: none
Hans-Joachim Meyer: none
Arno Deister: none
Rolf Michels: none
Stephanie Herr: none
Alexander Konnopka: none
Hannah König: none
Karl Wegscheider: none
Anne Daubmann: none
Antonia Zapf: none
Judith Peth: none
Hans-Helmut König: none
Holger Schulz: none

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Figure 1. The RECOVER evidence-based, stepped and coordinated care model

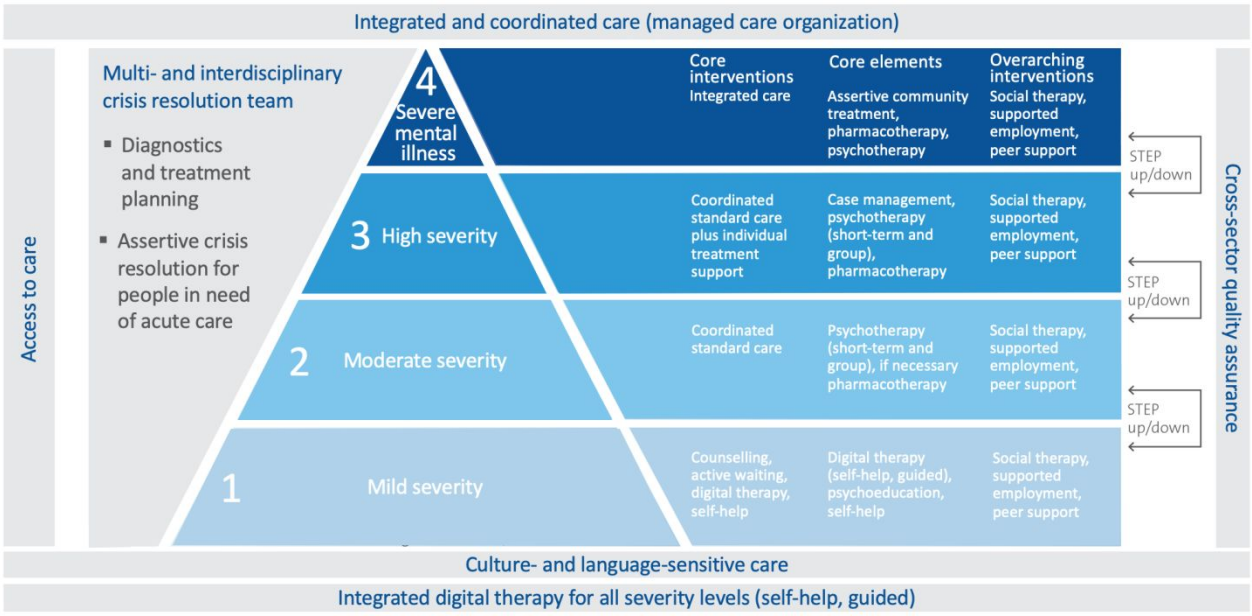

Figure 2. Consort flow diagram of the RECOVER study

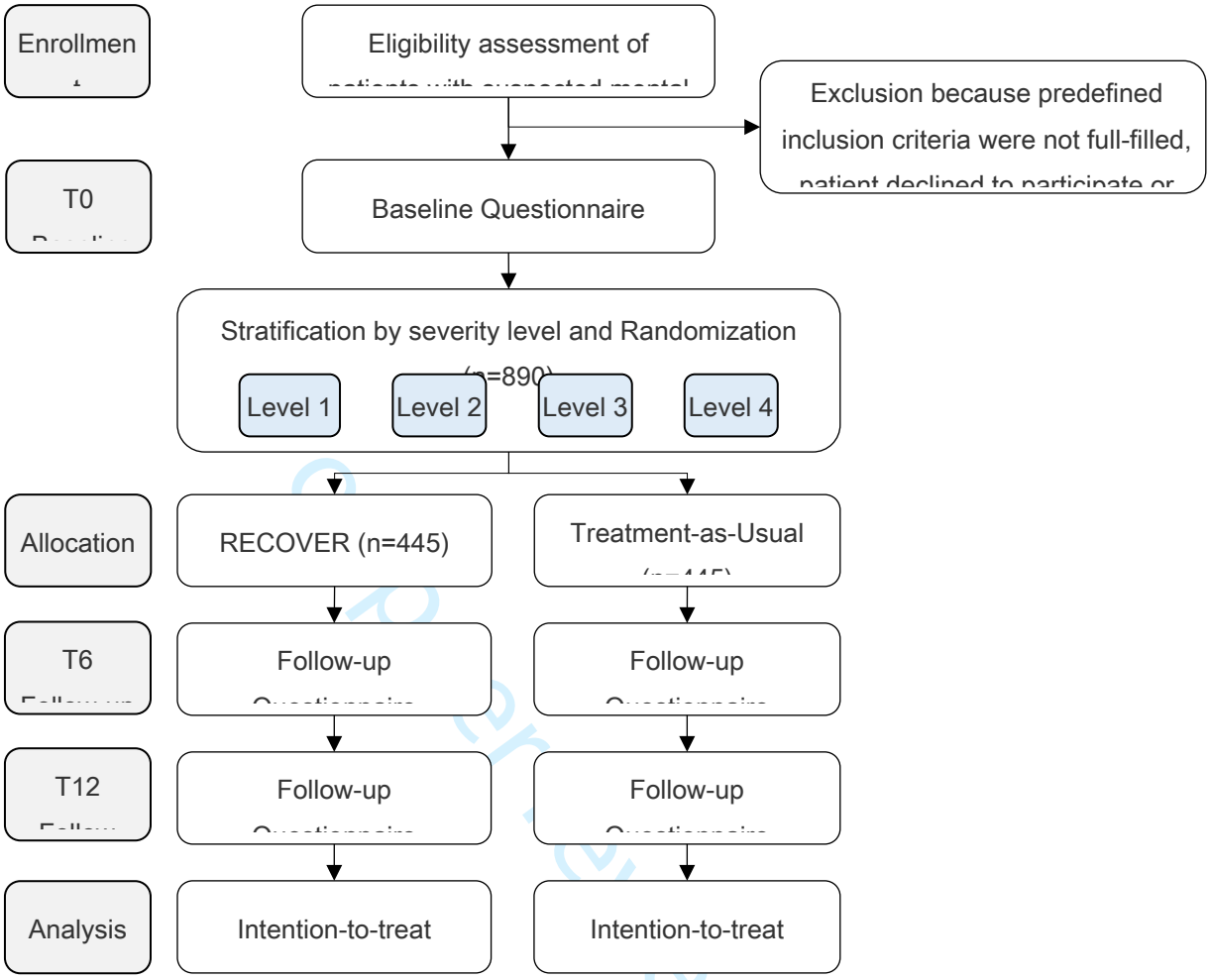

Table 1. Classification into four severity levels

Measurement	Severity levels			
	Level 1 (mild)	Level 2 (medium)	Level 3 (medium to severe)	Level 4 (severe)
Main disorder according to DSM-V	296.x, 300.x, 307.x, 309.x, 314.0x	296.x, 300.x, 301.x, 307.x, 309.x	296.x, 300.x, 301.22, 307.x, 309.8, 301.x	295.x, 296.4/5 (incl. psychosis), 296.34, 297.1, 298.x, 301.x
Main disorder according to ICD-10	F32, F40, F41, F43.2, F45, F90	F32, F40, F41, F42, F43.1, F43.2, F45, F50, F90	F20, F22, F23, F25, F31, F33, F41, F42, F43.1, F45, F50, F60, F61	F20, F22, F23, F25, F31, F32.3, F33.3, F60
Global Assessment of Functioning GAF)	GAF score 61-100: No or mild symptoms in the last 4 weeks	GAF score 51-60: Moderate symptoms in the last 4 weeks	GAF score 31-50: Serious symptoms or impairments in the last 4 weeks	GAF score ≤ 50 for the last 6 months: serious or major impairments
Clinical Global Impressions-Severity Scale (CGI-S)	CGI 1-3	CGI 3-4	CGI 4-6	CGI 5-7

Table 2. Key characteristics of RECOVER intervention and TAU control groups

Dimensions	RECOVER group	TAU group
1. Access to care	▪ Outpatient appointment within 3-7 days, crisis resolution 24h/day	▪ Often long waiting time for outpatient appointments, with respect to psychotherapy 4-6 months ▪ Emergency department 24h/day
2. Standardized assessment at service entry	▪ Standardized psychological, somatic and social assessment ▪ Multi-professional and interdisciplinary review	▪ Assessment often not standardized, often focus solely on psychological issues ▪ No multi-professional and interdisciplinary review
3. Indication and treatment planning	▪ Multi-professional and interdisciplinary indication position and treatment planning	▪ Mostly no multi-professional and interdisciplinary indication position and treatment planning in outpatient care
4. Managed and coordinated care	▪ Organization of the therapy plan in the network and coordination of therapy	▪ Managed and coordinated care not part of standard care
5. Crisis Resolution (CR) for people with all mental disorders	▪ Multi-professional and interdisciplinary crisis resolution team with 24h crisis resolution ▪ Coordinated inpatient and day-clinic care	▪ Inpatient care ▪ Day-clinic care
6. Assertive Community Treatment (ACT) for people with severe mental illness	▪ Multi-professional ACT-Teams including psychotherapy and 24h crisis resolution	▪ ACT not part of standard care ▪ ≤ 5% of patients with SMI receive psychotherapy
7. Access to primary care	▪ Integrated access to primary care physicians in the network	▪ Access to primary care physicians with waiting time ▪ Not integrated into other mental health care
8. Access to psychotherapy	▪ Access to stepped psychotherapy within the network with short waiting time	▪ Access to short- or long-term psychotherapy with long waiting time
9. E-mental-Health	▪ Digital self-help, guided or blended digital therapy	▪ Not part of routine care ▪ Dependent on health insurance access via special supply contracts ▪ Not integrated into other mental health care
10. Supported Employment (SE)	▪ Access to supported employment workers	▪ Not part of routine care
11. Culture and language-sensitive care	▪ Access to specialists within the crisis resolution team ▪ Systematic involvement of interpreters	▪ Not part of routine outpatient care ▪ Systematic involvement of interpreters in inpatient care possible
12. Peer Support	▪ Peer Support workers in CR and ACT teams	▪ Not part of routine outpatient care

Table 3. Measurement used for measuring primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
Primary outcomes			
Direct costs	FIMA[43], FIMPsy[44]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services and monetarily valuation using standardized unit costs[40,41]	Interviewer
Indirect costs	RECOVER questionnaire	Assessment of indirect costs as productivity loss due to days off work/ sick leave or early retirement	Interviewer
Disease remission and response	Health-49[45], CGI[46]	Rating of general aspects of psychosocial health (Health-49) and severity of patient's illness (CGI-S)	Study participant/ Interviewer
Symptoms and illness severity	Diagnosis-specific questionnaires	Rating of the severity of symptoms using several diagnosis-specific questionnaires	Interviewer
Functioning level	GAF[47]	Rating of every day functioning level	Interviewer
Health-related quality of life	EQ-5D-5L[48], SF-12[49], ReQoL[50]	Rating of health-related quality of life and calculation of QALYs using the results of the EQ-5D-5L	Study participant
Secondary outcomes			
Inpatient and day-care admissions, inpatient day-care days	Clinic documentation, FIMA[44], FIMPsy[45]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services	Clinician/ Interviewer
Days with inability to work	RECOVER questionnaire	Assessment of days off work/ on sick leave	Interviewer
Service disengagement rate	Clinical documentation	Interrupt contact with the treatment facility and is not traceable	Clinician
Waiting time until start of application psychotherapy	RECOVER questionnaire	Assessment of active search for outpatient psychotherapeutic treatment after 6 months (t6) and 12 months (t12)	Study participant
Group and individual psychotherapy for patients with SMI	Clinic documentation, RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Clinician/ Study participant
Use of digital therapy	RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant
Use of peer-support	FIMPsy[43] (t0), RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant/ Interviewer

BMJ Open

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-036021.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Feb-2020
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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Health economics
Keywords:	Adult psychiatry < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Original article

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

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Running title: Study protocol for RECOVER randomized controlled trial
Word count text body: 5.428
Word count abstract: 301
For publication in: BMJ Open (Impact 2.413)

ABSTRACT

Introduction

Health care systems around the world are looking for solutions to the growing problem of mental disorders. RECOVER is the synonym for an evidence-based, stepped and cross-sectoral coordinated care service model for mental disorders. RECOVER implements a cross-sectoral network with managed care, comprehensive psychological, somatic and social diagnostics, crisis resolution and a general structure of four severity levels, each with assigned evidence-based therapy models (e.g. assertive community treatment) and therapies (e.g. psychotherapy). The study rationale is the investigation of the effectiveness and efficiency of stepped and integrated care in comparison to standard care.

Methods and analysis

The trial is conducted in accordance to the SPIRIT Statement. The study aims to compare the RECOVER model with treatment as usual (TAU). The following questions are examined: Does RECOVER reduce mental health care costs compared to TAU? Does RECOVER improve patient relevant outcomes? Is RECOVER cost-effective compared to TAU? A total sample of 890 patients with mental disorders will be assessed at baseline and individually randomized into RECOVER or TAU. Follow-up assessments are conducted after 6 and 12 months. As primary outcomes, cost reduction, improvement in symptoms, daily functioning and quality of life as well as cost-effectiveness-ratios will be measured. In addition, several secondary outcomes will be assessed. Primary and secondary outcomes are evaluated according to the intention-to-treat principle. Mixed linear or logistic regression models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. The evaluation of therapy utilization and productivity losses is done with difference-in-difference regressions.

Ethics and dissemination

Ethical approval from the Ethics committee of the Hamburg Medical Association has been obtained (PV5672). The results will be disseminated to service users and their families via the media, to healthcare professionals via professional training and meetings and to researchers via conferences and publications.

Key words

Stepped care, coordinated care, mental disorders, severe mental illness, e-mental-health

Trial registration number and registry name

ClinicalTrials.gov (NCT03459664), RECOVER

Protocol version

05.02.2020 (Version 2.0)

STRENGHTS AND LIMITATIONS

- Implementation of an evidence-based, cross-sectoral care network for mental disorders with managed care, comprehensive diagnostic procedures, and a crisis resolution for all patients in acute crises was achieved.
- Fidelity and integrity of the RECOVER service model was established by 12 standard operating procedure (SOP) manuals for all core components.
- The study provides a unique opportunity to evaluate the impact of such a stepped care service model on health care costs, cost-effectiveness and on patients' outcomes with respect to symptoms, functioning, quality of life and satisfaction with care.
- The RECOVER project was initially supported by 4 and now 19 health insurance funds, which represent a high proportion (about 80%) of all insured persons.
- Network management was and is a central task, because there are no established incentives in the German health care system that promote binding participation.

BACKGROUND AND RATIONALE

About 30 % of the German population are affected by a mental disorder per year [1], and about 20 % of the patients experience relevant losses of their functional level.[1,2] This means that approximately 15 million people in Germany are affected by a relevant mental disorder every year. The Organization for Economic Cooperation and Development (OECD) [3,4] has calculated that the share of direct and indirect costs for mental disorders in Germany in the gross domestic product was 4.8% in 2015, approximately 146 billion €.

These costs are also caused by structural problems of the German health care system for mental disorders. [3,5,6] The Organization for Economic Cooperation and Development (OECD[3]), the Advisory Councils on Health Care [5] and Macroeconomic Development [6], professional society (German Society of Psychiatry, Psychotherapy and Neurology; DGPPN [7]), health insurances (DAK-Gesundheit [8], BARMER [9]) as well as patient and family associations (BapK [10]) criticize the fragmented structures and services, the lack of trans-sectoral coordination, permeability and cooperation, inefficient use of funds due to overuse and underuse as well as strong regional discrepancies. Additionional problems remain likely access to care, inadequate standardization in diagnostics and indications, long waiting times for psychotherapy, misdistribution in outpatient psychotherapy to the detriment of severe mental illnesses (SMI) and the lack of implementation of assertive treatment models for short-term acute treatment and for long-term treatment of patients with SMI. Furthermore, the digitalization of the care system and the use of E-Mental-Health has not yet been implemented. [6]

Like many other countries, Germany has responded to these structural deficits with a largely non-systematic increase in quantity of care. Since 2005, almost all indicators of the health care system have shown an increase: number of hospitals (especially clinics for psychosomatic medicine), inpatient and day-clinic treatment places, number of psychiatric outpatient departments and treated cases, number of psychotherapists in private practice, etc. [11] In contrast to almost all other European countries, which have often promoted the development of the community psychiatry, even inpatient treatment places have risen (+14% in Germany vs -17% other European countries).[12] In other health care systems such an increase has not led to a reduced prevalence of common mental disorders. [13] Accordingly, many experts and associations like the OECD recommend an improvement in quality of care and the implementation of evidence-based structures and interventions.[3,13]

Accordingly, the Advisory Councils on Health Care [5] and Macroeconomic Development [6] as well as professional associations [7] in Germany call for the *"introduction of stepped, needs-based, person-centered, cross-sector and setting-spanning care"* and the *"introduction of digital health including the use of e-mental-health solutions in all sectors of the health care system".* However, when implementing such an evidence-based, stepped and coordinated care service model, including e-mental-health, some evidence-based principles must be taken into account. [14,15]

(1) Stepped care models exist for certain mental disorders (e.g. for major depression [16-18], anxiety disorders[17], personality disorders [19,20] or psychosis [21]) or so-called "service models",[14,15,22] in which evidence-based therapy models and therapies are logically linked in one evidence-based stepped care model. The inter- and trans-sectoral treatment processes are based on components of managed and coordinated care. Service models work cross-sectoral in a network of service providers that jointly cover the entire spectrum of care, including inpatient, day-care, outpatient and rehabilitative care. [14]

(2) Stepped care is a system of treatment delivery and monitoring in which the most effective and resource-saving treatment is the first treatment option. [14] Coordinated (or collaborative) care refers to care that is coordinated between service providers across sectors and disciplines and is also referred to as integrated care. Stepped and coordinated care has four main principles: (a) Service providers work together and coordinate across sector boundaries; (b) Interventions depend on the severity of the disease, the most effective and resource-saving treatment is always initiated first; (c) As many treatment models and therapies as possible are evidence-based and demonstrably effective (effective therapies are more efficient) and (d) an up- or downgrading takes place according to pre-defined rules (e.g. disease progression). [22]

(3) Severity levels are based on epidemiology with respect to the severity distribution of 20% of patients with relevant functional deficits: (a) 9-12% have a mild severity, (b) 4-6% a moderate severity and (c) 1-2% a moderate to severe severity. [2] Most of these patients suffer from a so-called Common Mental Disorder (henceforth CMD), i.e. mental diseases with a comparatively high prevalence, but a low risk for the development of a severe mental illness (e.g. unipolar depression, anxiety disorders). The remaining 1-2% of the 20% of patients suffer from a so-called severe mental illness (SMI). [2,23,24] The definition of SMI comprises (a) the diagnosis of a mental disorder and (b) a functional level that is consistently and severely impaired by the disorder. [22,23] The highest risk for SMI is in schizophrenia (90% will develop an SMI), followed by schizophrenia spectrum disorders (60%), bipolar I disorder and unipolar severe depression with psychotic symptoms (both 40%) and personality disorders (30%; especially the emotionally unstable personality disorder [23]). Relative to 100%, 60% of all SMI are psychotic disorders. [24]

(4) Regarding the integration of evidence-based therapy models and guidelines therapies into the model, the OECD Report of 2014 [3] systematizes evidence-based interventions for patients with CMD and SMI. With regard to CMD, these are psychotherapy, e-mental-health and work(re)integration. For patients with SMI it is short-term crisis resolution, early intervention services and assertive community treatment as well as psychotherapy, e-mental-health and work (re)integration (e.g. supported employment) and peer support.

(5) In principle, the approach is to achieve improved care without increasing resources. [14-21] To this end, various cost approaches could be integrated: (a) outpatient care before inpatient or day-clinic care, (b) stepped outpatient care, (c) care for mild (or moderate) mental disorders primarily by e-mental-health

instead of face-to-face psychotherapy, (d) stepped psychotherapy (e.g. group or short-term psychotherapy before long-term), (e) outreach crisis resolution to prevent or shorten inpatient or day-clinic care, (f) assertive community treatment for people with SMI to prevent and shorten inpatient or day-clinic care, (g) rapid access to supported employment to reduce days with inability to work and (h) access to evidence-based care with better recovery and less consecutive costs.

The overall objective of RECOVER is to improve the care of those affected by mental disorders and their relatives on an evidence-based and sustainable basis through structured cross-sectoral cooperation between service providers and targeted additions to the care system, particularly for the treatment of severely ill patients.

Objectives

Efficiency and effectiveness of the RECOVER care model are evaluated from 2017 to the end of 2020 in a prospective, monocentric, randomized controlled trial (RCT). This article reports on the study protocol for the RECOVER RCT. The trial is conducted in accordance to the SPIRIT Statement for reporting parallel group randomized trials.[25] The primary hypotheses include that RECOVER leads to cost savings compared to standard care within the 1-year treatment period, that RECOVER leads to greater benefits in terms of improving the patient's state of health, and that RECOVER has a better efficiency (cost-effectiveness) than standard care.

Trial design and conceptual framework: RECOVER model

The so-called RECOVER model was developed on the basis of these structural, therapeutic and cost-saving approaches. RECOVER is the synonym for an evidence-based, stepped and coordinated care service model for mental disorders. The evaluation is funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020 (funding code: 01NVF16018). The G-BA is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

The RECOVER model was developed by a consortium of representatives from Hamburg, Itzehoe and Germany including the Hamburg Health Authority, Hamburg patient and family associations, the Hamburg Chambers and Associations of Physicians, General Practitioners and Psychotherapists, the behavioural therapy centre "*Behavioural Therapy Falkenried clinics GmbH"* and the work integration centre "*ARINET GmbH"*, the German expert associations of adult and child and youth psychiatry and psychotherapy (DGPPN, DGKJP), the Centre for Psychosocial Medicine of the Hospital Itzehoe and the University Hospital Hamburg-Eppendorf (UKE) as consortium leader with 9 departments and institutes. The accompanying research is carried out by three independent institutes for health economics, health care research and medical epidemiology and biometrics. The application and execution of studies within the Innovation Fund is tied to the participation of health insurances. RECOVER as initially supported by 4 health insurances including BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg and HEK. Since the introduction of the model in January 2018, he network is constantly growing to by now over 270 participating institutions,

registered physicians, general practitioners, psychotherapists and staff. In addition, 14 further health insurances joined the RECOVER model. In 2018, the German Society for Psychiatry, Psychotherapy and Neurology awarded the RECOVER model as the reference model for sustainable psychiatry in the future in Germany. [7]

RECOVER combines three approaches: [14,15] Firstly, managed and coordinated care across sectors within a sectoral partner network. Secondly, stepped care within four severity levels from mild mental disorders (level 1) to severe mental disorders (level 4) with associated treatment packages, always with the proviso that the most effective resource-saving interventions are used first. Thirdly, as many interventions as possible are evidence-based, because evidence-based interventions are more efficient and thus save resources.

The RECOVER service model consists of 9 innovative care components, which are described in more detail in the following section. Each care component has been documented in a standard operating procedure (SOP) manual (e.g. see www.recover-hamburg.de). [26-28] For more details, see figure 1.

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(1) Improvement of managed and coordinated care

The UKE has established a Competence Centre for Integrated Mental Health Care. This centre has the task of improving the management and coordination of all cross-sectoral forms of care. This includes, for example, the involvement of institutions and clinicians through cooperation agreements, the establishment of a sectoral care network, care management (i.e. case management, allocation of therapy appointments, documentation), training and quality assurance. Access to care is improved by immediate appointments mostly within three to five days and the possibility of 24h crisis intervention. Information on access to care is available from all cooperation partners and can be accessed by patients and their relatives via the publicly accessible website. In addition, the centre is the operator of a new E-Mental-Health platform (eRECOVER; see www.erecover.de; see 6), which was developed within the framework of RECOVER. An online outpatient clinic for digital therapy has been integrated. [26]

(2) Improvement of diagnostics and crisis resolution

The improvement of diagnostics and crisis intervention is achieved through the implementation of a Crisis Resolution Team (so-called AID & CARE Team). AID stands for **A**mbulance for **I**ndication and **D**iagnostics, CARE for **C**risis **A**nd **RE**solution. It is a specialized, multi-professional and interdisciplinary team of physicians, psychologists, nursing staff, social workers and recovery counsellors from adult psychiatry, child and youth psychiatry, psychosomatics, medical psychology, general practice, sexual medicine and forensic psychiatry as well as a network partner for supported employment. The tasks include standardised interdisciplinary biological, psychological and social initial diagnostics, indication and treatment planning,

cross-sector outreach crisis intervention and managed care (implementation of the cross-sector treatment plan). The team works with an electronic board (called AID & CARE Board), in which all patients are discussed twice a day, especially those in crisis resolution treatment. The team assigns patients to one of four severity levels and the corresponding treatment plan is implemented by the Competence Centre in cooperation within the care network. The CARE treatment can be used whenever necessary during the entire therapy period. [27]

(3) Improvement of care for people with severe mental illness

Improvement of care for people with SMI is supported by the integration of Therapeutic Assertive Community Treatment (TACT) for severe psychotic disorders including schizophrenia spectrum disorders (F2) and bipolar I disorder (F31), severe unipolar depression with psychotic features and severe borderline personality disorders (F60.3). [28] These indications were chosen because these diagnoses have the highest risk for the development of SMI and account for about 80% of all patients with SMI. [24] This so-called "Hamburg integrated care model" has been financed since 2007 as Integrated care contract by 5 health insurances and was included into the RECOVER model for people in severity level 4. [29-32] Currently, there are four TACT teams: two for multiple-episode patients with severe psychoses, one team for adolescents and young adults with a first-episode psychosis and one team for patients with borderline personality disorders. Each team is responsible for around 80-100 patients in a 1:15-1:25 clinician-patient ratio with 24h/365days emergency interventions. The TACT teams have extensive expertise and are multidisciplinary including psychiatrists, psychologists, nurses, social workers and peers, ≥ 80% are psychiatrists and psychologists. The Hamburg model was examined in three major evaluations with regard to effectiveness and efficiency. These studies showed a good efficacy regarding symptoms, functional level, quality of life, remission and recovery [29-32] with high efficiency. [33]

(4) Integration of general practice

People with mental disorders, especially those with SMI, display a high morbidity and mortality risk. [31,34] Various models have attempted to improve coordination between primary care and psychiatry with unclear success. [31] One of the most recommended models is the so-called Reverse Integrated Care model (RIC), in which primary health care providers are co-located in the mental health setting. [31] In RECOVER, this is achieved by integrating general practitioners into the AID & CARE team. They are responsible for all somatic assessments, the organisation of further examinations and therapies in the network and the establishment, management and training of a network of general practitioners.

(5) Integration and increased flexibility of psychotherapy

Due to the long waiting times for psychotherapy of 5 months [35] on average and the preference of patients with mild and moderate mental illness [36], RECOVER has developed various incentives for psychotherapists together with the Psychotherapists' Chamber in Hamburg. The objectives are to shorten waiting times, to take over patients with higher degrees of severity through joint treatment with the Crisis Resolution team

and case manager, and more frequent use of stepped and flexible psychotherapy. The incentives include for example the waiver of the application procedure, which is now supported by all health insurances, the increase in short-term and group psychotherapies, the possibility of utilisation of the Crisis Resolution Team at any time and treating crises together on an outpatient basis as well as the qualification of staff through certified, training courses, case conferences and quality circles. In the future, psychotherapists in private practice can also use the E-Mental-Health platform eRECOVER.

(6) Integration of E-Mental-Health

Despite its great potential and meanwhile also evident benefits[37-39], E-Mental-Health is hardly integrated into the German health care system, it is not part of the standard care and is currently used by less than 1% of all clinics as well as outpatient clinicians and psychotherapists. Within RECOVER, E-Mental-Health is integrated into the stepped care model. The E-Mental-Health platform eRECOVER (see www.erecover.de) provides digital diagnostics and therapy for all severity levels. In level 1, this is the first intervention before face-to-face psychotherapy. In other levels it accompanies other interventions. Within eRECOVER, the following variants of digital therapy can be performed: (a) digital self-help programs, (b) guided digital therapy, (c) blended digital therapy. In the future, video individual therapy and video group therapy will be added.

(7) Integration of Supported Employment

Individual Placement and Support (IPS) is a further development of Supported Employment (SE). It includes training and work (re)integration with reintegration or integration on the first (paid) training or labour market with promotion of the sustainability of the intervention through job coaching. [40] The basis of this intervention is that 95% of all days of incapacity to work in Germany are generated by patients with CMD and that these patients in particular do not have access to evidence-based work (re)integration. Accordingly, a partnership was initiated with a provider of SE (ARINET GmbH) which offers the following interventions: (a) systematic screening and examination of occupational perspectives, (b) for patients with incapacity to work, measures such as job coaching or clarification assistance for early employability with initial counselling, in-company training, training on the job and support on the job at the workplace, (c) advice and support for taking a vocational rehabilitation measure. Supported Employment offers counselling for people who are unable to work, clarification of prerequisites or integration and placement in the existing labour market. The know-how is passed on to network partners and gradually a cooperation network with employers is established.

(8) Integration of culture- and language-sensitive care for migrants and refugees

The integration of cultural aspects in the therapy of mental disorder is becoming increasingly important. A number of measures have been implemented to improve integration: Within the AID & CARE team, specially trained employees work who in turn instruct other employees and provide further education in

regard to cross-cultural competencies. In addition, culturally sensitive diagnostics has been implemented. A manual has been developed to ensure quality standards for culturally sensitive care.

(9) Participation of peers and relatives and implementation of peer support

The aim is to improve the empowerment and participation of patients and their families in the organisation, treatment and research. This is chieved by representing patient and family associations on the RECOVER advisory board and by peer support in all major clinical units (crisis resolution team and assertive community treatment teams). In addition, the goals of the project and the accompanying research were coordinated with a special committee of patients and relatives.

Improvement of evidence-based treatment is achieved by assigning evidence-based treatment models and therapies to the four severity levels (levels 1-4) as shown in the 9 innovative care components. Regardless of severity, all patients will have access to managed and coordinated care, diagnostics and crisis resolution, social work, supported employment and peer support. Depending on the degree of severity, patients in levels 1-4 have access to he following treatment packages:

a) **Level 1:** mild severity (mostly CMD): counselling, active waiting, self-help, guided digital therapy, social work, supported employment and peer support.

b) **Level 2:** moderate severity (mostly CMD): Coordinated standard care with stepped individual and/or group psychotherapy (≤ 12h), digital therapy, social work, supported employment and peer support.

c) **Level 3:** moderate to severe severity (mostly CMD): coordinated standard care plus case management with stepped individual and/or group psychotherapy (> 12h to long term), digital therapy, social work, supported employment and peer support.

d) **Level 4:** Severe mental illness (1-2%, SMI): Therapeutic assertive community treatment (TACT) including 24h crisis resolution and individual and/or group psychotherapy, digital therapy, social work, supported employment and peer support.

METHODS AND ANALYSIS

Study design

The RECOVER study is a prospective, monocentric, randomized controlled trial (RCT) conducted in the catchment area of the University Medical Center Hamburg-Eppendorf, Germany.

Changes of trial design

In addition to the 4 health insurance funds, another 15 health insurance funds have joined the model, which has not resulted in any changes of the study design.

Study setting

The study takes place within the catchment area of the University Medical Center Hamburg-Eppendorf, Hamburg, Germany from January 2018 to December 2020. The Department of Psychiatry and Psychotherapy covers an area of approximately 330.000 inhabitants. The area omprises about 20 psychiatric institutions and about 100 registered specialists in psychiatry and psychotherapy, general practice and psychosomatics and about 200 registered psychological psychotherapists. The RCT is conducted by three independent institutions: the Department of Medical Psychology (UKE), the Department of Health Economics (UKE) and the Department of Biostatistics (UKE). As part of the study implementation, the research institutions also have the task of data monitoring.

Inclusion criteria

Eligible participants are people at the age of ≥16 years, insured with one of the 19 health insurances involved and living in the catchment area of the UKE (8km radius) when they suffer from at least one relevant mental disorder according to the International statistical classification of diseases and related health problems - 10th revision, German Modification [41]: schizophrenic spectrum disorders (ICD-10: F20, F22, F23, F25), bipolar disorder (ICD-10: F31), major depression (ICD-10: F32, F33), anxiety disorder (ICD-10: F40, F41), obsessive-compulsive disorder (ICD-10: F42), post-traumatic stress disorder (ICD-10: F43.1), adjustment disorder (ICD-10: F43.2), somatoform disorders (ICD-10: F45), eating disorder (ICD-10: F50), personality disorder (ICD-10: F60, F61) or attention deficit hyperactivity disorder (ICD-10: F90).

Exclusion criteria

Subjects are excluded from the study when fulfilling the criteria for organic mental disorders (ICD-10: F00-09); with a main diagnosis of addiction disorders (ICD-10: F10-19) (comorbid addiction disorders do not lead to exclusion), with severe or moderate mental retardation (pre-diagnosed ICD-10: F72/F73), with insufficient knowledge of German, with uncorrectable impairment of vision and/or hearing.

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Interventions

Upon inclusion in the study, all participants receive a detailed psychological assessment. This consists of standardized questionnaires regarding the main diagnosis, comorbid disorders, social problem areas, functional level and quality of life. On the basis of combined criteria consisting of severity of the disease and functional level, the classification into the 4 severity levels is carried out (see table 1). Subsequently, the randomization and thus the allocation to the intervention and control group takes place. With regard to the comparison of structures and interventions between intervention and control groups, table 2 compares all essential care components (see table 2).

RECOVER treatment (Intervention Group, IG)

Patients assigned to the RECOVER model are first admitted to the center and registered in the IT file. The patient is then automatically assigned to a case manager of the AID & CARE team. On the basis of the preceding standardized diagnostics, the case manager carries out a re-evaluation of the psychosocial diagnostics, transfers the data to the AID board and calls in a social worker in case of social problems. As a standard, each patient receives somatic diagnostics from the general practitioner. Subsequently, the patient is discussed in the twice-daily multi-professional and interdisciplinary meetings and a treatment plan is drawn up. In acute crises, the patient is admitted to the CARE treatment. In contrast to standard care, the treatment plan is organized in the network for the patient. The case manager always remains the patient's primary contact person, even when referrals are made to the network. If another acute crisis occurs, the patient can be treated again with CARE at any time.

Treatment-As-Usual (Control Group, CG)

The control group receives standard care that is provided n the sector of the University Hospital Hamburg-Eppendorf. This includes the use of full and day-clinic inpatient treatment within the Clinic for Psychiatry and Psychotherapy of the UKE and the Clinic for Child and Adolescent Psychiatry of the UKE, the treatment in the Psychiatric Outpatient Clinic of the UKE, the use of therapy from specialists in general practice and psychiatry as well as psychological psychotherapists and treatment at institutions of assisted living and rehabilitation of mental illnesses.

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Outcomes and hypotheses

Primary outcomes

1) 12 months treatment in RECOVER compared to TAU result in a reduction of a) costs of care by the health insurance system (SHI), b) costs of care by other payers, c) costs due to loss of productivity (indirect costs). RECOVER is cost-saving compared to TAU.

2) 12 months treatment in RECOVER compared to TAU is associated with a) improved disease remission and response, b) reduced symptoms and illness severity, c) improved functioning and d) improved health-related quality of life. These measures will be linearly transformed and added up to one measure "psycho-functional level".

3) 12 months treatment in RECOVER compared to TAU lead to a gain in quality-adjusted life years (QALYs) across all patients, with simultaneously unchanged or reduced direct (SHI perspective) or direct and indirect (societal perspective) costs.

Secondary outcomes

12 months treatment in RECOVER compared to TAU leads to the following secondary outcomes: 1) a reduction of inpatient and day-care admissions and inpatient and day-care days, 2) a reduction of days ith inability to work, 3) a lower service disengagement rate, 4) a reduction of waiting time until start of psychotherapy aid by SHI, 5) a higher percentage of patients with SMI receiving roup and individual psychotherapy, 6) a higher use of digital therapy, and 7) a higher use of peer support.

Changes to trial outcomes after trial commenced

None

Sample size

The sample size is based on a power calculation to detect a statistically significant difference between the intervention and control group of a small to medium effect size (Cohen's f of 0.175) after 12 months (t12)). 234 study participants in total (117 in each group) are required given a statistical power of at least 80% (with a type-1 error rate of 5% in a 2-sided test and 10% explained variance by the baseline value). The sample size is increased to 384 to include interactions of the interventions with a small to medium effect size (Cohen's f of 0.175). Diagnostics is performed centrally. After the individual randomisation of each study participant, the therapy in RECOVER and in TAU takes place in approximately 50 clusters with approximately 21 participants each. To take this cluster effect into account, an intra-class correlation (ICC) = .05 is assumed. So we obtain a design effect of 2.0 for the primary, continuous outcome, which leads to a total number of 890 patients that have to be included (dropout rate of about 30% is included).

Assignment of interventions

Single blinded study (outcomes assessor): Individuals who evaluate the outcomes of interest will remain blinded regarding a participant's condition (RECOVER/TAU) over the course of the study. The individual stratified randomization (i.e. four severity levels) will be conducted after baseline assessment and communicated to the participant by a person that is not the outcome assessor. We have used the procedure “ralloc” (STATA-SE 14) with variable block sizes within each stratum. During follow-up assessments after 6 and 12 month the outcome assessor will remain blinded regarding a participant's condition.

Data collection, management, and analysis

Data will be collected before intervention (t0) after 6 (t6) and 12 months (t12) (See Figure 2 for the CONSORT flow diagram). The following instruments are used: Diagnostic and Statistical Manual of Mental disorders (DSM-V) (structured clinical interview (SKID I and II [42]), psychiatric use of care services (FIMPsy questionnaire[43]), general use of health services (FIMA questionnaire[44]), disease remission or responses (HEALTH-49[45]; CGI[46]). Moreover, the use of additional, study specific health services like the use of digital therapy is assessed in a questionnaire. The severity of the symptoms is also measured for the different

diagnostic groups (diagnosis-specific). Further questionnaires measure everyday functioning level (observer rated: GAF [47]), health-related quality of life (EQ-5D-5L [48], SF-12 [49], ReQOL [50]), and QALYs (based on EQ-5D-5L index[48]). Various risk parameters and comorbid diseases are recorded across all diagnoses. A sample of relatives will be interviewed (questionnaire and interview). The collected health data are enriched with secondary data obtained from external data owner (e.g. inpatient performance data, outpatient medical performance data, etc.). After 12 months (at t12), this data is requested from the health insurance companies for the past 36 months. A monetary valuation is then performed according to standardized monetary valuation rates.[51,52] For more details, see table 3.

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The primary and secondary outcomes are evaluated according to the intention-to-treat principles. For the primary outcome psycho-functional level, the change from baseline to 12 months follow-up will be analyzed by calculating a linear mixed model with group (RECOVER, TAU), severity level and interaction between group and severity level as fixed effects, cluster as random effect and the baseline value of psycho-functional level as a covariate. Disease remission and response to treatment are analyzed using mixed logistic regression. Remission is assumed if a predefined cut-off value is achieved at follow-up (e.g. PHQ-9≤5). Response to treatment is assumed if a patient has improved by 50% of the initial symptoms. Changes in disease symptoms, everyday functioning level and HQOL are analyzed using mixed linear regression models. For the evaluation of the primary outcome direct and indirect costs during the 12 month follow-up, multiple difference-in-difference regressions are used. We assume that the intervention is cost saving, if the negative difference in costs is statistically significant ($p<0.05$). Results are interpreted as cost neutral, if the difference in costs is negative and not statistically significant (intervention is less expensive) or if the difference in costs is positive with a p-value >0.5 (intervention is more expensive). All models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. Adjusted means and odds ratios, respectively, with their 95% confidence intervals and p-values will be reported. The two-sided type I error will be set at .05. Interim analyses are not planned. Cost-effectiveness will be analyzed by incremental cost-effectiveness ratios (ICER). Cost-effectiveness acceptability curves based on net benefit regressions will be used to evaluate uncertainty of the ICER. A detailed statistical analysis plan will be prepared and finalized before the code is broken. Results will be reported according to the SPIRIT guidelines. Only the analysis of primary outcomes will be considered in a confirmatory manner. For sensitivity analyses, missing values are replaced by multiple imputations and per-protocol analyses are performed.

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Secondary outcomes are examined with multivariate methods (logistic regression, difference-in-difference regression). The secondary outcomes will be evaluated according to the scale level with mixed linear or logistic regression models. For the analysis of inhibiting and promoting factors for the overall treatment model and an effective and efficient implementation of RECOVER in clinical routine, qualitative methods are used. The results of the study will be evaluated using descriptive and inferential statistical analyses of sociodemographic and diagnostic data. The predictive value of different factors will be tested by logistic regression.

Patient and Public Involvement

Within RECOVER, patients, relatives and the public were systematically involved: (1) Peer support is a separate intervention module, which provides the systematic integration of trained patients into the provision of care, e.g. in the Crisis Resolution Team and in the Assertive Community Treatment Teams; (2) The entire care model and research project RECOVER was planned and carried out in coordination with the patient and relatives organisation "EmPeeRie - Empower Peers to Research" regarding content and study questions; (3) RECOVER was led by a steering committee. Patient and family member organisations from Hamburg are represented in this committee; (4) The public was informed via a separate project website. Here, all materials developed are also available for download.

DISCUSSION

Health systems around the world are looking for efficient solutions to the growing problem of mental health care and its funding. In Germany, the Advisory Councils on Health Care and Macroeconomic Development as well as professional associations call for the introduction of stepped, integrated and coordinated care. RECOVER is the synonym or such an evidence-based, stepped and cross-sectoral coordinated care service model for all main common and severe mental disorders. RECOVER implements a cross-sectoral care network with managed care, a comprehensive psychological, somatic and social initial diagnosis, crisis resolution for all patients in acute crises and four severity levels (from mild to severe mental illness), each with assigned evidence-based therapy models and therapies. The RECOVER study will be able to answer important questions regarding costs, efficiency and effectiveness of the model. In addition, it evaluates the transfer of the model to another region in Germany.

The RECOVER model could have the following limitations: (1) It is possible that not enough partners from the outpatient sector participate in the model with regard to network formation; (2) It is possible that patients at level 3 in particular already are too impaired for placement in outpatient psychotherapeutic care; (3) With regard to the sustainability of RECOVER, there is a need to introduce treatment models into

standard care that are currently internationally evidence-based but are not yet part of mainstream care in Germany.

Successful confirmation of the efficiency and effectiveness of the RECOVER model can make theoretical, clinical and societal contributions. First, the findings will generate new knowledge about stepped care service models, effective integrated therapy models and therapies as well as efficient care processes. Specifically, the integration of e-mental health will help to increase acceptance and use of digital diagnostics and therapy. Second, the proof of effectiveness and efficiency creates all the prerequisites to transfer the model into standard care. How this can be achieved is already the subject of intensive cooperation between the developers of the RECOVER model and the participating health insurance funds. Third, the proof of effectiveness and efficiency, together with the accompanying research and experience with the transfer of the model as well as the 12 quality assurance manuals create optimal prerequisites for the further transfer of the whole model or essential components into other German regions.

ETHICS AND DISSEMINATION

This study has obtained ethics approval from the Ethics committee of the Hamburg Medical Association (PV5672).

The written consent of all participants will be obtained and they will receive a detailed explanation of the study objectives, the voluntary nature of their participation, their right to withdraw their participation and the risks and benefits of the study.

RECOVER is a care model that should not cause any physical or psychological harm to participants. In the event of an unforeseen problem or if the participant experiences inconvenience or anxiety while filling out the questionnaire or answering the questions in the interview, the researcher will report this to the head of data collection. The researchers will help the participants to get additional support from experts. Participants can also choose not to answer the questions or stop the interview. Participants are asked to sign two copies of the informed consent form, one to be given to the participants and the other to be returned to the principal investigator of this study for recording purposes. The consent forms will be kept separate from the data. All data collected, without personal names, will be stored in the locked cabinet of the principal investigator (PI), while all digital or electronic records will be password-protected and kept in the PI computer for 5 years. Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

The current RCT will improve our understanding of the impact of RECOVER on the results of service users, especially as far as they are concerned:

1) Demonstrate the benefits and unintended consequences of recovery-oriented, strength-based services for people with mental illness.

2) Highlight the key therapeutic ingredients of RECOVER and how they affect SMCM outcomes.

3) Review how you can best use RECOVER in Germany.

Post trial care of the study participants is ensured by the possibility of further treatment in the standard care setting.

Our disimination policy aims at several important target groups. To share our knowledge with service users and their families, PI and the team will work with the local community and media. Healthcare professionals will benefit from the study's contribution to staff training and expert interviews. We will share our findings with researchers at home and abroad through conference presentations and publications in peer-reviewed journals. Our results are also disseminated through seminars organized by the PI Department and RECOVER websites.

OTHER INFORMATION

Registration

Ethics committee of the Hamburg Medical Association (PV5672).

Registration number with ClinicalTrials.gov (NCT03459664).

Protocol

The full trial protocol can be accessed through ClinicalTrials.gov

Funding

The evaluation of RECOVER is funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020 (funding code: 01NVF16018). The G-BA is responsible for the development of new forms of health care and health care research with the aim of improving the quality of SHI care. To this end, the Federal Government has set up an innovation fund which will provide annual funding of 300 million euros between 2016 and 2019. The funder had no role in study design, data collection and analysis, writing of the report, and decision to submit the study protocol for publication.

Steering committee

The RECOVER study was coordinated, monitored and accompanied by a steering committee. The steering committee included study directors, study coordinators, representatives of the Hamburg Ministry of Health and Consumer Protection, representatives of the three independent scientific research institutions, representatives of the University Hospital and the Itzehoe Hospital (for the transfer), representatives of the participating health insurance funds, representatives of the Hamburg Chamber of Psychotherapists and Medical Association as well as representatives of the Hamburg patient and family associations.

Data statement section

Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

Acknowledgement

We thank all employees and partners of the RECOVER project who are not mentioned. In particular, we would like to thank the partners of the participating health insurances and their representatives: BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg, HEK, IKK Classic, BKK Mobil Oil, BKK Salzgitter, BKK Public, BKK RWE, BKK Linde, BKK Technoform, BKK Verbund Plus, Energie BKK, Heimat BKK, TUI BKK, Salus BKK, VIACTIV Krankenkasse, WMF Betriebskrankenkasse.

Authors contributions

Martin Lambert, Anne Karow, Jürgen Gallinat, Holger Schulz, Heike Peper, Hans-Helmut König, Arno Deister, Gunda Ohm, Helmut Peter, Bernd Löwe, Peer Briken, Martin Scherer and Vivien Kraft were mainly responsible for the conception and design of the study. The manuscript is mainly drafted by Martin Lambert, Anne Karow, Anne Daubmann, Hannah König and Anja Rohenkohl. Karl Wegscheider, Antonia Zapf and Anne Daubmann are responsible for the statistics of the project. The acquisition of the data and conduction of the study was mainly done by Judith Peth, Rolf Michels, Stephanie Herr, Romy Schröter, Constanze Finter, Anna-Katharina Siem, Lisa Tlach, Nathalie Werkle, Michael Schweiger, Daniel Lüdecke, Claudia Mews, Susanne Pruskil, Johannes Lüke. Drafting the work or revising it critically for important intellectual content was carried out mainly by Susann Bargel, Martin Hoff, Martin Härter, Jörg Dirmaier, Michael Schulte-Markwort, Mike Mösko, Thomas Bock, Martin Wittzack, Hans-Jochim Meyer, Alexander Konnopka, Karl Wegscheider, Antonia Zapf.

All authors have fulfilled authorship criteria according to following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of interests

1) Conflicts of interest regarding the present research project

All authors: None

2) Conflicts of interest in general

Martin Lambert: consultant or speaker fees AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH, Sanovi Aventis, Trommsdorff GmbH & Co. KG
Anne Karow: consultant or speaker fees from AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH
Jürgen Gallinat: speaker fees from Lundbeck GmbH, Otsuka Pharma GmbH, Janssen Cilag GmbH
Daniel Lüdecke: speaker fees Janssen Cilag GmbH

Vivien Kraft: none
Anja Rohenkohl: none
Romy Schröter: none
Constanze Finter: none
Anna-Katharina Siem: none
Lisa Tlach: none
Nathalie Werkle: none
Susann Bargel: none
Gunda Ohm: none
Martin Hoff: none
Helmut Peter: none
Martin Scherer: none
Claudia Mews: none
Susanne Pruskil: none
Johannes Lüke: none
Martin Härter: none
Jörg Dirmaier: none
Michael Schulte-Markwort: none
Bernd Löwe: none
Peer Briken: none
Heike Peper: none
Michael Schweiger: none
Mike Mösko: none
Thomas Bock: honoraria from Astra Zeneca
Martin Wittzack: none
Hans-Jochim Meyer: none
Arno Deister: none
Rolf Michels: none
Stephanie Herr: none
Alexander Konnopka: none
Hannah König: none
Karl Wegscheider: none
Anne Daubmann: none
Antonia Zapf: none
Judith Peth: none
Hans-Helmut König: none
Holger Schulz: none

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Figure caption

Figure 1. The RECOVER evidence-based, stepped and coordinated care model

Figure 2. Consort flow diagram of the RECOVER study

Table 1. Classification into four severity levels

Measurement	Severity levels			
	Level 1 (mild)	Level 2 (medium)	Level 3 (medium to severe)	Level 4 (severe)
Main disorder according to DSM-V	296.x, 300.x, 307.x, 309.x, 314.0x	296.x, 300.x, 301.x, 307.x, 309.x	296.x, 300.x, 301.22, 307.x, 309.8, 301.x	295.x, 296.4/5 (incl. psychosis), 296.34, 297.1, 298.x, 301.x
Main disorder according to ICD-10	F32, F40, F41, F43.2, F45, F90	F32, F40, F41, F42, F43.1, F43.2, F45, F50, F90	F20, F22, F23, F25, F31, F33, F41, F42, F43.1, F45, F50, F60, F61	F20, F22, F23, F25, F31, F32.3, F33.3, F60
Global Assessment of Functioning GAF)	GAF score 61-100: No or mild symptoms in the last 4 weeks	GAF score 51-60: Moderate symptoms in the last 4 weeks	GAF score 31-50: Serious symptoms or impairments in the last 4 weeks	GAF score ≤ 50 for the last 6 months: serious or major impairments
Clinical Global Impressions-Severity Scale (CGI-S)	CGI 1-3	CGI 3-4	CGI 4-6	CGI 5-7

Table 2. Key characteristics of RECOVER intervention and TAU control groups

Dimensions	RECOVER group	TAU group
1. Access to care	▪ Outpatient appointment within 3-7 days, crisis resolution 24h/day	▪ Often long waiting time for outpatient appointments, with respect to psychotherapy 4-6 months ▪ Emergency department 24h/day
2. Standardized assessment at service entry	▪ Standardized psychological, somatic and social assessment ▪ Multi-professional and interdisciplinary review	▪ Assessment often not standardized, often focus solely on psychological issues ▪ No multi-professional and interdisciplinary review
3. Indication and treatment planning	▪ Multi-professional and interdisciplinary indication and treatment planning	▪ Mostly no multi-professional and interdisciplinary indication and treatment planning in outpatient care
4. Managed and coordinated care	▪ Organization of the therapy plan in the network and coordination of therapy	▪ Managed and coordinated care not part of standard care
5. Crisis Resolution (CR) for people with all mental disorders	▪ Multi-professional and interdisciplinary crisis resolution team with 24h crisis resolution ▪ Coordinated inpatient and day-clinic care	▪ Inpatient care ▪ Day-clinic care
6. Assertive Community Treatment (ACT) for people with severe mental illness	▪ Multi-professional ACT-Teams including psychotherapy and 24h crisis resolution	▪ ACT not part of standard care ▪ ≤ 5% of patients with SMI receive psychotherapy
7. Access to primary care	▪ Integrated access to primary care physicians in the network	▪ Access to primary care physicians with waiting time ▪ Not integrated into other mental health care
8. Access to psychotherapy	▪ Access to stepped psychotherapy within the network with short waiting time	▪ Access to short- or long-term psychotherapy with long waiting time
9. E-mental-Health	▪ Digital self-help, guided or blended digital therapy	▪ Not part of standard care ▪ Dependent on health insurance access via special supply contracts ▪ Not integrated into other mental health care
10. Supported Employment (SE)	▪ Access to supported employment workers	▪ Not part of standard are
11. Culture and language-sensitive care	▪ Access to specialists within the crisis resolution team ▪ Systematic involvement of interpreters	▪ Not part of standard outpatient care ▪ Systematic involvement of interpreters in inpatient care available
12. Peer Support	▪ Peer Support workers in CR and ACT teams	▪ Not part of standard outpatient care

Table 3. Measurement used for measuring primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
Primary outcomes			
Direct costs	FIMA[43], FIMPsy[44]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services and monetary evaluation using standardized unit costs[40,41]	Interviewer
Indirect costs	RECOVER questionnaire	Assessment of indirect costs as productivity loss due to days off work/ sick leave or early retirement	Interviewer
Disease remission and response	Health-49[45], CGI[46]	Rating of general aspects of psychosocial health (Health-49) and severity of patient's illness (CGI-S)	Study participant/ Interviewer
Symptoms and illness severity	Diagnosis-specific questionnaires	Rating of the severity of symptoms using several diagnosis-specific questionnaires	Interviewer
Functioning level	GAF[47]	Rating of everyday functioning level	Interviewer
Health-related quality of life	EQ-5D-5L[48], SF-12[49], ReQoL[50]	Rating of health-related quality of life and calculation of QALYs using the results of the EQ-5D-5L	Study participant
Secondary outcomes			
Inpatient and day-care admissions, inpatient day-care days	Clinic documentation, FIMA[44], FIMPsy[45]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services	Clinician/ Interviewer
Days with inability to work	RECOVER questionnaire	Assessment of days off work/ on sick leave	Interviewer
Service disengagement rate	Clinical documentation	Patient interrupts contact with the treatment facility and cannot be reengaged again	Clinician
Waiting time until start of psychotherapy	RECOVER questionnaire	Assessment of active search for outpatient psychotherapeutic treatment after 6 months (t6) and 12 months (t12)	Study participant
Group and individual psychotherapy for patients with SMI	Clinic documentation, RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Clinician/ Study participant
Use of digital therapy	RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant
Use of peer-support	FIMPsy[43] (t0), RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant/ Interviewer

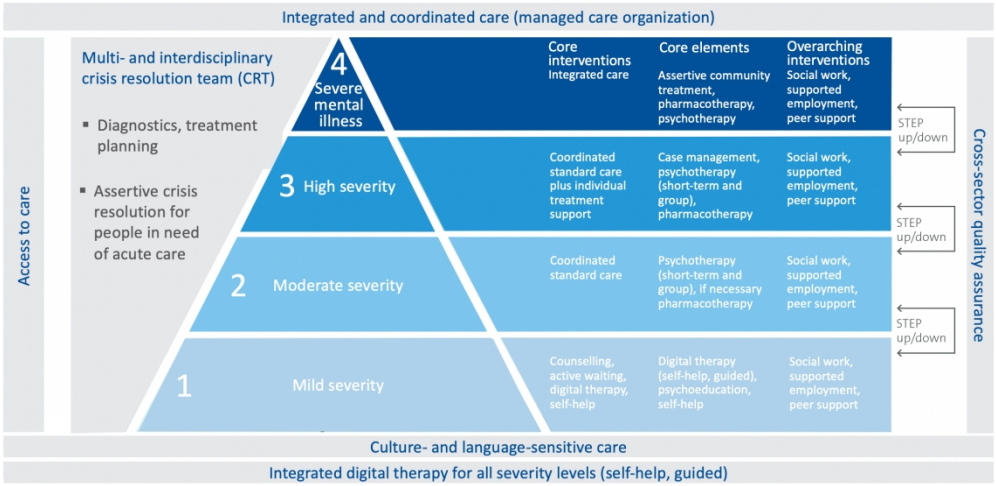

Figure 1. The RECOVER evidence-based, stepped and coordinated care model

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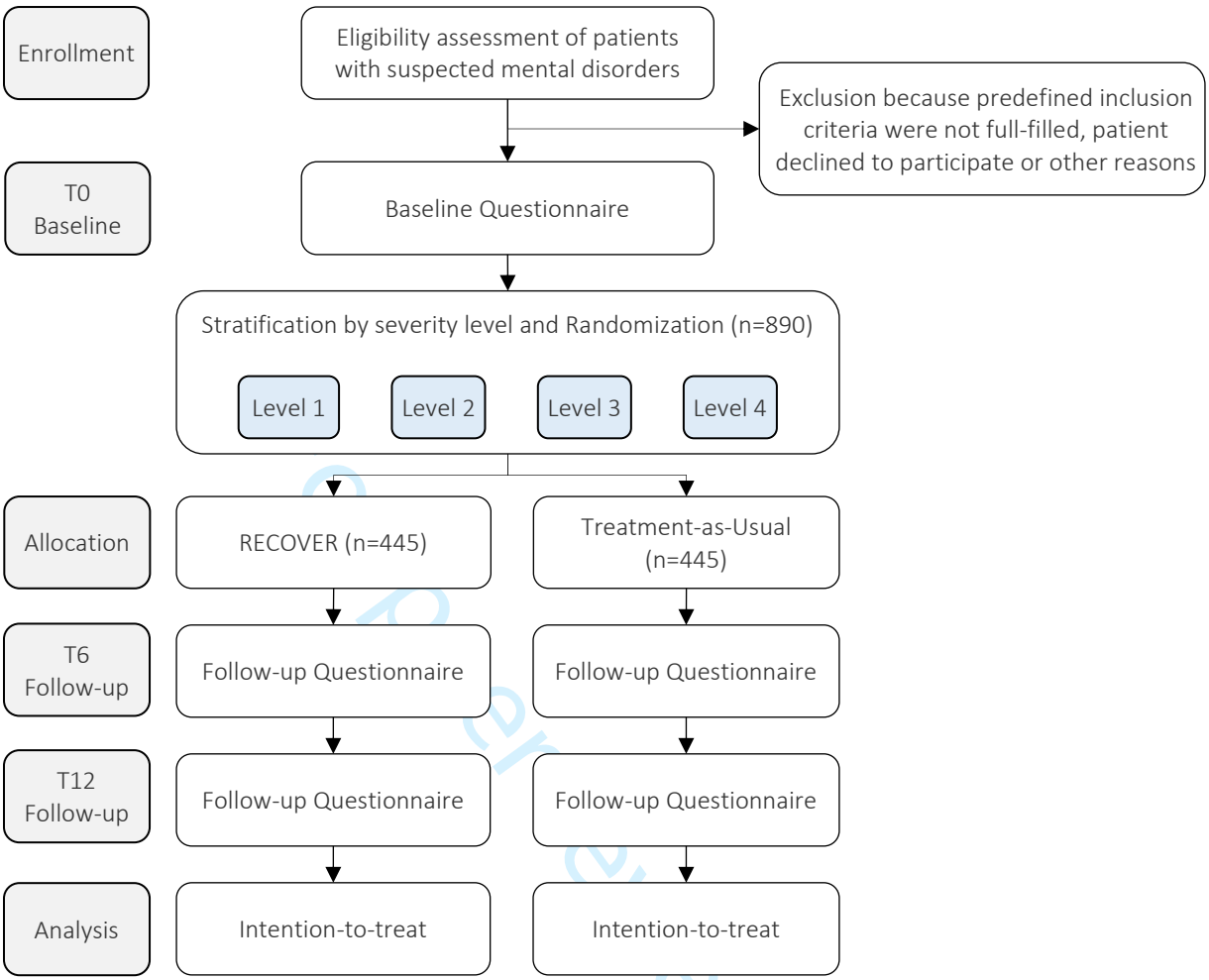

BMJ Open

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-036021.R2
Article Type:	Protocol
Date Submitted by the Author:	23-Mar-2020
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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Health economics
Keywords:	Adult psychiatry < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Original article

Study protocol for a randomized controlled trial evaluating an evidence-based, stepped and coordinated care service model for mental disorders (RECOVER)

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Running title: Study protocol for RECOVER randomized controlled trial
Word count text body: 5.910
Word count abstract: 300
For publication in: BMJ Open (Impact 2.413)

ABSTRACT

Introduction

Health care systems around the world are looking for solutions to the growing problem of mental disorders. RECOVER is the synonym for an evidence-based, stepped and cross-sectoral coordinated care service model for mental disorders. RECOVER implements a cross-sectoral network with managed care, comprehensive psychological, somatic and social diagnostics, crisis resolution and a general structure of four severity levels, each with assigned evidence-based therapy models (e.g. assertive community treatment) and therapies (e.g. psychotherapy). The study rationale is the investigation of the effectiveness and efficiency of stepped and integrated care in comparison to standard care.

Methods and analysis

The trial is conducted in accordance to the SPIRIT Statement. The study aims to compare the RECOVER model with treatment as usual (TAU). The following questions are examined: Does RECOVER reduce health care costs compared to TAU? Does RECOVER improve patient-relevant outcomes? Is RECOVER cost-effective compared to TAU? A total sample of 890 patients with mental disorders will be assessed at baseline and individually randomized into RECOVER or TAU. Follow-up assessments are conducted after 6 and 12 months. As primary outcomes, cost reduction, improvement in symptoms, daily functioning and quality of life as well as cost-effectiveness-ratios will be measured. In addition, several secondary outcomes will be assessed. Primary and secondary outcomes are evaluated according to the intention-to-treat principle. Mixed linear or logistic regression models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. Costs due to health care utilization and productivity losses are evaluated using difference-in-difference regressions.

Ethics and dissemination

Ethical approval from the Ethics committee of the Hamburg Medical Association has been obtained (PV5672). The results will be disseminated to service users and their families via the media, to healthcare professionals via professional training and meetings and to researchers via conferences and publications.

Key words

Stepped care, coordinated care, mental disorders, severe mental illness, e-mental-health

Trial registration number and registry name

ClinicalTrials.gov (NCT03459664), RECOVER

Protocol version

19.03.2020 (Version 3.0)

STRENGTHS AND LIMITATIONS

- Implementation of an evidence-based, cross-sectoral care network for mental disorders with managed care, comprehensive diagnostic procedures, and a crisis resolution for all patients in acute crises was achieved.
- Fidelity and integrity of the RECOVER service model was established by 12 standard operating procedure (SOP) manuals for all core components.
- The study provides a unique opportunity to evaluate the impact of such a stepped care service model on health care costs, cost-effectiveness and on patients' outcomes with respect to symptoms, functioning, quality of life and satisfaction with care.
- The RECOVER project was initially supported by 4 and now 19 health insurance funds, which represent a high proportion (about 80%) of all insured persons.
- Network management was and is a central task, because there are no established incentives in the German health care system that promote binding participation.

BACKGROUND AND RATIONALE

About 30 % of the German population are affected by a mental disorder per year [1], and about 20 % of the patients experience relevant losses of their functional level.[1,2] This means that approximately 15 million people in Germany are affected by a relevant mental disorder every year. The Organization for Economic Cooperation and Development (OECD) [3,4] has calculated that the share of direct and indirect costs for mental disorders in Germany in the gross domestic product was 4.8% in 2015, approximately 146 billion €.

These costs are also caused by structural problems of the German health care system for mental disorders. [3,5,6] The OECD [3], the Advisory Councils on Health Care [5] and Macroeconomic Development [6], professional society (German Society of Psychiatry, Psychotherapy and Neurology; DGPPN [7]), statutory health insurance providers (DAK-Gesundheit [8], BARMER [9]) as well as patient and family associations (BapK [10]) criticize the fragmented structures and services, the lack of trans-sectoral coordination, permeability and cooperation, inefficient use of funds due to overuse and underuse, as well as strong regional discrepancies. Additional problems remain likely access to care, inadequate standardization in diagnostics and indications, long waiting times for psychotherapy, misdistribution in outpatient psychotherapy to the detriment of severe mental illnesses (SMI), and the lack of implementation of assertive treatment models for short-term acute treatment and for long-term treatment of patients with SMI. Furthermore, the digitalization of the care system and the use of E-Mental-Health has not yet been implemented. [6]

Like many other countries, Germany has responded to these structural deficits with a largely non-systematic increase in quantity of care. Since 2005, almost all indicators of the health care system have shown an increase: number of hospitals (especially clinics for psychosomatic medicine), inpatient and day-clinic treatment places, number of psychiatric outpatient departments and treated cases, number of psychotherapists in private practice, etc. [11] In contrast to almost all other European countries, which have often promoted the development of the community psychiatry, even inpatient treatment places have risen (+14% in Germany vs -17% other European countries).[12] In other health care systems such an increase has not led to a reduced prevalence of common mental disorders. [13] Accordingly, many experts and associations like the OECD recommend an improvement in quality of care and the implementation of evidence-based structures and interventions.[3,13]

Accordingly, the Advisory Councils on Health Care [5] and Macroeconomic Development [6] as well as professional associations [7] in Germany call for the *"introduction of stepped, needs-based, person-centered, cross-sector and setting-spanning care"* and the *"introduction of digital health including the use of e-mental-health solutions in all sectors of the health care system".* However, when implementing such an evidence-based, stepped and coordinated care service model, including e-mental-health, some evidence-based principles must be taken into account. [14,15]

(1) Stepped care models exist for certain mental disorders (e.g. for major depression [16-18], anxiety disorders[17], personality disorders [19,20] or psychosis [21]) or so-called "service models",[14,15,22] in which evidence-based therapy models and therapies are logically linked in one evidence-based stepped care model. The inter- and trans-sectoral treatment processes are based on components of managed and coordinated care. Service models work cross-sectoral in a network of service providers that jointly cover the entire spectrum of care, including inpatient, day-care, outpatient and rehabilitative care. [14]

(2) Stepped care is a system of treatment delivery and monitoring in which the most effective and resource-saving treatment is the first treatment option. [14] Coordinated (or collaborative) care refers to care that is coordinated between service providers across sectors and disciplines and is also referred to as integrated care. Stepped and coordinated care has four main principles: (a) Service providers work together and coordinate across sector boundaries; (b) Interventions depend on the severity of the disease, the most effective and resource-saving treatment is always initiated first; (c) As many treatment models and therapies as possible are evidence-based and demonstrably effective (effective therapies are more efficient) and (d) an up- or downgrading takes place according to pre-defined rules (e.g. disease progression). [22]

(3) Severity levels are based on epidemiology with respect to the severity distribution of 20% of patients with relevant functional deficits: (a) 9-12% have a mild severity, (b) 4-6% a moderate severity and (c) 1-2% a moderate to severe severity. [2] Most of these patients suffer from a so-called Common Mental Disorder (CMD), i.e. mental diseases with a comparatively high prevalence, but a low risk for the development of a severe mental illness (e.g. unipolar depression, anxiety disorders). The remaining 1-2% of the 20% of patients suffer from a SMI. [2,23,24] The definition of SMI comprises (a) the diagnosis of a mental disorder and (b) a functional level that is consistently and severely impaired by the disorder. [22,23] The highest risk for SMI is in schizophrenia (90% will develop an SMI), followed by schizophrenia spectrum disorders (60%), bipolar I disorder and unipolar severe depression with psychotic symptoms (both 40%) and personality disorders (30%; especially the emotionally unstable personality disorder [23]). Relative to 100%, 60% of all SMI are psychotic disorders. [24]

(4) Regarding the integration of evidence-based therapy models and guidelines therapies into the model, the OECD Report of 2014 [3] systematizes evidence-based interventions for patients with CMD and SMI. With regard to CMD, these are psychotherapy, e-mental-health and work(re)integration. For patients with SMI, these are short-term crisis resolution, early intervention services and assertive community treatment as well as psychotherapy, e-mental-health and work (re)integration (e.g. supported employment) and peer support.

(5) In principle, the approach is to achieve improved care without increasing resources. [14-21] To this end, various cost approaches could be integrated: (a) outpatient care before inpatient or day-clinic care, (b) stepped outpatient care, (c) care for mild (or moderate) mental disorders primarily by e-mental-health

instead of face-to-face psychotherapy, (d) stepped psychotherapy (e.g. group or short-term psychotherapy before long-term), (e) outreach crisis resolution to prevent or shorten inpatient or day-clinic care, (f) assertive community treatment for people with SMI to prevent and shorten inpatient or day-clinic care, (g) rapid access to supported employment to reduce days with inability to work and (h) access to evidence-based care with better recovery and less consecutive costs.

The overall objective of RECOVER is to improve the care of those affected by mental disorders and their relatives on an evidence-based and sustainable basis through structured cross-sectoral cooperation between service providers and targeted additions to the care system, particularly for the treatment of severely ill patients.

Objectives

Efficiency and effectiveness of the RECOVER care model are evaluated from 2017 to the end of 2020 in a prospective, monocentric, randomized controlled trial (RCT). This article reports on the study protocol for the RECOVER RCT. The trial is conducted in accordance to the SPIRIT Statement for reporting parallel group randomized trials.[25] The primary hypotheses include that RECOVER leads to cost savings compared to standard care within the 1-year treatment period, that RECOVER leads to greater benefits in terms of improving the patient's state of health, and that RECOVER has a better efficiency (cost-effectiveness) than standard care.

Trial design and conceptual framework: RECOVER model

The so-called RECOVER model was developed on the basis of these structural, therapeutic and cost-saving approaches. RECOVER is the synonym for an evidence-based, stepped and coordinated care service model for mental disorders. The evaluation is funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020 (funding code: 01NVF16018). The G-BA is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

The RECOVER model was developed by a consortium of representatives from Hamburg, Itzehoe and Germany including the Hamburg Health Authority, Hamburg patient and family associations, the Hamburg Chambers and Associations of Physicians, General Practitioners and Psychotherapists, the behavioural therapy centre "*Behavioural Therapy Falkenried clinics GmbH"* and the work integration centre "*ARINET GmbH"*, the German expert associations of adult and child and youth psychiatry and psychotherapy (DGPPN, DGKJP), the Centre for Psychosocial Medicine of the Hospital Itzehoe and the University Hospital Hamburg-Eppendorf (UKE) as consortium leader with 9 departments and institutes. The accompanying research is carried out by three independent institutes for health economics and health services research, clinical health care research, and medical biometry and epidemiology. The application and execution of studies within the Innovation Fund is tied to the participation of health insurances. RECOVER was initially supported by 4 statutory health insurance providers, including BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg and HEK. Since the introduction of the model in January 2018, the network is

constantly growing to by now over 270 participating institutions, registered physicians, general practitioners, psychotherapists and staff. In addition, 15 further statutory health insurance providers joined the RECOVER model. In 2018, the German Society for Psychiatry, Psychotherapy and Neurology awarded the RECOVER model as the reference model for sustainable psychiatry in the future in Germany. [7]

RECOVER combines three approaches: [14,15] Firstly, managed and coordinated care across sectors within a sectoral partner network. Secondly, stepped care within four severity levels from mild mental disorders (level 1) to severe mental disorders (level 4) with associated treatment packages, always with the proviso that the most effective resource-saving interventions are used first. Thirdly, as many interventions as possible are evidence-based, because evidence-based interventions are more efficient and thus save resources.

The RECOVER service model consists of 9 innovative care components, which are described in more detail in the following section. Each care component has been documented in a standard operating procedure (SOP) manual (e.g. see www.recover-hamburg.de). [26-28] For more details, see figure 1.

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(1) Improvement of managed and coordinated care

The UKE has established a Competence Centre for Integrated Mental Health Care. This centre has the task of improving the management and coordination of all cross-sectoral forms of care. This includes, for example, the involvement of institutions and clinicians through cooperation agreements, the establishment of a sectoral care network, care management (i.e. case management, allocation of therapy appointments, documentation), training and quality assurance. Access to care is improved by immediate appointments mostly within three to five days and the possibility of 24h crisis intervention. Information on access to care is available from all cooperation partners and can be accessed by patients and their relatives via the publicly accessible website. In addition, the centre is the operator of a new E-Mental-Health platform (eRECOVER; see www.erecover.de; see 6), which was developed within the framework of RECOVER. An online outpatient clinic for digital therapy has been integrated. [26]

(2) Improvement of diagnostics and crisis resolution

The improvement of diagnostics and crisis intervention is achieved through the implementation of a Crisis Resolution Team (so-called AID & CARE Team). AID stands for **A**mbulance for **I**ndication and **D**iagnostics, CARE for **C**risis **A**nd **RE**solution. It is a specialized, multi-professional and interdisciplinary team of physicians, psychologists, nursing staff, social workers and recovery counsellors from adult psychiatry, child and youth psychiatry, psychosomatics, medical psychology, general practice, sexual medicine and forensic psychiatry as well as a network partner for supported employment. The tasks include standardised

interdisciplinary biological, psychological and social initial diagnostics, indication and treatment planning, cross-sector outreach crisis intervention and managed care (implementation of the cross-sector treatment plan). The team works with an electronic board (called AID & CARE Board), in which all patients are discussed twice a day, especially those in crisis resolution treatment. The team assigns patients to one of four severity levels and the corresponding treatment plan is implemented by the Competence Centre in cooperation within the care network. The CARE treatment can be used whenever necessary during the entire therapy period. [27]

(3) Improvement of care for people with severe mental illness

Improvement of care for people with SMI is supported by the integration of Therapeutic Assertive Community Treatment (TACT) for severe psychotic disorders including schizophrenia spectrum disorders (F2) and bipolar I disorder (F31), severe unipolar depression with psychotic features and severe borderline personality disorders (F60.3). [28] These indications were chosen because these diagnoses have the highest risk for the development of SMI and account for about 80% of all patients with SMI. [24] This so-called "Hamburg integrated care model" has been financed since 2007 as Integrated care contract by 5 health insurances and was included into the RECOVER model for people in severity level 4. [29-32] Currently, there are four TACT teams: two for multiple-episode patients with severe psychoses, one team for adolescents and young adults with a first-episode psychosis and one team for patients with borderline personality disorders. Each team is responsible for around 80-100 patients in a 1:15-1:25 clinician-patient ratio with 24h/365days emergency interventions. The TACT teams have extensive expertise and are multidisciplinary including psychiatrists, psychologists, nurses, social workers and peers, ≥ 80% are psychiatrists and psychologists. The Hamburg model was examined in three major evaluations with regard to effectiveness and efficiency. These studies showed a good efficacy regarding symptoms, functional level, quality of life, remission and recovery [29-32] with high efficiency. [33]

(4) Integration of general practice

People with mental disorders, especially those with SMI, display a high morbidity and mortality risk. [31,34] Various models have attempted to improve coordination between primary care and psychiatry with unclear success. [31] One of the most recommended models is the so-called Reverse Integrated Care model (RIC), in which primary health care providers are co-located in the mental health setting. [31] In RECOVER, this is achieved by integrating general practitioners into the AID & CARE team. They are responsible for all somatic assessments, the organisation of further examinations and therapies in the network and the establishment, management and training of a network of general practitioners.

(5) Integration and increased flexibility of psychotherapy

Due to the long waiting times for psychotherapy of 5 months [35] on average and the preference of patients with mild and moderate mental illness [36], RECOVER has developed various incentives for psychotherapists together with the Psychotherapists' Chamber in Hamburg. The objectives are to shorten waiting times, to

take over patients with higher degrees of severity through joint treatment with the Crisis Resolution team and case manager, and more frequent use of stepped and flexible psychotherapy. The incentives include for example the waiver of the application procedure, which is now supported by all health insurances, the increase in short-term and group psychotherapies, the possibility of utilisation of the Crisis Resolution Team at any time and treating crises together on an outpatient basis as well as the qualification of staff through certified, training courses, case conferences and quality circles. In the future, psychotherapists in private practice can also use the E-Mental-Health platform eRECOVER.

(6) Integration of E-Mental-Health

Despite its great potential and meanwhile also evident benefits[37-39], E-Mental-Health is hardly integrated into the German health care system, it is not part of the standard care and is currently used by less than 1% of all clinics as well as outpatient clinicians and psychotherapists. Within RECOVER, E-Mental-Health is integrated into the stepped care model. The E-Mental-Health platform eRECOVER (see www.erecover.de) provides digital diagnostics and therapy for all severity levels. In level 1, this is the first intervention before face-to-face psychotherapy. In other levels it accompanies other interventions. Within eRECOVER, the following variants of digital therapy can be performed: (a) digital self-help programs, (b) guided digital therapy, (c) blended digital therapy. In the future, video individual therapy and video group therapy will be added.

(7) Integration of Supported Employment

Individual Placement and Support (IPS) is a further development of Supported Employment (SE). It includes training and work (re)integration with reintegration or integration on the first (paid) training or labour market with promotion of the sustainability of the intervention through job coaching. [40] The basis of this intervention is that 95% of all days of incapacity to work in Germany are generated by patients with CMD and that these patients in particular do not have access to evidence-based work (re)integration. Accordingly, a partnership was initiated with a provider of SE (ARINET GmbH) which offers the following interventions: (a) systematic screening and examination of occupational perspectives, (b) for patients with incapacity to work, measures such as job coaching or clarification assistance for early employability with initial counselling, in-company training, training on the job and support on the job at the workplace, (c) advice and support for taking a vocational rehabilitation measure. Supported Employment offers counselling for people who are unable to work, clarification of prerequisites or integration and placement in the existing labour market. The know-how is passed on to network partners and gradually a cooperation network with employers is established.

(8) Integration of culture- and language-sensitive care for migrants and refugees

The integration of cultural aspects in the therapy of mental disorder is becoming increasingly important. A number of measures have been implemented to improve integration: Within the AID & CARE team, specially trained employees work who in turn instruct other employees and provide further education in

regard to cross-cultural competencies. In addition, culturally sensitive diagnostics has been implemented. A manual has been developed to ensure quality standards for culturally sensitive care.

(9) Participation of peers and relatives and implementation of peer support

The aim is to improve the empowerment and participation of patients and their families in the organisation, treatment and research. This is chieved by representing patient and family associations on the RECOVER advisory board and by peer support in all major clinical units (crisis resolution team and assertive community treatment teams). In addition, the goals of the project and the accompanying research were coordinated with a special committee of patients and relatives.

Improvement of evidence-based treatment is achieved by assigning evidence-based treatment models and therapies to the four severity levels (levels 1-4) as shown in the 9 innovative care components. Regardless of severity, all patients will have access to managed and coordinated care, diagnostics and crisis resolution, social work, supported employment and peer support. Depending on the degree of severity, patients in levels 1-4 have access to he following treatment packages:

a) **Level 1:** mild severity (mostly CMD): counselling, active waiting, self-help, guided digital therapy, social work, supported employment and peer support.

b) **Level 2:** moderate severity (mostly CMD): Coordinated standard care with stepped individual and/or group psychotherapy (≤ 12h), digital therapy, social work, supported employment and peer support.

c) **Level 3:** moderate to severe severity (mostly CMD): coordinated standard care plus case management with stepped individual and/or group psychotherapy (> 12h to long term), digital therapy, social work, supported employment and peer support.

d) **Level 4:** Severe mental illness (1-2%, SMI): Therapeutic assertive community treatment (TACT) including 24h crisis resolution and individual and/or group psychotherapy, digital therapy, social work, supported employment and peer support.

METHODS AND ANALYSIS

Study design

The RECOVER study is a prospective, monocentric, randomized controlled trial (RCT) conducted in the catchment area of the University Medical Center Hamburg-Eppendorf, Germany.

Changes of trial design

In addition to the 4 statutory health insurance funds, another 15 statutory health insurance funds have joined the model, which has not resulted in any changes of the study design.

Study setting

The study takes place within the catchment area of the University Medical Center Hamburg-Eppendorf, Hamburg, Germany from January 2018 to December 2020. The Department of Psychiatry and Psychotherapy covers an area of approximately 330.000 inhabitants. The area omprises about 20 psychiatric institutions and about 100 registered specialists in psychiatry and psychotherapy, general practice and psychosomatics and about 200 registered psychological psychotherapists. The RCT is conducted by three independent institutions: the Department of Medical Psychology (UKE), the Department of Health Economics (UKE) and the Department of Biostatistics (UKE). As part of the study implementation, the research institutions also have the task of data monitoring.

The recruitment of the participating patients took place via a systematic, daily screening in the psychiatric regular care of the UKE. In addition, all partners involved have received a screening form to refer patients to the UKE. We have also made a screening form available on the homepage that interested parties could use to contact us directly. This form is adapted to the following inclusion and exclusion criteria.

Inclusion criteria

Eligible participants are people at the age of ≥16 years, insured with one of the 19 health insurances involved and living in the catchment area of the UKE (8 km radius), when they suffer from at least one relevant mental disorder according to the International statistical classification of diseases and related health problems - 10th revision, German Modification (ICD-10) [41]: schizophrenic spectrum disorders (ICD-10: F20, F22, F23, F25), bipolar disorder (ICD-10: F31), major depression (ICD-10: F32, F33), anxiety disorder (ICD-10: F40, F41), obsessive-compulsive disorder (ICD-10: F42), post-traumatic stress disorder (ICD-10: F43.1), adjustment disorder (ICD-10: F43.2), somatoform disorders (ICD-10: F45), eating disorder (ICD-10: F50), personality disorder (ICD-10: F60, F61) or attention deficit hyperactivity disorder (ICD-10: F90).

Exclusion criteria

Subjects are excluded from the study when fulfilling the criteria for organic mental disorders (ICD-10: F00-09); with a main diagnosis of addiction disorders (ICD-10: F10-19) (comorbid addiction disorders do not lead to exclusion), with severe or moderate mental retardation (pre-diagnosed ICD-10: F72/F73), with insufficient knowledge of German, with uncorrectable impairment of vision and/or hearing.

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Interventions

Upon inclusion in the study, all participants receive a detailed psychological assessment. This consists of standardized questionnaires regarding the main diagnosis, comorbid disorders, social problem areas, functional level and quality of life. On the basis of combined criteria consisting of severity of the disease and functional level, the classification into the 4 severity levels is carried out (see table 1). Subsequently,

the randomization and thus the allocation to the intervention and control group takes place. With regard to the comparison of structures and interventions between intervention and control groups, table 2 compares all essential care components (see table 2).

RECOVER treatment (Intervention Group, IG)

Patients assigned to the RECOVER model are first admitted to the center and registered in the IT file. The patient is then automatically assigned to a case manager of the AID & CARE team. On the basis of the preceding standardized diagnostics, the case manager carries out a re-evaluation of the psychosocial diagnostics, transfers the data to the AID board and calls in a social worker in case of social problems. As a standard, each patient receives somatic diagnostics from the general practitioner. Subsequently, the patient is discussed in the twice-daily multi-professional and interdisciplinary meetings and a treatment plan is drawn up. In acute crises, the patient is admitted to the CARE treatment. In contrast to standard care, the treatment plan is organized in the network for the patient. The case manager always remains the patient's primary contact person, even when referrals are made to the network. If another acute crisis occurs, the patient can be treated again with CARE at any time.

Treatment-As-Usual (Control Group, CG)

The control group receives standard care that is provided n the sector of the University Hospital Hamburg-Eppendorf. This includes the use of full and day-clinic inpatient treatment within the Clinic for Psychiatry and Psychotherapy of the UKE and the Clinic for Child and Adolescent Psychiatry of the UKE, the treatment in the Psychiatric Outpatient Clinic of the UKE, the use of therapy from specialists in general practice and psychiatry as well as psychological psychotherapists and treatment at institutions of assisted living and rehabilitation of mental illnesses.

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Outcomes and hypotheses

Primary outcomes

1) 12 months treatment in RECOVER compared to TAU result in a reduction of a) costs of health care as covered by the statutory health insurance (SHI), b) costs of care as covered by other payers, c) costs due to productivity losses (indirect costs). RECOVER is cost-saving compared to TAU.
2) 12 months treatment in RECOVER compared to TAU is associated with a) improved disease remission and response, b) reduced symptoms and illness severity, c) improved functioning and d) improved health-related quality of life. These measures will be linearly transformed and added up to one measure "psycho-functional level".
3) 12 months treatment in RECOVER compared to TAU lead to a gain in quality-adjusted life years

(QALYs) across all patients, with simultaneously unchanged or reduced direct (SHI perspective) or direct and indirect (societal perspective) costs.

Secondary outcomes

12 months treatment in RECOVER compared to TAU leads to the following secondary outcomes: 1) a reduction of inpatient and day-care admissions and inpatient and day-care days, 2) a reduction of days ith inability to work, 3) a lower service disengagement rate, 4) a reduction of waiting time until start of psychotherapy aid by SHI, 5) a higher percentage of patients with SMI receiving roup and individual psychotherapy, 6) a higher use of digital therapy, and 7) a higher use of peer support.

Changes to trial outcomes after trial commenced

None

Sample size

The sample size is based on a power calculation to detect a statistically significant difference between the intervention and control group of a small to medium effect size (Cohen's f of 0.175) after 12 months (t12)). 234 study participants in total (117 in each group) are required given a statistical power of at least 80% (with a type-1 error rate of 5% in a 2-sided test and 10% explained variance by the baseline value). The sample size is increased to 384 to include interactions of the interventions with a small to medium effect size (Cohen's f of 0.175). Diagnostics is performed centrally. After the individual randomisation of each study participant, the therapy in RECOVER and in TAU takes place in approximately 50 clusters with approximately 21 participants each. To take this cluster effect into account, an intra-class correlation (ICC) = .05 is assumed. So we obtain a design effect of 2.0 for the primary, continuous outcome, which leads to a total number of 890 patients that have to be included (dropout rate of about 30% is included).

Assignment of interventions

Single blinded study (outcomes assessor): Individuals who evaluate the outcomes of interest will remain blinded regarding a participant's condition (RECOVER/TAU) over the course of the study. The individual stratified randomization (i.e. four severity levels) will be conducted after baseline assessment and communicated to the participant by a person that is not the outcome assessor. We have used the procedure “ralloc” (STATA-SE 14) with variable block sizes within each stratum. During follow-up assessments after 6 and 12 month the outcome assessor will remain blinded regarding a participant's condition.

Data collection, management, and analysis

Data will be collected before intervention (t0) after 6 (t6) and 12 months (t12) (See Figure 2 for the CONSORT flow diagram). The following instruments are used: Diagnostic and Statistical Manual of Mental disorders (DSM-V) (structured clinical interview (SKID I and II [42]), psychiatric use of care services (FIMPsy

questionnaire[43]), general use of health services (FIMA questionnaire[44]), disease remission or responses (HEALTH-49[45]; CGI[46]). Moreover, the use of additional, study specific health services like the use of digital therapy is assessed in a questionnaire. The severity of the symptoms is also measured for the different diagnostic groups (diagnosis-specific). Further questionnaires measure everyday functioning level (observer rated: GAF [47]), health-related quality of life (EQ-5D-5L [48], SF-12 [49], ReQOL [50]), and QALYs (based on EQ-5D-5L index[48]). Various risk parameters and comorbid diseases are recorded across all diagnoses. A sample of relatives will be interviewed (questionnaire and interview). The collected health data are enriched with secondary data obtained from external data owner (e.g. inpatient performance data, outpatient medical performance data, etc.). After 12 months (at t12), this data is requested from the health insurance companies for the past 36 months. A monetary valuation is then performed according to standardized monetary valuation rates.[51,52] For more details, see table 3.

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The primary and secondary outcomes are evaluated according to the intention-to-treat principles. For the primary outcome psycho-functional level, the change from baseline to 12 months follow-up will be analyzed by calculating a linear mixed model with group (RECOVER, TAU), severity level and interaction between group and severity level as fixed effects, cluster as random effect and the baseline value of psycho-functional level as a covariate. Disease remission and response to treatment are analyzed using mixed logistic regression. Remission is assumed if a predefined cut-off value is achieved at follow-up (e.g. PHQ-9≤5). Response to treatment is assumed if a patient has improved by 50% of the initial symptoms. Changes in disease symptoms, everyday functioning level and HQOL are analyzed using mixed linear regression models. For the evaluation of the primary outcome direct and indirect costs during the 12 month follow-up, multiple difference-in-difference regressions are used. We assume that the intervention is cost saving, if the negative difference in costs is statistically significant ($p<0.05$). Results are interpreted as cost neutral, if the difference in costs is negative and not statistically significant (intervention is less expensive) or if the difference in costs is positive with a p-value >0.5 (intervention is more expensive). All models are used with the direct maximum likelihood estimation procedure which results in unbiased estimators under the missing-at-random assumption. Adjusted means and odds ratios, respectively, with their 95% confidence intervals and p-values will be reported. The two-sided type I error will be set at .05. Interim analyses are not planned. Cost-effectiveness will be analyzed by incremental cost-effectiveness ratios (ICER). Cost-effectiveness acceptability curves based on net benefit regressions will be used to evaluate uncertainty of the ICER. A detailed statistical analysis plan will be prepared and finalized before the code is broken. Results will be reported according to the SPIRIT guidelines. Only the analysis of primary outcomes will be considered in a confirmatory manner. For sensitivity analyses, missing values are replaced by multiple imputations and per-protocol analyses are performed.

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Secondary outcomes are examined with multivariate methods (logistic regression, difference-in-difference regression). The secondary outcomes will be evaluated according to the scale level with mixed linear or logistic regression models. For the analysis of inhibiting and promoting factors for the overall treatment model and an effective and efficient implementation of RECOVER in clinical routine, qualitative methods are used. The results of the study will be evaluated using descriptive and inferential statistical analyses of sociodemographic and diagnostic data. The predictive value of different factors will be tested by logistic regression.

Patient and Public Involvement

Within RECOVER, patients, relatives and the public were systematically involved: (1) Peer support is a separate intervention module, which provides the systematic integration of trained patients into the provision of care, e.g. in the Crisis Resolution Team and in the Assertive Community Treatment Teams; (2) The entire care model and research project RECOVER was planned and carried out in coordination with the patient and relatives organisation "EmPeeRie - Empower Peers to Research" regarding content and study questions; (3) RECOVER was led by a steering committee. Patient and family member organisations from Hamburg are represented in this committee; (4) The public was informed via a separate project website. Here, all materials developed are also available for download.

DISCUSSION

Health systems around the world are looking for efficient solutions to the growing problem of mental health care and its funding. In Germany, the Advisory Councils on Health Care and Macroeconomic Development as well as professional associations call for the introduction of stepped, integrated and coordinated care. RECOVER is the synonym or such an evidence-based, stepped and cross-sectoral coordinated care service model for all main common and severe mental disorders. RECOVER implements a cross-sectoral care network with managed care, a comprehensive psychological, somatic and social initial diagnosis, crisis resolution for all patients in acute crises and four severity levels (from mild to severe mental illness), each with assigned evidence-based therapy models and therapies. The RECOVER study will be able to answer important questions regarding costs, efficiency and effectiveness of the model. In addition, it evaluates the transfer of the model to another region in Germany.

The RECOVER model could have the following limitations: (1) It is possible that not enough partners from the outpatient sector participate in the model with regard to network formation; (2) It is possible that patients at level 3 in particular already are too impaired for placement in outpatient psychotherapeutic

care; (3) With regard to the sustainability of RECOVER, there is a need to introduce treatment models into standard care that are currently internationally evidence-based but are not yet part of mainstream care in Germany.

Successful confirmation of the efficiency and effectiveness of the RECOVER model can make theoretical, clinical and societal contributions. First, the findings will generate new knowledge about stepped care service models, effective integrated therapy models and therapies as well as efficient care processes. Specifically, the integration of e-mental health will help to increase acceptance and use of digital diagnostics and therapy. Second, the proof of effectiveness and efficiency creates all the prerequisites to transfer the model into standard care. How this can be achieved is already the subject of intensive cooperation between the developers of the RECOVER model and the participating health insurance funds. Third, the proof of effectiveness and efficiency, together with the accompanying research and experience with the transfer of the model as well as the 12 quality assurance manuals create optimal prerequisites for the further transfer of the whole model or essential components into other German regions.

ETHICS AND DISSEMINATION

This study has obtained ethics approval from the Ethics committee of the Hamburg Medical Association (PV5672).

The written consent of all participants will be obtained and they will receive a detailed explanation of the study objectives, the voluntary nature of their participation, their right to withdraw their participation and the risks and benefits of the study.

RECOVER is a care model that should not cause any physical or psychological harm to participants. In the event of an unforeseen problem or if the participant experiences inconvenience or anxiety while filling out the questionnaire or answering the questions in the interview, the researcher will report this to the head of data collection. The researchers will help the participants to get additional support from experts. Participants can also choose not to answer the questions or stop the interview. Participants are asked to sign two copies of the informed consent form, one to be given to the participants and the other to be returned to the principal investigator of this study for recording purposes. The consent forms will be kept separate from the data. All data collected, without personal names, will be stored in the locked cabinet of the principal investigator (PI), while all digital or electronic records will be password-protected and kept in the PI computer for 5 years. Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

The current RCT will improve our understanding of the impact of RECOVER on the results of service users, especially as far as they are concerned:

1) Demonstrate the benefits and unintended consequences of recovery-oriented, strength-based

services for people with mental illness.

2) Highlight the key therapeutic ingredients of RECOVER and how they affect SMCM outcomes.

3) Review how you can best use RECOVER in Germany.

Post trial care of the study participants is ensured by the possibility of further treatment in the standard care setting.

Our disimination policy aims at several important target groups. To share our knowledge with service users and their families, PI and the team will work with the local community and media. Healthcare professionals will benefit from the study's contribution to staff training and expert interviews. We will share our findings with researchers at home and abroad through conference presentations and publications in peer-reviewed journals. Our results are also disseminated through seminars organized by the PI Department and RECOVER websites.

OTHER INFORMATION

Registration

Ethics committee of the Hamburg Medical Association (PV5672).

Registration number with ClinicalTrials.gov (NCT03459664).

Protocol

The full trial protocol can be accessed through ClinicalTrials.gov

Funding

The evaluation of RECOVER is funded by the Innovation Fund of the Joint Federal Committee (G-BA) from 2017 to 2020 (funding code: 01NVF16018). The G-BA is responsible for the development of new forms of health care and health care research with the aim of improving the quality of SHI care. To this end, the Federal Government has set up an innovation fund which will provide annual funding of 300 million euros between 2016 and 2019. The funder had no role in study design, data collection and analysis, writing of the report, and decision to submit the study protocol for publication.

Steering committee

The RECOVER study was coordinated, monitored and accompanied by a steering committee. The steering committee included study directors, study coordinators, representatives of the Hamburg Ministry of Health and Consumer Protection, representatives of the three independent scientific research institutions, representatives of the University Hospital and the Itzehoe Hospital (for the transfer), representatives of the participating health insurance funds, representatives of the Hamburg Chamber of Psychotherapists and Medical Association as well as representatives of the Hamburg patient and family associations.

Data statement section

Only the PI and the local co-chairs of this research project have access to the original experimental data set for research purposes only.

Acknowledgement

We thank all employees and partners of the RECOVER project who are not mentioned. In particular, we would like to thank the partners of the participating health insurances and their representatives: BARMER, DAK-Gesundheit, AOK Rheinland/Hamburg, HEK, IKK Classic, BKK Mobil Oil, BKK Salzgitter, BKK Public, BKK RWE, BKK Linde, BKK Technoform, BKK Verbund Plus, Energie BKK, Heimat BKK, TUI BKK, Salus BKK, VIACTIV Krankenkasse, WMF Betriebskrankenkasse.

Authors contributions

Martin Lambert, Anne Karow, Jürgen Gallinat, Holger Schulz, Heike Peper, Hans-Helmut König, Arno Deister, Gunda Ohm, Helmut Peter, Bernd Löwe, Peer Briken, Martin Scherer and Vivien Kraft were mainly responsible for the conception and design of the study. The manuscript is mainly drafted by Martin Lambert, Anne Karow, Anne Daubmann, Hannah König and Anja Rohenkohl. Karl Wegscheider, Antonia Zapf and Anne Daubmann are responsible for the statistics of the project. The acquisition of the data and conduction of the study was mainly done by Judith Peth, Rolf Michels, Stephanie Herr, Romy Schröter, Constanze Finter, Anna-Katharina Siem, Lisa Tlach, Nathalie Werkle, Michael Schweiger, Daniel Lüdecke, Claudia Mews, Susanne Pruskil, Johannes Lüke. Drafting the work or revising it critically for important intellectual content was carried out mainly by Susann Bargel, Martin Hoff, Martin Härter, Jörg Dirmaier, Michael Schulte-Markwort, Mike Mösko, Thomas Bock, Martin Wittzack, Hans-Jochim Meyer, Alexander Konnopka, Karl Wegscheider, Antonia Zapf.

All authors have fulfilled authorship criteria according to following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Declaration of interests

1) Conflicts of interest regarding the present research project

All authors: None

2) Conflicts of interest in general

Martin Lambert: consultant or speaker fees AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH, Sanovi Aventis, Trommsdorff GmbH & Co. KG
Anne Karow: consultant or speaker fees from AstraZeneca, Bristol-Myers Squibb, Lilly Deutschland GmbH, Janssen Cilag GmbH, Lundbeck GmbH, Otsuka Pharma GmbH, Roche Deutschland Holding GmbH

Jürgen Gallinat: speaker fees from Lundbeck GmbH, Otsuka Pharma GmbH, Janssen Cilag GmbH
Daniel Lüdecke: speaker fees Janssen Cilag GmbH
Vivien Kraft: none declared
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Figure caption

Figure 1. The RECOVER evidence-based, stepped and coordinated care model

Figure 2. Consort flow diagram of the RECOVER study

Table 1. Classification into four severity levels

Measurement	Severity levels			
	Level 1 (mild)	Level 2 (medium)	Level 3 (medium to severe)	Level 4 (severe)
Main disorder according to DSM-V	296.x, 300.x, 307.x, 309.x, 314.0x	296.x, 300.x, 301.x, 307.x, 309.x	296.x, 300.x, 301.22, 307.x, 309.8, 301.x	295.x, 296.4/5 (incl. psychosis), 296.34, 297.1, 298.x, 301.x
Main disorder according to ICD-10	F32, F40, F41, F43.2, F45, F90	F32, F40, F41, F42, F43.1, F43.2, F45, F50, F90	F20, F22, F23, F25, F31, F33, F41, F42, F43.1, F45, F50, F60, F61	F20, F22, F23, F25, F31, F32.3, F33.3, F60
Global Assessment of Functioning GAF)	GAF score 61-100: No or mild symptoms in the last 4 weeks	GAF score 51-60: Moderate symptoms in the last 4 weeks	GAF score 31-50: Serious symptoms or impairments in the last 4 weeks	GAF score ≤ 50 for the last 6 months: serious or major impairments
Clinical Global Impressions-Severity Scale (CGI-S)	CGI 1-3	CGI 3-4	CGI 4-6	CGI 5-7

Table 2. Key characteristics of RECOVER intervention and TAU control groups

Dimensions	RECOVER group	TAU group
1. Access to care	▪ Outpatient appointment within 3-7 days, crisis resolution 24h/day	▪ Often long waiting time for outpatient appointments, with respect to psychotherapy 4-6 months ▪ Emergency department 24h/day
2. Standardized assessment at service entry	▪ Standardized psychological, somatic and social assessment ▪ Multi-professional and interdisciplinary review	▪ Assessment often not standardized, often focus solely on psychological issues ▪ No multi-professional and interdisciplinary review
3. Indication and treatment planning	▪ Multi-professional and interdisciplinary indication and treatment planning	▪ Mostly no multi-professional and interdisciplinary indication and treatment planning in outpatient care
4. Managed and coordinated care	▪ Organization of the therapy plan in the network and coordination of therapy	▪ Managed and coordinated care not part of standard care
5. Crisis Resolution (CR) for people with all mental disorders	▪ Multi-professional and interdisciplinary crisis resolution team with 24h crisis resolution ▪ Coordinated inpatient and day-clinic care	▪ Inpatient care ▪ Day-clinic care
6. Assertive Community Treatment (ACT) for people with severe mental illness	▪ Multi-professional ACT-Teams including psychotherapy and 24h crisis resolution	▪ ACT not part of standard care ▪ ≤ 5% of patients with SMI receive psychotherapy
7. Access to primary care	▪ Integrated access to primary care physicians in the network	▪ Access to primary care physicians with waiting time ▪ Not integrated into other mental health care
8. Access to psychotherapy	▪ Access to stepped psychotherapy within the network with short waiting time	▪ Access to short- or long-term psychotherapy with long waiting time
9. E-mental-Health	▪ Digital self-help, guided or blended digital therapy	▪ Not part of standard care ▪ Dependent on health insurance access via special supply contracts ▪ Not integrated into other mental health care
10. Supported Employment (SE)	▪ Access to supported employment workers	▪ Not part of standard are
11. Culture and language-sensitive care	▪ Access to specialists within the crisis resolution team ▪ Systematic involvement of interpreters	▪ Not part of standard outpatient care ▪ Systematic involvement of interpreters in inpatient care available
12. Peer Support	▪ Peer Support workers in CR and ACT teams	▪ Not part of standard outpatient care

Table 3. Measurement used for measuring primary and secondary outcomes

Outcome measure	Measurement	Details of the measurement	Completed by
Primary outcomes			
Direct costs	FIMA[43], FIMPsy[44]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services and monetary evaluation using standardized unit costs[40,41]	Interviewer
Indirect costs	RECOVER questionnaire	Assessment of indirect costs as productivity loss due to days off work/ sick leave or early retirement	Interviewer
Disease remission and response	Health-49[45], CGI[46]	Rating of general aspects of psychosocial health (Health-49) and severity of patient's illness (CGI-S)	Study participant/ Interviewer
Symptoms and illness severity	Diagnosis-specific questionnaires	Rating of the severity of symptoms using several diagnosis-specific questionnaires	Interviewer
Functioning level	GAF[47]	Rating of everyday functioning level	Interviewer
Health-related quality of life	EQ-5D-5L[48], SF-12[49], ReQoL[50]	Rating of health-related quality of life and calculation of QALYs using the results of the EQ-5D-5L	Study participant
Secondary outcomes			
Inpatient and day-care admissions, inpatient day-care days	Clinic documentation, FIMA[44], FIMPsy[45]	Assessment of psychiatric (FIMPsy) and general (FIMA) use of health care services	Clinician/ Interviewer
Days with inability to work	RECOVER questionnaire	Assessment of days off work/ on sick leave	Interviewer
Service disengagement rate	Clinical documentation	Patient interrupts contact with the treatment facility and cannot be reengaged again	Clinician
Waiting time until start of psychotherapy	RECOVER questionnaire	Assessment of active search for outpatient psychotherapeutic treatment after 6 months (t6) and 12 months (t12)	Study participant
Group and individual psychotherapy for patients with SMI	Clinic documentation, RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Clinician/ Study participant
Use of digital therapy	RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant
Use of peer-support	FIMPsy[43] (t0), RECOVER questionnaire	Assessment of service use of specific interventions after 6 months (t6) and 12 months (t12)	Study participant/ Interviewer

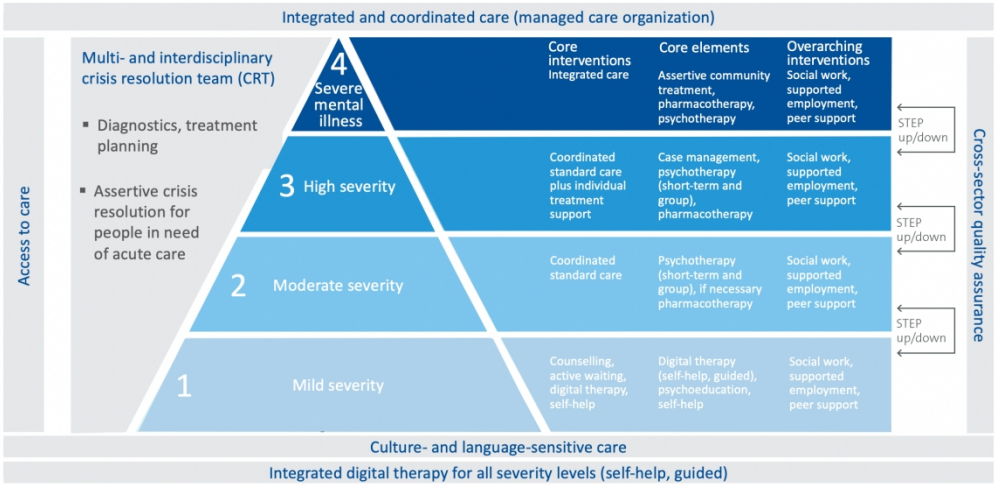

Figure 1. The RECOVER evidence-based, stepped and coordinated care model

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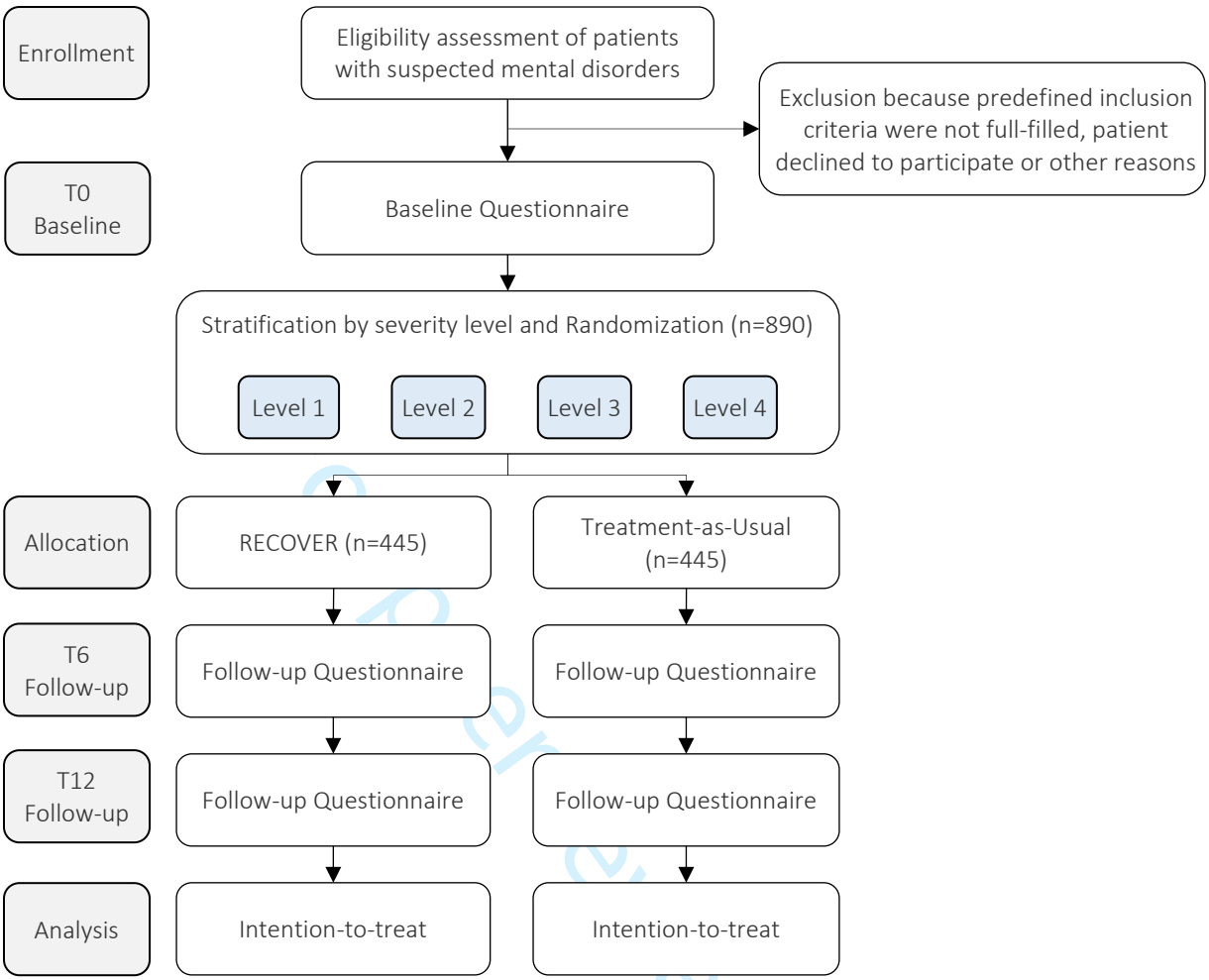

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	17

Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 18
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	NA
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4/12
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6-10
Methods: Participants,			

interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10, 11
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	11, 12
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	11, 12, 16
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	12, 13
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	13, Fig. 2
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including	13

		clinical and statistical assumptions supporting any sample size calculations	
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate	13, 14

		measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11, 16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14, 15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14, 15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14, 15
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	11

Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	14
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16, 17
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18, 19

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	16,17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	17
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Available on request in German
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA