BMJ Open

Effectiveness and cost-effectiveness of a web-based routine assessment with integrated recommendations for action for depression and anxiety – RehaCAT+: study protocol of a cluster randomized controlled trial for patients with elevated depressive symptoms in rehabilitation facilities.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061259
Article Type:	Protocol
Date Submitted by the Author:	20-Jan-2022
Complete List of Authors:	Knauer, Johannes; Ulm University, Department of Clinical Psychology and Psychotherapy Terhorst, Yannik; Ulm University, Department of Clincial Psychology and Psychotherapy Philippi, Paula; Ulm University, Department of Clinical Psychology and Psychotherapy Kallinger, Selina; Ulm University, Department of Clinical Psychology and Psychotherapy Eiler, Sandro; Ulm University, Department of Clinical Psychology and Psychotherapy Kilian, Reinhold; Ulm University, Department of Psychiatry and Psychotherapy II Waldmann, Tamara; Ulm University, Department of Psychiatry and Psychotherapy II Moshagen , Morten ; Ulm University, Department of Psychological Research Methods Bader, Martina; Ulm University, Department of Psychological Research Methods Baumeister, Harald; Universitat Ulm, Department of Clinical Psychology and Psychotherapy
Keywords:	Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, HEALTH ECONOMICS, MENTAL HEALTH, PRIMARY CARE, REHABILITATION MEDICINE

Effectiveness and cost-effectiveness of a web-based routine assessment with integrated recommendations for action for depression and anxiety – RehaCAT+: study protocol of a cluster randomized controlled trial for patients with elevated depressive symptoms in rehabilitation facilities.

Johannes Knauer[1], Yannik Terhorst[1], Paula Philippi[1], Selina Kallinger[1], Sandro Eiler[1], Reinhold Kilian[2], Tamara Waldmann[2], Morten Moshagen[3], Martina Bader[3], Harald Baumeister[1]

[1]Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University, Germany

[2]Section Health Economics and Health Services Research, Department of Psychiatry and Psychotherapy II, Ulm University, Germany

[3]Department of Psychological Research Methods, Institute of Psychology and Education, Ulm University, Germany

Corresponding Author: Johannes Knauer (Lise-Meitner-Straße 16, D-89081 Ulm, johannes.knauer@uni-ulm.de, +49 731/50 32805)

Email Addresses of Co-authors:

Yannik Terhorst (yannik.terhorst@uni-ulm.de)

Paula Philippi (paula.philippi@uni-ulm.de)

Selina Kallinger (selina.kallinger@uni-ulm.de)

Sandro Eiler (sandro.eiler@uni-ulm.de)

Reinhold Kilian (reinhold.kilian@uni-ulm.de)

Tamara Waldmann (tamara.waldmann@uni-ulm.de)

Morten Moshagen (morten.moshagen@uni-ulm.de)

Martina Bader (martina.bader@uni-ulm.de)

Harald Baumeister (harald.baumeister@uni-ulm.de)

Abstract

Introduction The integration of a web-based computer-adaptive patient reported outcome test (CAT) platform with persuasive design optimized features including recommendations for action into routine health care could provide a promising way to translate reliable diagnostic results into action. The present study aims to evaluate the effectiveness and cost-effectiveness of such a platform for depression and anxiety (RehaCAT+) compared to the standard diagnostic system (RehaCAT) in cardiological and orthopedic health clinics in routine care.

Methods and analysis A two-arm, pragmatic, cluster-randomized controlled trial (cRCT) will be conducted. Twelve participating rehabilitation clinics will be randomly assigned to control (RehaCAT) or experimental group (RehaCAT+) in a 1:1 design. A total sample of N = 1,848 participants will be recruited across all clinics. The primary outcome, depression severity at 12-months follow up (T3), will be assessed using the CAT PROMIS Emotional Distress – Depression Item set. Secondary outcomes are depression at discharge (T1) and 6 months follow-up (T2) as well as anxiety, satisfaction with participation in social roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy, physical functioning, alcohol, personality, and health economic specific general quality of life and socioeconomic cost and benefits at T1-3. User behavior, acceptance, facilitating and hindering factors will be assessed with semi-structured qualitative interviews. Additionally, a smart sensing sub-study will be conducted, with daily ecological momentary assessments and passive collection of smartphone usage variables. Data-analysis will follow the intention-to-treat principle with additional per-protocol analyses. Cost-effectiveness analyses will be conducted from a societal perspective and the perspective of the statutory pension insurance.

Ethics and dissemination The study will be conducted according to the Declaration of Helsinki. The Ethics Committee of the University Ulm, has approved the study (on 24 February

2021 ref. 509/20). Written informed consent will be obtained. Results will be published via peer reviewed journals.

Trial Registration The trial is registered in the German Clinical Trials Register (DRKS00027447, date of registration: 11.01.2022)

Word Count: 5110

Keywords: cluster randomized controlled trial, patient reported outcome, depression, computer adaptive testing, routine care

Strengths and limitations of this study

- Large pragmatic, cluster-randomized controlled trial.
- First integration of a computer-adaptive patient reported outcome platform for screening with action recommendations regarding depression and anxiety in orthopedic and cardiologic health care.
- Comprehensive effectiveness, cost-effectiveness and feasibility analyses.
- Fine granular disease and treatment trajectories by means of smart sensing.
- Representative for German rehabilitation health care system.

RehaCAT+ Protocol Version 1 - 20.01.2022

1 Introduction

Bio-psycho-social health care in patients with somatic diseases such as musculoskeletal or cardiovascular diseases is faced with the challenge of designing the initiation and implementation of medical and psycho-social measures in a needs-based manner (1–4). Patient reported outcome measures (PROMs) could become important means to achieve this goal in somatic health care (5–8). For instance, they can serve as a basis for screening mental health comorbidities, quality of life and functioning in daily living. Based on these test results, treatment planning, process and outcome measurement and quality assurance can take place (5,7).

To promote acceptance and to optimize the quality of psychodiagnostics, there is a demand for an economical, resource-saving assessment that minimizes the burden on patients (measurement efficiency) and facilitates evaluation and interpretation of results (usefulness) (1). Besides, a reliable assessment of differences between patients (measurement precision) and changes in the condition of patients during and after treatment (change sensitivity of the assessment) is a necessary prerequisite (1). Paper-and-pencil testing procedures are most commonly used, but have crucial limitations, amongst others the limited scope or the test load of such an assessment and difficulties in collecting these measures before, during, and after the treatment process (1,9–13).

A computer-based implementation of PROM assessments is considered as a possible solution for an equally precise and time-efficient, user-friendly and useful assessment (1,5,14). Furthermore, a likewise web-based implementation of such an assessment removes time- and location dependencies. Hence, assessments of patients before and after the end of treatment could be implemented more easily in routine care settings.

However, PROMs are often static and non-adaptive to the user's responses, resulting in limited accuracy, presentation of inappropriate items for the individual, and an overall long assessment duration (15–17). Computer-adaptive testing (CAT), which is based on item response theory models, is a promising option in this context, substantially reducing the burden on patients (personalized testing) and health care institutions (e.g., immediate test evaluations) (10,18–23). In CAT, the items providing the maximum information about the respective patient are selected and assessed during test administration based on the previous answers of a patient (24). In this way, besides a considerable reduction in test duration, an estimation accuracy that is equally good or sometimes even better compared to non-adaptive procedures can be achieved (18,23,25–27).

Whereas PROMs are often used in clinical research, the usefulness and effectiveness of routine PROM assessment in somatic health care is still controversially discussed (8,28–33). On the one hand, routine PROMs allow for real-time monitoring. Moreover, PROMs have been shown to lead to improved communication between clinician and patient, decision-making and patient satisfaction with care, and improved health outcome and detection of symptoms and mental comorbidities. On the other hand, there are barriers such as limited ability of clinicians for score interpretation, unfamiliarity with PROM software usage and less time for controlling (8,23,39–42,31–38). Additionally one of the central challenges is the implementation of further evidence-based measures on the basis of the assessment results (43). Action plans directly derivable from assessment results are regarded as a prerequisite to implement PROMs beneficially (31,33,44,45). However, there is still an insufficient linkage between assessment results and implementation of existing evidence-based guidelines and recommendations for action in everyday clinical practice (33,46).

One way to promote the desired probability of action following diagnostic results could be persuasive design components, such as reminder features that are automatically triggered

depending on the test environment (47–49). Persuasive designed technological approaches are defined as interactive systems that purposefully influence the user, aiming to change behavior or attitudes (50). Supplementary, the provision of computer-based databases and concrete decision-making aids and recommendations for action is seen as one way of reducing these existing barriers (51,52). In this context, it could be useful to link the individual test results with therapy standards as well as recommendations for action and guideline knowledge. These have been formulated in particular for the areas of comorbid depression and anxiety in patient populations with somatic diseases (53–57). Such a combination could offer the practitioner a) background knowledge, b) recommendations for action as well as c) documentation aids. Ideally, such elements should be directly integrated into testing systems (e.g., web- and CAT-based) to provide a comprehensive platform from screening to action.

Hence, the aim of the present trial is to examine a persuasive design optimized CAT system (RehaCAT+) providing background knowledge, recommendations for action as well as documentation aids against a standard CAT system (RehaCAT). This will be exemplified with a focus on depression as the primary outcome and anxiety as major mental health comorbidities in cardiological and orthopedic care. The following research questions will be addressed:

1) Does RehaCAT+ improve rehabilitation patients' depression after one year (T3)?

2) Does RehaCAT+ improve depression, anxiety, satisfaction with participation in social roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy, physical function, and alcohol use at discharge (T1) and six months (T2) as well as one year regarding all the secondary outcomes (T3)?

3) Does RehaCAT+ lead to improved documentation and improved follow-up and post-rehabilitation recommendations?

4) Does RehaCAT+ lead to improved utilization of rehabilitation therapy standard and guideline compliant health care services during and after rehabilitation?

5) What is the cost-effectiveness of RehaCAT+ compared to RehaCAT?

6) What is the acceptance and feasibility of RehaCAT?

7) What are facilitators, hindering factors, mediators and potential risks associated with RehaCAT+?

A web-based CAT system provides a powerful way to assess PROM, however, it is still subject to limitations: 1) it requires active input of the patient – even if reduced through computer adaptive testing, 2) the assessment is limited to fixed time points, which may lead to long unassessed time intervals in which significant symptom change may occur, and 3) due to the nature of self-report the answers by patients may be biased (e.g., social desirability or recall bias) (58–61).

One solution to this could be the addition of ecological momentary assessment and smart sensing to allow for digital phenotyping (62,63). Digital phenotyping is defined as the moment-by-moment quantification of the individual health in situ through digital variables and data generated by personal devices (e.g., smartphone or smart-watch) (62,63). First studies show promising results highlighting the potential of this method to complement PROM assessments for monitoring and predicting symptoms with minimal added patient burden (64–70). In future the combination of high quality PROM at fixed timepoints combined with continuous monitoring through smart sensing and information from the clinical information system could become a promising data base, which could be used to 1) predict symptom trajectories, 2) build early-detection of adverse events systems (RED-flag) or 3) personalized treatment recommendation systems (71–74).

Hence, the present study additionally investigates the extent to which smart sensing is suitable for assessing mental health in a routine care setting. In the context of this exploratory study, we will focus on the following research questions:

8) What are the associations between digital markers and health-related variables?

9) Are digital markers suitable for predicting health-related variables and disease or disorder status?

10) What is patient acceptance, adherence, and perceived usefulness of smart sensing?

2 Methods and analysis

2.1 Study design

A two-arm, pragmatic, cluster-randomized controlled trial (cRCT) will be conducted, comparing the experimental group receiving an enhanced version of a PROM system called "RehaCAT+" to the control group receiving the basic version of the PROM system called "RehaCAT" in a 1:1 design (Figure 1). See below for detailed description of the experimental and control group.

----------insert Figure 1 about here----------

This cRCT has been approved by the ethics committee of Ulm University (509/20 – FSt/Sta) and will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement 2010 and the extensions for reporting pragmatic trials and cluster randomized trials (75–77). Cost-effectiveness analyses will be reported following the Consolidated Health Economic Evaluation Reporting Standards statement (CHEERS) (78) and the guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (79). This trial protocol was created according to SPIRIT guidelines (80). The trial has been registered in the German clinical trial register under DRKS00027447.

2.1.1 Procedure and recruitment

The testing systems RehaCAT (control group) and RehaCAT+ (experimental group) will be implemented in the clinic routine. Clinic personnel will be trained during the implementation phase on how to use the platform and how to provide technical assistance to rehabilitation patients if needed. After the implementation, all patients go through the respective version of the testing system. A subset of patients in routine care fulfilling the inclusion criteria (see 2.1.1) is included in the present study. Study participants receive all questionnaires from routine care and additional research questionnaires. Patients go through the diagnostic measures at admission (T0) and before discharge (T1), as well as at six months (T2) follow-up as part of their clinical routine. Study participants are additionally assessed at twelve-months (T3) follow up. The procedure is outlined in Figure 2.

----------insert Figure 2 about here----------

2.1.2 Inclusion and exclusion criteria

Since this is a cRCT, inclusion and exclusion are differentiated at two levels a) cluster level (i.e., eligibility of clinics) and b) patient level: To be eligible rehabilitation clinics must be located in Germany, focus on cardiological or orthopedic rehabilitation and sign the cooperation agreement with Ulm University. There are no further exclusion criteria for clinics. Within each cluster (i.e. rehabilitation clinic) patients who are 18 years or older, German-speaking, and show elevated depression scores (PROMIS Emotional Distress Depression: T-value $\geq$ 65) at the initial assessment will be informed about the study and consecutively asked for their participation consent (Informed Consent). There are no further exclusion criteria for patients.

2.2 Randomization, allocation, and masking

Randomization and allocation regarding the control (RehaCAT) and experimental group (RehaCAT+) of the participating rehabilitation clinics will be performed by an independent researcher to avoid selection bias. Randomization will be done on cluster-level.

The patients remain obscured to their study arm assignment. Clinics are aware of their condition. For the primary outcome analyses the conducting analyst will be obscured to group allocation. The study flow is presented in Figure 1.

2.3 Conditions

RehaCAT-Control Group: RehaCAT is a server- and web-based, device-independent test system, which allows the use of classical test procedures as well as Computer-adaptive procedures. RehaCAT does not interfere with the (clinic specific) standard treatment and patients have unrestricted access to treatment as usual (TAU). RehaCAT is divided into four user areas: 1) patient, 2) staff, 3) administrator, 4) researcher. The platform allows system administrators to upload and manage patients. Patients go through the diagnostic measures. Clinicians can view the test results of the different patient reported health outcomes of their respective patients. For a full overview of the assessment see 2.5.

RehaCAT+-Experimental Group: In addition to the structure of RehaCAT, RehaCAT+ follows a persuasive design optimized technology (e.g., motivation, ability, and automatic trigger considering test environment) (47,48) to increase the desired probability of action. RehaCAT+ offers additional (1) system features (reminders), (2) clinician features (stored recommendations for action for depression and anxiety based on respective patient results, call to action plans, individualized documentation aids and supporting information material for the dimensions of depression and anxiety), and (3) patient features (individual symptomatic information at discharge and T2/3, possible points of contact/help). A summary of the two conditions is provided in Figure 3.

----------insert Figure 3 about here----------

The basis for recommendations for action is formed by the rehabilitation therapy standards and framework concepts (81–84), the practice recommendations for orthopedic and cardiological rehabilitation (54,55), the recommendations for psychodiagnostics in somatic rehabilitation (53), and the S3 guidelines for depression (56) and anxiety (57).

The clinics will be compensated with 100€ per recruited patient for the resulting hospital expenses in the context of participant recruitment, data collection, study documentation as well as provision of the discharge reports. Study patients will receive an expense allowance of 20€ each for their participation in the T2 and T3 measurements.

RehaCAT(+) is developed as an open-source platform. It is currently in the certification process according to the medical device regulation. The platform is developed according to the requirements of the German Medical Devices Act and the Medical Device Regulation (MDR). Hence, the software development and validation process is taking the IEC 62304 (safety class B), the GAMP5 (category 4), the General Principles of Software Validation of the FDA as well as the Pharmaceutical Inspection Cooperation Scheme (PIC/S) 11-3 into account. Furthermore, technical requirements and standards for the interoperability between different medical devices (e.g. HL7 FHIR) are under development. The certification process of the platform is planned to be completed in 2022.

2.4 Sample size and power calculation

The sample calculation is based on the primary outcome, depression severity 12 months after the end of rehabilitation. It is assumed that the experimental group is superior to the control group in the way that patients show fewer depressive symptoms at twelve-months follow-up. In view of the additive study design testing for incremental benefit of RehaCAT+ over RehaCAT and the distal outcome, a small additional effect of d = .24 compared to the standard

condition is regarded as clinically significant following the recommendation of Cuijpers et al. (85). With 2*6 cluster-randomized rehabilitation clinics, each clinic requires a sample of 110 (SD = 25) participating rehabilitants with elevated depression scores to achieve a test power of 80% given an alpha error (two-sided) of .05, an estimated ICC of .02 (86,87), and an assumed correlation with baseline depression scores of .50. With an estimated drop-out rate (rehabilitation start-end) of 20% (88) and the assumption of a doubling drop-out rate by T3, a total sample of N=1,848 rehabilitants is required.

2.5 Assessments

Quantitative outcome assessment is performed at baseline/ beginning of rehabilitation (T0), at discharge/ end of rehabilitation (T1), and at 6 and 12 months (T2, T3). Primary outcome is the depression severity score twelve months after rehabilitation (T3). An overview is provided in Table 1.

Table 1

Assessments

Variable	Instrument	CAT	Time of measurement			
			T0	T1	T2	T3
Depression	PROMIS® Emotional Distress – Depression	✓	✓	✓	✓	✓
Anxiety	PROMIS® Emotional Distress – Anxiety	✓	✓	✓	✓	✓
Satisfaction with Participation in Social Roles and Activities	PROMIS® Satisfaction with Social Roles and Activities	✓	✓	✓	✓	✓
Pain impairment	PROMIS® Pain Interference	✓	✓	✓	✓	✓

Fatigue	PROMIS® Fatigue	✓	✓	✓	✓	✓
Sleep	PROMIS® Sleep Disturbance	✓	✓	✓	✓	✓
Health-related quality of life	PROMIS® Global Health		✓	✓	✓	✓
Self-Efficacy	PROMIS® Self-Efficacy General		✓	✓	✓	✓
Physical Function	PROMIS Physical Function	✓	✓	✓	✓	✓
Alcohol use	AUDIT		✓	✓	✓	✓
Personality	BFI-10		✓			
Generic quality of life	EQ5D-5L		✓		✓	✓
Health and social services use and costs	CSSRI		✓		✓	✓
Medical record data	Provided by clinicians (e.g. discharge reports)			✓		

CAT, Computer-Adaptive Patient Reported Outcome Test; T0, Baseline; T1, Discharge; T,2 6-month follow-up; T3, 12-month follow-up; PROMIS, Patient Reported Outcome Measurement Information System; AUDIT, Alcohol Use Disorders Identification Test; BFI-10, 10 item Big Five Inventory; EQ5D-5L, European Quality of Life 5 Dimension - 5 Level Questionnaire; CSSRI, Client Sociodemographic and Service Receipt Inventory.

2.5.1 Primary outcome

Depression severity will be assessed with the computer-adaptive PROMIS Emotional Distress - Depression Item Set including an item bank with 28 items that capture negative mood, decrease in positive emotions, cognitive deficits, as well as negative self-image and negative social cognition (89). All items are rated on a five-point response scale asking respondents to rate the frequency of their symptoms in the past seven days (never, rarely, often, sometimes, always). A Cronbach's Alpha of 0.99 was found for the internal consistency of the item set (90).

2.5.2 Secondary outcomes

Anxiety will be assessed with the computer-adaptive PROMIS Emotional Distress - Anxiety Item Set including 29 items that assess emotional distress caused by hypersensitivity, anxiety, and stress, as well as associated somatic symptoms (89). All items are rated on a five-point response scale asking respondents to rate the frequency of their symptoms in the past seven days (never, rarely, often, sometimes, always). The internal consistency of the item set was found to be good (89).

The computer-adaptive PROMIS Satisfaction with Participation in Social Roles and Activities Item Set comprising 14 items will be used to assess the perceived ability to perform usual social roles and participate in social activities. All items are phrased in terms of perceived limitations and answered using a five-point response scale. Reliability was estimated to be $\alpha > 0.90$ (91).

Pain impairment will be assessed with the computer-adaptive PROMIS Pain Interference Item Set including 40 items that capture self-assessment of the consequences of pain in one's life. This includes the extent to which pain interferes with engagement in social, cognitive, emotional, physical, as well as leisure activities (92). The items refer to the past seven days and are rated on three different five-point Likert scales. The internal consistency of the item set was found to be good (92).

Fatigue will be assessed with the computer-adaptive PROMIS Fatigue Scale comprising 95 items and measures both fatigue experience and the impact of fatigue on daily life and functionality. The intensity, frequency, and duration of fatigue were graded on a five-point response scale. Reliability was estimated to be $\alpha > 0.90$ (93).

Sleep will be assessed with the computer-adaptive PROMIS Sleep Dimension that measures subjective sleep quality and quantity and sleep-related impairment in daily functioning. The scale comprises 27 items and is rated on a response scale from 1 (not at all or never) to 5 (very

much or always). It is a validated instrument and has good psychometric properties with $\alpha > 0.90$ (94,95).

Health-related quality of life will be assessed with the PROMIS scale on global health aspects (Global Health) is used. The scale includes 10 items that capture global physical health (physical health, physical functioning, fatigue, pain), and global mental health (general quality of life, mental health, satisfaction with social activities and relationships, and emotional distress) (96). Nine items are scored on a response scale of 1 to 5, and the item assessing pain is scored from 0 to 10. Internal consistency was estimated to be good with $\alpha > 0.82$ (Katzan & Lapin, 2018).

Self-efficacy will be assessed with the short scale of the PROMIS General Self-Efficacy Scale which contains 4 items. It can be used to assess how much confidence one has in one's own abilities to master tasks and situations. Items are rated on a response scale from 1 (I am not at all confident) to 5 (I am very confident). Internal consistency was estimated to be high ($\alpha = 0.96$) (97,98).

Physical function will be assessed using the computer-adaptive PROMIS Physical Function Item Set that measures the ability to perform daily life activities that require physical activity such as walking or lifting objects. It comprises 164 items that are assessed on a 5-point scale ranging from 1 (Without any difficulty) to 5 (Unable to do). Internal consistency was found to be very good with $\alpha > 0.88$ (99).

Alcohol use will be assessed with the AUDIT (Alcohol Use Disorders Identification Test) which is a 10-item questionnaire developed by the WHO as a screening tool for hazardous and harmful alcohol use. Responses to each question are scored from 0 to 4, allowing a maximum of 40 points. Reliability has been investigated in some studies and is considered good with a median of $\alpha = 0.80$ (100).

Discharge reports will be analyzed regarding a) frequency of documented screening results, b) therapy standard and guideline appropriate therapeutic services (documented services / therapy standard recommendations as a function of depression and anxiety results), c) therapy standard and guideline appropriate follow-up and post-rehabilitation recommendations (documented recommendations / therapy standard/guideline recommendations as a function of depression and anxiety results).

2.5.3 Moderators

As potential moderators, socio-demographic data (age, gender, nationality) and personality will be recorded at admission (T0). Personality will be assessed with the BFI-10 (Big Five Inventory – 10), a short version of the Big Five Inventory that has good psychometric properties and a retest-reliabilities of $\alpha = 0.73$ (101). Additionally, data from medical records will be used as moderators (e.g. indication area orthopedic or cardiologic, chronic conditions, rehabilitation duration, etc.).

2.5.4 Health economics

Generic quality of life will be assessed with the EQ5D-5L (European Quality of Life 5 Dimension - 5 Level Questionnaire) from the EuroQol foundation (www.euroqol.org) (102). The five dimensions surveyed are mobility, self-care, general activities, pain/physical discomfort, and anxiety/dejection. Each of the five areas is ranked on a five-point scale. Based on the answers, the respective health status is recorded (103).

Health and social services use and costs will be assessed with the CSSRI (Client Sociodemographic and Service Receipt Inventory) which is a standardized but adaptable inventory. Five domains are queried, including sociodemographic information, usual living situation, income and employment status, use of mental health services, and medication treatment (104).

2.5.5 Usage behavior, acceptance, facilitating and hindering factors

Questions about usage behavior, potential risks of the platforms, as well as barriers and facilitators to implementation, will be elicited based on qualitative semi-structured interviews conducted with both patients and clinic staff centrally involved in the implementation of RehaCAT and RehaCAT+. The semi-structured interview is conducted with the help of an interview guide, based on existing instruments of previous studies (53,105).

2.5.6 Smart Sensing sub-study

Smart Sensing data will be collected actively and passively via the mobile application AWARE for smartphones. The AWARE Framework is an open-source framework that allows to passively collect digital behavioural data via an app as well as to send ecological momentary assessments (e.g., short questions: "how are you feeling right now?") to the app user for answering (106). The AWARE framework has been tested in previous studies (64,68,106,107) without technical, privacy or ethical issues. All data that is collected is stored pseudonymized and personal data (e.g., contact numbers) are anonymized using a cryptographic hash function (SHA-256) (106).

All patients of all participating rehabilitation clinics (without regard to (non-) participation in the main trial) will be informed about the optional mobile sensing sub-study and asked whether they would like to participate. Participants who provide their informed consent will be instructed to install the research application on their personal smartphones. After installation participants can choose which data points will be collected over the six months.

2.5.6.1 Active Assessment

Gender, age, and personality with the BFI-10 (The Big Five Inventory – 10) will be assessed (101) once after installing the application.

Furthermore, acceptance of and satisfaction with smart sensing will be measured using the UTAUT (Unified Theory of Acceptance and Use of Technology) questionnaire (108,109), satisfaction with the research application will be measured with the User Version of the Mobile Application Rating Scale (uMARS) (110). Both questionnaires will be assessed once after 6 months before deinstalling the application.

The following clinical questionnaires will be assessed every two weeks: Depression (dimensional and categorical) with the PHQ-8 (if PHQ-2 score > 2) (111–113); anxiety with the GAD-7 (114); stress with the PSS-10 (115); sleep with the ISI-7 (116); loneliness with the UCLA 3 item version (117).

Every morning, participants will be asked short questions about mood (valence), drive (arousal), control, unpredictability, stress experience and sleep, at midday about mood (valence), drive (arousal), control, unpredictability, and stress experience, and in the evening, participants are again asked about mood (valence), drive (arousal), control, unpredictability, stress experience, and activity during the day. This assessment is based on previous studies (65,68,118,119).

2.5.6.2 Passive Outcomes

The research app allows to track a broad range of sensors (accelerometer, application usage, barometer, battery, Bluetooth, communication, gravity, gyroscope, light, locations, magnetometer, network, proximity, rotation, screen sensor). However, each user can freely decide which sensors are activated and access permissions can always be activated and deactivated without giving reasons. In addition, sensible location data (e.g., GPS coordinates) will be obscured, so pseudonymization can be upheld all the time.

The following digital markers can be collected (depending on permissions of user): frequency and duration of smartphone and individual app usage, frequency and duration/length of calls and text messages, randomly distorted GPS, and type of movement.

2.6 Data management and data sharing plan

Data collection will be completed online using the server-based system RehaCAT(+) and the research application in pseudonymized form. Retrieved data will be stored encrypted by responsible employees. All data will be anonymized after completion of the trial. Furthermore, an independent Data Safety and Monitoring Board (DSMB) with long-standing experience in clinical trials has been established. The function of the DSMB is to monitor the course of the study and, if necessary, give recommendations to the steering committee for discontinuation, modification or continuation of the study.

Individual participant data will be made available on request after de-identification beginning 12 months following article publication of the effectiveness paper. Data will be made available to researchers who provide a methodologically sound proposal, not already covered by others. Proposals should be directed to HB. Data requestors will need to sign a data access agreement. Provision of data is subject to data security regulations. Investigator support depends on available resources.

2.7 Measures to reduce methodological sources of error

Selection bias: Randomization and allocation regarding the group allocation (RehaCAT/ RehaCAT+) of the participating rehabilitation clinics will be done by an independent researcher. Performance bias: Rehabilitation staff centrally involved in the implementation will be trained along training materials, as well as continuously supervised regarding the training materials. RehaCAT(+) and its application will be described in detail in a test manual. Deviations from the test manual will be recorded and formatively reduced during the

implementation process of RehaCAT(+) in the individual clinics. Contamination bias: Cluster randomization is used to avoid study arm contamination. Detection bias: rating procedures (analysis of discharge reports) are performed by independent raters who are obscured to the study arm affiliation of the clinics and thus the patients. Patients also remain obscured to their study arm assignment, as the differentiation between RehaCAT and RehaCAT(+) is not obvious to them. Only for clinic personnel obscuring cannot be realized. Reporting bias: A detailed definition of all methodological aspects of the present clinical study is provided in this study protocol, submitted for publication prior to randomization start. Evaluating representativeness: To assess the representativeness of the results, quantitative and qualitative analyses will be performed regarding the reasons that may lead to a non-existent 100% exhaustion in the routine assessment.

2.8 Patient and public involvement

Patient and public involvement (PPI) representatives have provided input to the present study in several stages. Results of previous projects including patient feedback, were used to further develop and optimize study design and procedures. PPI representatives (e.g. as members of an advisory board) are included to improve usability, design and comprehensibility but have no influence on the outcomes, data analysis methods or study design.

2.9 Statistical analyses

2.9.1 Clinical analyses

Study data will be centrally processed and analyzed by an independent researcher. Missing values and missingness patterns will be explored and analysis will be adjusted accordingly using multiple imputation strategies (based on heteroscedastic two-level linear models considering the metric of outcome). The analysis will follow the intention-to-treat principle. In addition, per-protocol analyses will be conducted. The primary outcome as well as all other

continuous outcomes will be analyzed based on Hierarchical Linear Models (HLM) considering cluster structure and baseline values. Binary outcomes will be analyzed using Mixed Logistic Regression Models. Moderator and mediator analyses will be performed to determine differential effects with respect to key sociodemographic and medical variables.

The effect of study participation will also be measured (participation rate at T1-3) in order to be able to make statements about the transferability of the results from the present randomized study to routine care without research support.

2.9.2 Health economic evaluation

In the health economic evaluation, an incremental cost-utility analysis (ICUA) is performed from the societal perspective, as well as from the perspective of the German statutory pension insurance (SPI) according to the net benefit approach (78,120). The necessary maximum willingness to pay (MWTP) for a clinical improvement of depressive symptoms by 50% (= response) and for the gain of a quality-adjusted life year (QALY) is determined. The estimation of the stochastic uncertainty is done by means of nonparametric bootstrapping, the interpretation of the results is based on cost-effectiveness acceptance curves (121). These provide information on how high the MWTP must be to be judged cost-effective with a probability of 95%, or with what probability a pre-determined MWTP is judged to be cost-effective (120). Following international guidelines, a value range of the MWTP between 0 and 1250,000 € is chosen (122,123). The analysis of the health economic relevance of moderator and mediator variables is performed by means of net benefit regression models for net benefit ratios between 0 and 1250,000€ (124–127). The analysis from the macroeconomic perspective considers all direct and indirect disease costs (128), the analysis from the perspective of the SPI takes into account the disease costs to be borne by the SPI (e.g. for medical rehabilitation services) as well as the costs for the testing platform to be borne by the SPI.

2.9.3 Qualitative data analysis

Qualitative interviews of patients and clinic staff will be conducted and analyzed. The analysis of qualitative data will be based on qualitative content analysis. An inductive-deductive approach will be applied along the theory-based interview guide. Reliability of results will be established (indicated by intercoder agreement) with two independent raters coding all transcripts on the basis of coding guide and rules. This coding guide will be developed in an iterative process with consensus finding.

2.9.4 Smart sensing

2.9.4.1 Identification of prognostic factors

Correlation analysis and multilevel regression models will be used to identify bivariate relationships between PROMs, digital markers, disease-free survival, and postoperative complications. The presence of missing values and missingness patterns will be investigated and analysis will be adjusted accordingly (e.g., multiple imputation) (129).

2.9.4.2 Prediction modelling

Significance test-based methods as well as machine learning models will be used. In case of nested data structure (e.g., development of quality of life over time with repeated measures) multilevel regression models will also be used for prediction (130–132). For continuous outcomes (e.g., depression severity) linear models be used, while logistic models will be applied for dichotomous outcomes (e.g., depression state yes or no).

In addition to these significance test-based methods, machine learning models will be used. Machine learning is an iterative process and several modeling approaches will be tested (e.g., K-Nearest Neighbor algorithm (133) or gradient-boosted trees (134,135)). However, since the field is rapidly developing, we cannot a-priori define the exact approaches that will be used. Hyperparameter optimization will be conducted using grid-search.

3 Ethics and dissemination

Ethical approval has been obtained from Ulm University on 24 February 2021 (ref. 509/20). The study is conducted according to the Declaration of Helsinki. Informed consent is obtained.

Results will be published in peer-reviewed journals. They will also be made known through local conferences and research seminars, national and international scientific congresses, and through direct and indirect contacts with clinicians, public health managers and other healthcare professionals.

4 Author contributions

HB is principle investigator of RehaCAT+. HB, RK, MM obtained funding for this study. HB, JK, YT, PP, SK, MM, MB, RK, TW contributed to the study design. HB, SE, JK, YT, PP, SK developed the platform RehaCAT(+). MM and RK contributed to the design of the effectiveness and health-economic evaluation. JK drafted the manuscript. All authors contributed to the article and approved the submitted version.

5 Funding statement

This work was supported by the Federal Ministry of Education and Research (BMBF, 01GX1901). BMBF had no role in study design, decision to publish or preparation of this manuscript. BMBF will not be involved in data collection, analyses, decision to publish or preparation of future papers regarding this study.

6 Competing interests statement

Authors of the manuscript were partly involved in the development of RehaCAT(+). HB has been the beneficiary of study support (third party funding) from several public funding

organizations in the context of research on Computer-adaptive Testing and Patient Reported Outcome Systems.

7 Acknowledgments

Authors would like to thank the project members Minh Duc Duong, Erce Rodopman, Tobias Sterns, Aydin Spieler, Rebecca Knoll and Robin Kraft for their technical support and development of RehaCAT.

8 Figures

Figure 1. Flow chart

Figure 2. Procedure

Figure 3. Features

9 Tables

Table 1. Assessments

10 References

1. Baumeister H, Lin J, Ebert DD. Internet- and mobile-based approaches: Psycho-social diagnostics and treatment in medical rehabilitation. Bundesgesundheitsblatt - Gesundheitsforsch - Gesundheitsschutz. 2017;60(4):436–44.

2. Haywood KL. Patient-reported outcome I: Measuring what matters in musculoskeletal care. Musculoskeletal Care [Internet]. 2006;4(4):187–203. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/msc.94

3. Kelkar AA, Spertus J, Pang P, Pierson RF, Cody RJ, Pina IL, et al. Utility of Patient-Reported Outcome Instruments in Heart Failure. JACC Hear Fail. 2016;4(3):165–75.

4. Algurén B, Coenen M, Malm D, Fridlund B, Mårtensson J, Årestedt K. A scoping review and mapping exercise comparing the content of patient-reported outcome measures (PROMs) across heart disease-specific scales. J Patient-Reported Outcomes. 2020;4(1).

5. Calvert M, Kyte D, Price G, Valderas JM, Hjollund NH. Maximising the impact of patient reported outcome assessment for patients and society. BMJ [Internet]. 2019;364. Available from: https://www.bmj.com/content/364/bmj.k5267

6. Klag MJ, MacKenzie EJ, Carswell CI, Bridges JFP. The Role of The Patient in Promoting Patient-Centered Outcomes Research. Patient Patient-Centered Outcomes Res [Internet]. 2008 Jan;1(1):1–3. Available from: http://link.springer.com/10.2165/01312067-200801010-00001

7. Nelson EC, Eftimovska E, Lind C, Hager A, Wasson JH, Lindblad S. Patient reported outcome measures in practice. BMJ [Internet]. 2015 Feb 10;g7818. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.g7818

8. Field J, Holmes MM, Newell D. PROMs data: can it be used to make decisions for individual patients? A narrative review . Patient Relat Outcome Meas. 2019;Volume 10:233–41.

9. Gibbons RD, Weiss DJ, Kupfer DJ, Frank E, Fagiolini A, Grochocinski VJ, et al. Using computerized adaptive testing to reduce the burden of mental health assessment. Psychiatr Serv. 2008;59(4):361–8.

10. Gamper EM, Martini C, Petersen MA, Virgolini I, Holzner B, Giesinger JM. Do patients consider computer-adaptive measures more appropriate than static questionnaires? J Patient-Reported Outcomes. 2019;3(1).

11. Forkmann T, Boecker M, Wirtz M, Glaesmer H, Brähler E, Norra C, et al. Validation of the Rasch-based depression screening in a large scale German general population sample. Health Qual Life Outcomes. 2010;8:105–12.

12. Abberger B, Haschke A, Tully PJ, Forkmann T, Berger J, Wirtz M, et al. Development and validation of parallel short forms PaSA-cardio for the assessment of general anxiety in cardiovascular rehabilitation patients using Rasch analysis. Clin Rehabil. 2017;31(1):104–14.

13. Sharpe JP, Gilbert DG, Patrick J, Gilbert DG. Effects of repeated administration of the Beck Depression Inventory and other measures of negative mood states. Pers Individ Dif [Internet]. 1998;24(4):457–63. Available from: file:///S:/Projekte/CAT/Literatur/Citavi 5/Projects/Literatur CAT Projekte/Citavi Attachments/Sharpe 1998 - Effects Repeated Administration Beck Depression and Other.pdf

14. Sehlen S, Ott M, Marten-Mittag B, Haimerl W, Dinkel A, Duehmke E, et al. Machbarkeit und Akzeptanz Computer-gestützter Indikationsdiagnostik (CgID) zur Identifizierung psychosozial belasteter Patienten im klinischen Alltag. PPmP - Psychother · Psychosom · Medizinische Psychol. 2012 Jul;62(07):276–83.

15. Wahl I, Löwe B, Bjorner JB, Fischer F, Langs G, Voderholzer U, et al. Standardization of depression measurement: a common metric was developed for 11 self-report depression measures. J Clin Epidemiol [Internet]. 2014 Jan 1 [cited 2020 Jan 9];67(1):73–86. Available from: https://www.sciencedirect.com/science/article/pii/S0895435613003168?via%3Dihub

16. Embretson, S., & Yang X. Item Response Theory. In: J L Green, G Camilli, & P B Elmore (Eds), Handbook of complementary methods in education research. Lawrence

Erlbaum Associates Publishers; 2006. p. 385–409.

17. Rose M, Wahl I, Löwe B. Computer Adaptive Tests in der Medizin. PPmP - Psychother · Psychosom · Medizinische Psychol [Internet]. 2013 Jan 22;63(01):48–54. Available from: http://www.thieme-connect.de/DOI/DOI?10.1055/s-0032-1329976

18. Abberger B, Haschke A, Wirtz M, Kroehne U, Bengel J, Baumeister H. Development and Evaluation of a Computer Adaptive Test to Assess Anxiety in Cardiovascular Rehabilitation Patients. Arch Phys Med Rehabil. 2013 Dec;94(12):2433–9.

19. Forkmann T, Kroehne U, Wirtz M, Norra C, Baumeister H, Gauggel S, et al. Adaptive screening for depression — Recalibration of an item bank for the assessment of depression in persons with mental and somatic diseases and evaluation in a simulated computer-adaptive test environment. J Psychosom Res. 2013;75(5):437–43.

20. Fischer HF, Klug C, Roeper K, Blozik E, Edelmann F, Eisele M, et al. Screening for mental disorders in heart failure patients using computer-adaptive tests. Qual Life Res. 2014;23(5):1609–18.

21. Papuga MO, Dasilva C, McIntyre A, Mitten D, Kates S, Baumhauer JF. Large-scale clinical implementation of PROMIS computer adaptive testing with direct incorporation into the electronic medical record. Heal Syst. 2018 Jan;7(1):1–12.

22. Ling G, Attali Y, Finn B, Stone EA. Is a Computerized Adaptive Test More Motivating Than a Fixed-Item Test? Appl Psychol Meas. 2017;41(7):495–511.

23. Cella D, Gershon R, Lai JS, Choi S. The future of outcomes measurement: Item banking, tailored short-forms, and computerized adaptive assessment. Qual Life Res. 2007;16(SUPPL. 1):133–41.

24. Gorin JS, Dodd BG, Fitzpatrick SJ, Shieh YY. Computerized adaptive testing with the partial credit model. Appl Psychol Meas. 2005;29(6):433–56.

25. Forkmann T, Böcker M, Norra C, Eberle N, Kircher T, Schauerte P, et al. Development of an item bank for the assessment of depression in persons with mental illnesses and physical diseases using Rasch analysis. Rehabil Psychol. 2009;54(2):186–97.

26. Linacre JM. Computer-Adaptive Testing : A Methodology Whose Time Has Come . By J ohn Michael Linacr e , Ph . D . MESA Psychometr ic Labor ator y Univer sity of Chicago. Test [Internet]. 2000;(69):27. Available from: https://www.cehd.umn.edu/EdPsych/C-Bas-R/Docs/Linacre2000_CAT.pdf.

27. Bjorner JB, Chang CH, Thissen D, Reeve BB. Developing tailored instruments: Item banking and computerized adaptive assessment. Qual Life Res. 2007;16(SUPPL. 1):95–108.

28. Vodicka E, Kim K, Devine EB, Gnanasakthy A, Scoggins JF, Patrick DL. Inclusion of patient-reported outcome measures in registered clinical trials: Evidence from ClinicalTrials.gov (2007-2013). Contemp Clin Trials [Internet]. 2015;43:1–9. Available from: http://dx.doi.org/10.1016/j.cct.2015.04.004

29. Rivera SC, Kyte DG, Aiyegbusi OL, Slade AL, McMullan C, Calvert MJ. The impact of patient-reported outcome (PRO) data from clinical trials: A systematic review and critical analysis. Health Qual Life Outcomes. 2019;17(1):1–19.

30. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. BMJ [Internet]. 2010;340. Available from: https://www.bmj.com/content/340/bmj.c186

31. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, et al. Patient-

reported outcomes in routine cancer clinical practice: A scoping review of use, impact on health outcomes, and implementation factors. Vol. 26, Annals of Oncology. Oxford University Press; 2015. p. 1846–58.

32. Turner GM, Litchfield I, Finnikin S, Aiyegbusi OL, Calvert M. General practitioners' views on use of patient reported outcome measures in primary care: A cross-sectional survey and qualitative study. BMC Fam Pract. 2020;21(1):1–10.

33. Porter I, Gonçalves-Bradley D, Ricci-Cabello I, Gibbons C, Gangannagaripalli J, Fitzpatrick R, et al. Framework and guidance for implementing patient-reported outcomes in clinical practice: Evidence, challenges and opportunities. J Comp Eff Res. 2016;5(5):507–19.

34. Tirosh O, Tran P, Renouf J, Pergaminelis N, Purdie CN, Ho A, et al. PROMsBase: Web-based repository portal for patient-reported outcome measures in orthopaedics. Health Informatics J. 2019;25(3):867–77.

35. Santana MJ, Feeny D. Framework to assess the effects of using patient-reported outcome measures in chronic care management. Qual Life Res. 2014;23(5):1505–13.

36. Munoz RF, Cuijpers P, Smit F, Barrera AZ, Leykin Y. Prevention of major depression. Annu Rev Clin Psychol. 2010;6(1):181–212.

37. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA [Internet]. 2017 Jul 11;318(2):197. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2017.7156

38. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom

Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. J Clin Oncol [Internet]. 2016 Feb 20;34(6):557–65. Available from: https://ascopubs.org/doi/10.1200/JCO.2015.63.0830

39. Gilbody SM. Routinely administered questionnaires for depression and anxiety: systematic review. BMJ [Internet]. 2001 Feb 17;322(7283):406–9. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.322.7283.406

40. Härter, Katrin Reuter, Katrin Gross M. Screening for anxiety, depressive and somatoform disorders in rehabilitation󒀔validity of HADS and GHQ-12 in patients with musculoskeletal disease. Disabil Rehabil. 2001 Jan;23(16):737–44.

41. Härter M, Woll S, Reuter K, Wunsch A, Bengel J. Recognition of psychiatric disorders in musculoskeletal and cardiovascular rehabilitation patients. Arch Phys Med Rehabil [Internet]. 2004 Jul;85(7):1192–7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0003999303011808

42. Härter M, Reuter K, Weisser B, Schretzmann B, Aschenbrenner A, Bengel J. A descriptive study of psychiatric disorders and psychosocial burden in rehabilitation patients with musculoskeletal diseases. Arch Phys Med Rehabil. 2002 Apr;83(4):461–8.

43. Siu AL, Bibbins-Domingo K, Grossman DC, Baumann LC, Davidson KW, Ebell M, et al. Screening for Depression in Adults. JAMA [Internet]. 2016 Jan 26;315(4):380. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2015.18392

44. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer settings: 10 lessons from 40 years of primary-care research. Psychooncology

[Internet]. 2011 Jun;20(6):572–84. Available from: http://doi.wiley.com/10.1002/pon.1943

45. Haverman L, Van Oers HA, Van Muilekom MM, Grootenhuis MA. Options for the Interpretation of and Recommendations for Acting on Different PROMs in Daily Clinical Practice Using KLIK. Med Care. 2019;57(5):S52–8.

46. Farin E, Glattacker M, Jäckel WH. Leitlinien und Leitlinienforschung. Bundesgesundheitsblatt - Gesundheitsforsch - Gesundheitsschutz [Internet]. 2011 Apr 1;54(4):429–35. Available from: http://link.springer.com/10.1007/s00103-011-1238-9

47. Marcus A. Mobile Persuasion Design: Changing Behaviour by Combining Persuasion Design with Information Design. Human–Computer Interaction. London: Springer-Verlag; 2015.

48. Fogg B. A behavior model for persuasive design. Proc 4th Int Conf Persuas Technol - Persuas '09 [Internet]. 2009;1. Available from: http://portal.acm.org/citation.cfm?doid=1541948.1541999

49. Baumeister H, Kraft R, Baumel A, Pryss R, Messner E-M. Persuasive e-health design for behavior change. In: Baumeister H, Montag C, editors. Mobile sensing and digital phenotyping: new developments in psychoinformatics. Berlin: Springer; 2019.

50. Fogg B. Persuasive Computers: Perspectives and Research Directions. Proc SIGCHI Conf Hum Factors Comput Syst - CHI '98. 1998;(April):225–32.

51. Imison C, Castle-Clarke S, Watson R, & Edwards N. Delivering the benefits of digital health care. London; 2016.

52. Sucher JF, Moore FA, Todd SR, Sailors RM, McKinley BA. Computerized Clinical

Decision Support: A Technology to Implement and Validate Evidence Based Guidelines. J Trauma Inj Infect Crit Care [Internet]. 2008 Feb;64(2):520–37. Available from: https://journals.lww.com/00005373-200802000-00049

53. Baumeister H, Jahed J, Vogel B, Härter M, Barth J, Bengel J. Diagnostik, Indikation und Behandlung von psychischen Störungen in der medizinischen Rehabilitation (DIBpS): Ein Leitfaden zur Implementierung eines psychodiagnostischen Stufenplans in der medizinischen Rehabilitation. Berlin: DRV M4 - Citavi; 2011.

54. Reese C, Mittag O. Psychologische Interventionen. Praxisempfehlungen für psychologische Interventionen in der Rehabilitation: Chronische Rückenschmerzen und Koronare Herzerkrankung. Berlin: Deutsche Rentenversicherung M4 - Citavi; 2013.

55. Reese C, Spieser A, Mittag O. Psychologische Interventionen in der Rehabilitation von Patienten mit koronarer Herzerkrankung: Zusammenfassung der Evidenz und der Empfehlungen aus systematischen Übersichtsarbeiten und Leitlinien. Rehabil. 06.06.2012. 2012;51(06):405–14.

56. DGPPN, BÄK, KBV, AWMF, AkdÄ, BPtK DAGSHG, DEGAM, DGPM, DGPS, DGRW Ba. S3-Leitlinie/Nationale VersorgungsLeitlinie Unipolare Depression. Langfassung. 2015.

57. Bandelow B, Wiltinkt J, Alpers GW, Benecke C, Deckert J, Eckhardt-Henn A, et al. Deutsche S3-Leitlinie Behandlung von Angststörungen. 2014;

58. Ben-Zeev D, Young MA. Accuracy of hospitalized depressed patients' and healthy controls' retrospective symptom reports: an experience sampling study. J Nerv Ment Dis. 2010 Apr;198(4):280–5.

59. Gorzelitz J, Peppard PE, Malecki K, Gennuso K, Nieto FJ, Cadmus-Bertram L.

Predictors of discordance in self-report versus device-measured physical activity measurement. Ann Epidemiol. 2018 Jul;28(7):427–31.

60. Paulhus DL. Socially Desirable Responding on Self-Reports. In: Encyclopedia of Personality and Individual Differences. Springer International Publishing; 2017. p. 1–5.

61. Stone AA, Shiffman S. Capturing momentary, self-report data: A proposal for reporting guidelines. Ann Behav Med. 2002 Aug;24(3):236–43.

62. Baumeister H, Montag C. Digital Phenotyping and Mobile Sensing [Internet]. Baumeister H, Montag C, editors. Cham: Springer International Publishing; 2019. 291 p. (Studies in Neuroscience, Psychology and Behavioral Economics). Available from: http://link.springer.com/10.1007/978-3-030-31620-4

63. Onnela J-P, Rauch SL. Harnessing Smartphone-Based Digital Phenotyping to Enhance Behavioral and Mental Health. Neuropsychopharmacology [Internet]. 2016 Jun 28;41(7):1691–6. Available from: http://dx.doi.org/10.1038/npp.2016.7

64. Low CA, Dey AK, Ferreira D, Kamarck T, Sun W, Bae S, et al. Estimation of Symptom Severity During Chemotherapy From Passively Sensed Data: Exploratory Study. J Med Internet Res [Internet]. 2017 Dec 19;19(12):e420. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29258977

65. Messner E-M, Sariyska R, Mayer B, Montag C, Kannen C, Schwerdtfeger A, et al. Insights: Future implications of passive smartphone sensing in the therapeutic context. Verhaltenstherapie [Internet]. 2019;1–11. Available from: https://www.karger.com/Article/FullText/501735

66. Mohr DC, Zhang M, Schueller SM. Personal Sensing: Understanding Mental Health Using Ubiquitous Sensors and Machine Learning. Annu Rev Clin Psychol [Internet].

2017 May 8;13(1):23–47. Available from: http://www.annualreviews.org/doi/10.1146/annurev-clinpsy-032816-044949

67. Montag C, Baumeister H, Kannen C, Sariyska R, Meßner E-M, Brand M. Concept, Possibilities and Pilot-Testing of a New Smartphone Application for the Social and Life Sciences to Study Human Behavior Including Validation Data from Personality Psychology. J [Internet]. 2019 Mar 27;2(2):102–15. Available from: https://www.mdpi.com/2571-8800/2/2/8

68. Moshe I, Terhorst Y, Opoku Asare K, Sander LB, Ferreira D, Baumeister H, et al. Predicting Symptoms of Depression and Anxiety Using Smartphone and Wearable Data. Front Psychiatry. 2021 Jan;12:625247.

69. Rohani DA, Faurholt-Jepsen M, Kessing LV, Bardram JE. Correlations Between Objective Behavioral Features Collected From Mobile and Wearable Devices and Depressive Mood Symptoms in Patients With Affective Disorders: Systematic Review. JMIR mHealth uHealth [Internet]. 2018 Aug 13;6(8):e165. Available from: http://mhealth.jmir.org/2018/8/e165/

70. Umbricht D, Cheng W-Y, Lipsmeier F, Bamdadian A, Lindemann M. Deep Learning-Based Human Activity Recognition for Continuous Activity and Gesture Monitoring for Schizophrenia Patients With Negative Symptoms. Front Psychiatry. 2020 Sep;11:574375.

71. Alyass A, Turcotte M, Meyre D. From big data analysis to personalized medicine for all: challenges and opportunities. BMC Med Genomics. 2015 Dec;8(1):33.

72. Hamburg MA, Collins FS. The Path to Personalized Medicine. N Engl J Med [Internet]. 2010 Jul 22 [cited 2019 May 15];363(4):301–4. Available from:

http://www.nejm.org/doi/abs/10.1056/NEJMp1006304

73. Obermeyer Z, Emanuel EJ. Predicting the Future — Big Data, Machine Learning, and Clinical Medicine. N Engl J Med. 2016;375(13):1216.

74. Wang F, Casalino LP, Khullar D. Deep Learning in Medicine—Promise, Progress, and Challenges. JAMA Intern Med. 2019 Mar;179(3):293.

75. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ (Clinical Res ed. 2012;345:e5661.

76. Zwarenstein M, Treweek S, Gagnier J, D.G. A, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390.

77. Montgomery P, Grant S, Mayo-Wilson E, Macdonald G, Michie S, Hopewell S, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension. Trials [Internet]. 2018 Dec 31;19(1):407. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2733-1

78. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. Value Heal J Int Soc Pharmacoeconomics Outcomes Res. 2013;16(2):e1-5.

79. Ramsey SD, Willke RJ, Glick H, Reed SD, Augustovski F, Jonsson B, et al. Cost-Effectiveness Analysis Alongside Clinical Trials II—An ISPOR Good Research Practices Task Force Report. Value Heal [Internet]. 2015 Mar;18(2):161–72. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1098301515000169

80. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al.

SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med [Internet]. 2013 Feb 5;158(3):200. Available from: http://annals.org/article.aspx?doi=10.7326/0003-4819-158-3-201302050-00583

81. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Depressive Störungen - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

82. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Chronischer Rückenschmerz - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

83. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Koronare Herzkrankheit - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

84. Deutsche Rentenversicherung Bund. Rahmenkonzept zur Nachsorge - für medizinische Rehabilitation nach §15 SGB VI. Geschäftsbereich Sozialmedizin und Rehabil. 2015;

85. Cuijpers P, Turner EH, Koole SL, van Dijke A, Smit F. What is the threshold for a clinically relevant effect? The case of major depressive disorders. Depress Anxiety. 2014 May;31(5):374–8.

86. Bell ML, McKenzie JE. Designing psycho-oncology randomised trials and cluster randomised trials: variance components and intra-cluster correlation of commonly used psychosocial measures. Psychooncology. 2013 Aug;22(8):1738–47.

87. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ. Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol. 2004 Aug;57(8):785–94.

88. Baumeister H, Kallinger S, Scharm H, Böcker M, Forkmann T, Wirtz M, et al. Sachbericht zum Zwischenverwendungsnachweis 2017 - Implementierung einer Computer-adaptiven Erst- und Verlaufsdiagnostik zur Erfassung der funktionalen Gesundheit in der orthopädischen und kardiologischen Rehabilitation (DRV-Bund gefördert). 2018.

89. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the patient-reported outcomes measurement information system (PROMIS®): Depression, anxiety, and anger. Assessment. 2011 Sep;18(3):263–83.

90. Nolte S, Coon C, Hudgens S, Verdam MGE. Psychometric evaluation of the PROMIS® Depression Item Bank: an illustration of classical test theory methods. J Patient-Reported Outcomes. 2019 Dec;3(1):46.

91. Terwee CB, Crins MHP, Boers M, de Vet HCW, Roorda LD. Validation of two PROMIS item banks for measuring social participation in the Dutch general population. Qual Life Res. 2019 Jan;28(1):211–20.

92. Crins MHP, Terwee CB, Ogreden O, Schuller W, Dekker P, Flens G, et al. Differential item functioning of the PROMIS physical function, pain interference, and pain behavior item banks across patients with different musculoskeletal disorders and persons from the general population. Qual Life Res. 2019 May;28(5):1231–43.

93. Cella D, Lai JS, Jensen SE, Christodoulou C, Junghaenel DU, Reeve BB, et al. PROMIS Fatigue Item Bank had Clinical Validity across Diverse Chronic Conditions. J Clin Epidemiol. 2016 May;73:128–34.

94. van Kooten JAMC, Terwee CB, Luijten MAJ, Steur LMH, Pillen S, Wolters NGJ, et

al. Psychometric properties of the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance and Sleep-Related Impairment item banks in adolescents. J Sleep Res. 2020;(February):1–12.

95. Wesselius HM, Van Den Ende ES, Alsma J, Ter Maaten JC, Schuit SCE, Stassen PM, et al. Quality and quantity of sleep and factors associated with sleep disturbance in hospitalized patients. JAMA Intern Med. 2018 Sep;178(9):1165–71.

96. Katzan IL, Lapin B. PROMIS GH (Patient-reported outcomes measurement information system global health) scale in stroke a validation study. Stroke [Internet]. 2018 Jan;49(1):147–54. Available from: https://www.ahajournals.org/doi/10.1161/STROKEAHA.117.018766

97. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. Qual Life Res. 2017 Jul;26(7):1915–24.

98. Salsman JM, Schalet BD, Merluzzi T V, Park CL, Hahn EA, Snyder MA, et al. Calibration and initial validation of a general self-efficacy item bank and short form for the NIH PROMIS®. Qual Life Res [Internet]. 2019 Sep;28(9):2513–23. Available from: https://pubmed.ncbi.nlm.nih.gov/31140041/

99. Liegl G, Rose M, Correia H, Fischer HF, Kanlidere S, Mierke A, et al. An initial psychometric evaluation of the German PROMIS v1.2 Physical Function item bank in patients with a wide range of health conditions. Clin Rehabil [Internet]. 2018 Jan 11;32(1):84–93. Available from: http://journals.sagepub.com/doi/10.1177/0269215517714297

100. Reinert DF, Allen JP. The Alcohol Use Disorders Identification Test (AUDIT): A

Review of Recent Research. Alcohol Clin Exp Res [Internet]. 2002 Feb [cited 2020 Nov 5];26(2):272–9. Available from: http://doi.wiley.com/10.1111/j.1530-0277.2002.tb02534.x

101. Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short version of the Big Five Inventory in English and German. J Res Pers [Internet]. 2007;41:203–12. Available from: www.elsevier.com/locate/jrp

102. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011 Dec;20(10):1727–36.

103. Ludwig K, Graf von der Schulenburg JM, Greiner W. German Value Set for the EQ-5D-5L. Pharmacoeconomics [Internet]. 2018 Jun;36(6):663–74. Available from: https://doi.org/10.1007/s40273-018-0615-8

104. Chisholm D, Knapp MRJ, Knudsen HC, Amaddeo F, Gaite L, van Wijngaarden B, et al. Client Socio-Demographic and Service Receipt Inventory – European Version: development of an instrument for international research. Br J Psychiatry [Internet]. 2000 Jul;177(S39):s28--s33. Available from: https://www.cambridge.org/core/product/identifier/S0007125000227736/type/journal_article

105. Baumeister H, Bengel J, Forkmann T, Böcker M, Wirtz M, (2015-2018). Implementierung einer Computer-adaptiven Erst- und Verlaufsdiagnostik zur Erfassung der funktionalen Gesundheit in der orthopädischen und kardiologischen Rehabilitation. Drittmittelprojekt, DRV-Bund. 2015;

106. Ferreira D, Kostakos V, Dey AK. AWARE: Mobile Context Instrumentation

Framework. Front ICT [Internet]. 2015 Apr 20;2(APR):1–9. Available from: http://journal.frontiersin.org/article/10.3389/fict.2015.00006/abstract

107. Bae S, Chung T, Ferreira D, Dey AK, Suffoletto B. Mobile phone sensors and supervised machine learning to identify alcohol use events in young adults: Implications for just-in-time adaptive interventions. Addict Behav [Internet]. 2018 Aug;83:42–7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S030646031730446X

108. Philippi P, Baumeister H, Apolinário-Hagen J, Ebert DD, Hennemann S, Kott L, et al. Acceptance towards digital health interventions – Model validation and further development of the Unified Theory of Acceptance and Use of Technology. Internet Interv [Internet]. 2021 Dec;26:100459. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2214782921000993

109. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Q [Internet]. 2003;27(3):425–78. Available from: http://www.jstor.org/stable/30036540

110. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS). JMIR mHealth uHealth [Internet]. 2016 Jun 10;4(2):e72. Available from: http://mhealth.jmir.org/2016/2/e72/

111. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord. 2009;114(1–3):163–73.

112. Löwe B, Spitzer RL, Zipfel S, Herzog W. Komplettversion und Kurzform Autorisierte

deutsche Version des. Nervenarzt. 2002;2–11.

113. Löwe B, Kroenke K, Herzog W, Grafe K, Gräfe K. Measuring depression outcome with a brief self-report instrument: Sensitivity to change of the Patient Health Questionnaire (PHQ-9). 2004;81(1):61–6.

114. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166:1092–7.

115. Klein EM, Brähler E, Dreier M, Reinecke L, Müller KW, Schmutzer G, et al. The German version of the Perceived Stress Scale – psychometric characteristics in a representative German community sample. BMC Psychiatry [Internet]. 2016;16(1):159. Available from: http://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-016-0875-9

116. Gerber M, Lang C, Lemola S, Colledge F, Kalak N, Holsboer-Trachsler E, et al. Validation of the German version of the insomnia severity index in adolescents, young adults and adult workers: results from three cross-sectional studies. BMC Psychiatry [Internet]. 2016;16(1):174. Available from: http://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-016-0876-8

117. Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. Res Aging. 2004;26(6):655–72.

118. Rathner E, Terhorst Y, Cummins N, Schuller B, Baumeister H. State of Mind: Classification through Self-reported Affect and Word Use in Speech. In: Interspeech 2018 [Internet]. ISCA: ISCA; 2018. p. 267–71. Available from: http://www.isca-speech.org/archive/Interspeech_2018/abstracts/2043.html

119. Fontaine JRJ, Scherer KR, Roesch EB, Ellsworth PC. The world of emotions is not two-dimensional. Psychol Sci. 2007;18(12):1050–7.

120. Glick HA, Doshi JA, Sonnad SS, Polsky D. Economic Evaluation in Clinical Trials - Handbooks in Health Economic Evaluation Series. Oxford: Oxford University Press; 2014.

121. Willan AR, Briggs AH. Statistical Analysis of Cost-Effectiveness Data. Statistical Analysis of Cost-Effectiveness Data. 2006. 1–196 p.

122. Marseille E, Larson B, Kazi DS, Kahn JG, Rosen S. Thresholds for the cost–effectiveness of interventions: alternative approaches. Bull World Health Organ. 2015 Feb;93(2):118–24.

123. Woods B, Revill P, Sculpher M, Claxton K. Country-Level Cost-Effectiveness Thresholds: Initial Estimates and the Need for Further Research. Value Heal. 2016 Dec;19(8):929–35.

124. Willan AR, Briggs AH, Hoch JS. Regression methods for covariate adjustment and subgroup analysis for non-censored cost-effectiveness data. Health Econ [Internet]. 2004 May [cited 2019 Jan 24];13(5):461–75. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15127426

125. Kilian R, Becker T, Frasch K. Effectiveness and cost-effectiveness of home treatment compared with inpatient care for patients with acute mental disorders in a rural catchment area in Germany. Neurol Psychiatry Brain Res. 2016 Jun;22(2):81–6.

126. Kilian R, Frasch K, Steinert T, Schepp W, Weiser P, Jaeger S, et al. Cost-effectiveness of psychotropic polypharmacy in routine schizophrenia care. Results of the ELAN prospective observational trial. Neurol Psychiatry Brain Res. 2018 Dec;30:47–55.

127. Hoch JS, Briggs AH, Willan AR. Something old, something new, something borrowed, something blue: a framework for the marriage of health econometrics and cost-effectiveness analysis. Health Econ [Internet]. 2002 Jul [cited 2019 Jan 24];11(5):415–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12112491

128. Salize HJ, Kilian R. Gesundheitsökonomie in der Psychiatrie - Konzepte, Methoden und Analysen. Stuttgart: Kohlhammer; 2010.

129. van Buuren S, Groothuis-Oudshoorn K. mice : Multivariate Imputation by Chained Equations in R. J Stat Softw [Internet]. 2011;45(3). Available from: http://www.jstatsoft.org/v45/i03/

130. Goldstein H. Multi-level statistical models. New York: Halsted; 1995. 64–88 p.

131. MacCallum RC, Cheongtan K, Malarkey WB. Studying multivariate change using multilevel models and latent curve models. Vol. 32, Multivariate Behavioral Research1. MacCallum RC, Cheongtan K, Malarkey WB. Studying multivariate change using multilevel models and latent curve models. Multivariate Behav Res. 1997;32(3):215-253. doi:10.1207/s15327906mbr3203_1. 1997. p. 215–53.

132. Nezlek JB. Multilevel modeling for psychologists. APA Handb Res methods Psychol Vol 3 Data Anal Res Publ. 2012;3:219–41.

133. Hastie T, Tibshirani R, Friedman J. Prototype Methods and Nearest-Neighbors. In 2009.

134. Freund, Yoav and LM. The alternating decision tree learning algorithm. Int Conf Mach Learn. 1999;

135. Freund Y, Schapire RE. A decision-theoretic generalization of on-line learning and an

application to boosting. In: Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics). 1995.

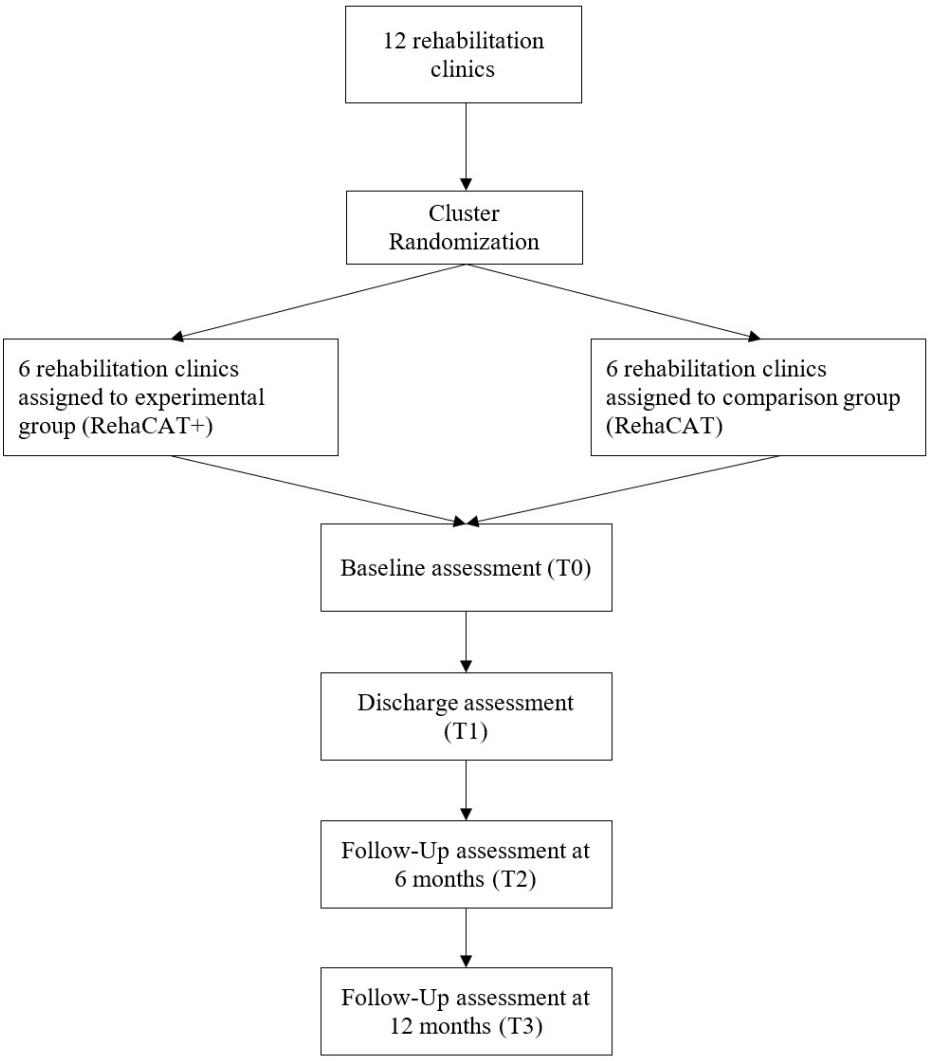

Figure 1. Flow chart

89x95mm (300 x 300 DPI)

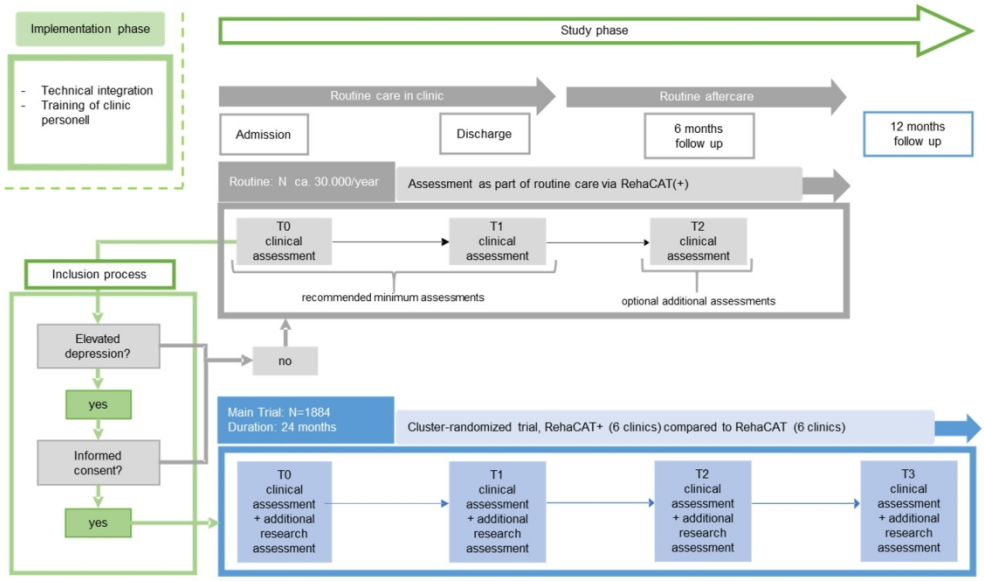

Figure 2. Procedure

149x89mm (300 x 300 DPI)

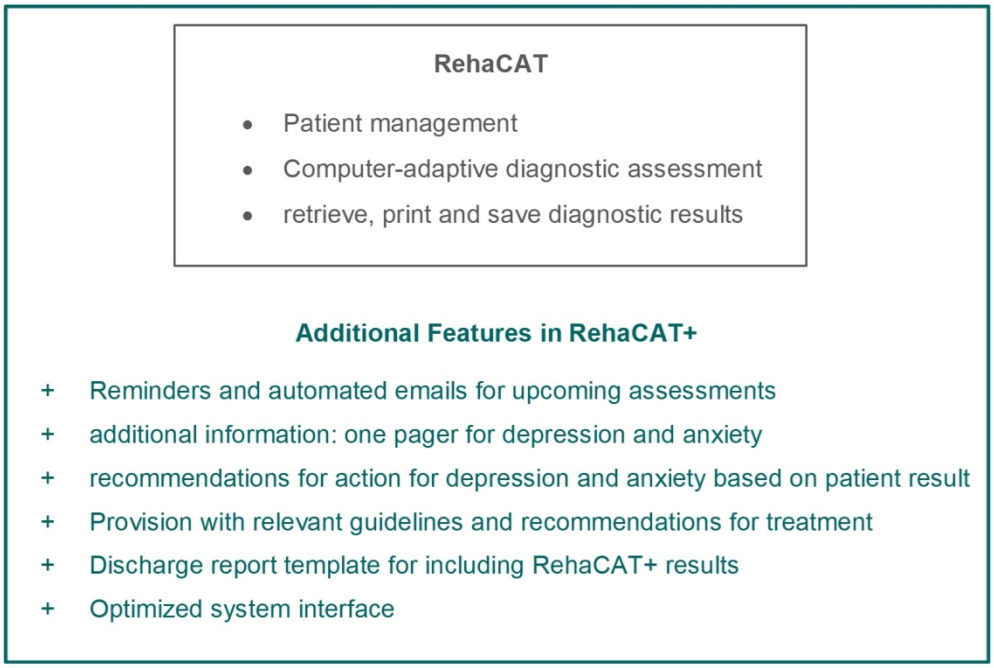

Figure 3. Features

141x94mm (300 x 300 DPI)

Faculty of Engineering, Computer Science and Psychology
Institute of Psychology and Education
Department. of Clinical Psychology and Psychotherapy

Prof. Dr. Harald Baumeister

Lise-Meitner-Str. 16,
89081 Ulm

Tel: +49 731 50-32814
Fax: +49 731 50-32809
harald.baumeister@uni-ulm.de

TEILNEHMENDEN-INFORMATION

Titel der Studie: RehaCAT+

Sehr geehrte Probandin, sehr geehrter Proband,

Herzlich willkommen zu unserer Studie RehaCAT+, wir danken Ihnen für Ihr Interesse!
Wir sind ein Studienteam der Abteilung für Klinische Psychologie und Psychotherapie des Instituts für Psychologie und Pädagogik an der Universität Ulm. Im Voraus möchten wir Sie darüber informieren, dass jede Teilnahme an einer wissenschaftlichen Studie freiwillig ist und wir aus diesem Grund für die Teilnahme ihre Einwilligung benötigen. Falls Sie nicht an der Studie teilnehmen möchten oder eine mögliche Teilnahme frühzeitig beenden möchten, entstehen Ihnen keine Nachteile. Mit diesem Schreiben möchten wir Sie umfassend zur Studie informieren und bitten Sie, den folgenden Text sorgfältig zu lesen. Sollten Sie im Nachhinein noch offene Fragen haben, können Sie uns telefonisch oder per Mail erreichen oder das Klinikpersonal fragen!

WARUM WIRD DIESE STUDIE DURCHGEFÜHRT?

Die medizinische Rehabilitation sieht sich der Herausforderung gegenüber, medizinische Maßnahmen bedarfsgerecht einzuleiten und zu gestalten sowie die Nachhaltigkeit von Behandlungseffekten zu sichern. Nicht selten treten bei Menschen, die aufgrund von schwerwiegenden medizinischen Problemen eine Rehabilitation durchlaufen Symptome psychischer Belastungen auf. Eine umfassende psychosoziale Diagnostik erfordert viel Zeit und Ressourcen und ist aufgrund dessen in der Rehabilitationsroutine für die Klinik nur schwer umsetzbar und auch für Sie als Rehabilitand:in sehr zeitaufwändig.
Um Sie und ihre Rehabilitationseinrichtung bei einer umfangreichen und fundierten Diagnostik zu unterstützen, haben wir RehaCAT+ entwickelt. RehaCAT+ ist ein Computer- und Web-basiertes Testsystem, das adaptive Testverfahren verwendet. Das bedeutet, dass das System basierend auf den gegebenen Antworten die relevanten Fragen heraussucht, sodass nicht mehr jede einzelne Frage durchlaufen werden muss. Das ist insbesondere auch für Sie als Rehabilitand:in von Vorteil, da sich die Zeit zum Ausfüllen von Fragebögen stark verkürzt, bei gleichbleibend hoher Genauigkeit des Testergebnisses.
Basierend auf Ihren Testergebnissen erhält Ihr behandelnder Arzt oder Ihre behandelnde Ärztin in der Rehabilitationsklinik Rückmeldung über mögliche psychosoziale Belastungen. Diese Ergebnisse können Ihrem Arzt:Ihrer Ärztin dabei helfen, die bestmögliche Behandlung für Sie einzuleiten.
Ziel der Studie ist es, zu untersuchen, ob es 12 Monate nach Entlassung aus der Rehabilitation einen Unterschied im Wohlbefinden der Rehabilitand:innen im Vergleich zu anderen Kliniken gibt.

ABLAUF DER STUDIE

Sie erhalten diese Informationen, da sie für eine Studienteilnahme in Frage kommen. Sofern Sie sich für eine Teilnahme entscheiden, bitten wir Sie der Einwilligungserklärung, welche im nächsten Teil folgen wird, zuzustimmen.
Im Rahmen der normalen Rehabilitationsmaßnahmen in Ihrer Klinik haben Sie bereits an der computer-adaptiven Befragung teilgenommen. Dies hilft dem Klinikpersonal, für Sie passende Behandlungsmaßnahmen einzuleiten. Im Zuge Ihrer Rehabilitation werden Sie bei Aufnahme, Entlassung sowie 6 Monate nach der Entlassung befragt, um festzustellen, wie es Ihnen geht und ob sich Ihre Symptome verbessert haben. Insgesamt durchlaufen Sie also routinemäßig 3 Befragungen.
Sollten Sie sich entscheiden an dieser Studie teilzunehmen, werden Ihnen zu jedem Befragungszeitpunkt noch einige zusätzliche Fragen gestellt, mit deren Beantwortung Sie einen wertvollen Beitrag zur Forschung leisten

und dabei helfen, künftige Behandlungen für Rehabilitand:innen wie Sie effektiver zu gestalten. Dabei werden sensible Daten zu Ihrer Gesundheit erfasst.
Basierend auf unseren Erfahrungen schätzen wir den zeitlichen Mehraufwand für Sie auf ca. 20 Minuten je Befragung. Zusätzlich befragen wir Sie 12 Monate nach der Rehabilitation, womit insgesamt vier Befragungen auf Sie zukommen.

ENTGELT
Das vollständige Ausfüllen der Onlinebefragungen wird mit einer finanziellen Aufwandsentschädigung vergütet. Für die Befragungen 6 und 12 Monate nach ihrem Rehabilitationsaufenthalt haben Sie die Möglichkeit jeweils 20 Euro elektronisch überwiesen zu bekommen.

UMGANG MIT IHREN DATEN
Im Rahmen der Studie werden Ihre Daten von der Abteilung Klinische Psychologie und Psychotherapie am Institut für Psychologie und Pädagogik Universität Ulm verwendet. Es haben nur diejenigen Personen innerhalb der Universität Zugriff auf Ihre pseudonymisierten Daten, die dies für einen ordnungsgemäßen Ablauf der Studie benötigen. Nach Abschluss der Studie wird die Kodierliste, welche Ihren Namen zu ihrer Reha-ID zuordnen und nur in ihrer Klinik vorliegt, gelöscht. Danach sind die Daten anonymisiert und es kann kein Personenbezug mehr hergestellt werden. Wissenschaftliche Veröffentlichungen erfolgen mit diesen anonymisierten Daten über viele Studienteilnehmende hinweg. Eine mögliche Weitergabe der anonymisierten Daten an Dritte beschränkt sich auf wissenschaftliche Nutzungszwecke. Zu keinem Zeitpunkt können Krankenversicherungen/ Leistungserbringer oder Arbeitgeber individualisierte Studiendaten einsehen. Nach der 6 und 12 Monatsbefragung möchten wir Ihnen jeweils eine Aufwandentschädigung elektronisch überweisen.

Dazu werden wir nach Abschluss der Befragung Ihre IBAN, Name und Reha-ID erfassen. Ihre Bankdaten werden nicht mit den Gesundheitsdaten verknüpft und abgespeichert. Ihre Bankdaten Daten werden nach der elektronischen Überweisung der Vergütung unmittelbar gelöscht. Die Angabe Ihrer Bankdaten ist freiwillig. Sollten Sie keine Aufwandsentschädigung erhalten möchten, brauchen Sie Ihre Daten nicht angeben.

GIBT ES RISIKEN DURCH DIE TEILNAHME AN DER STUDIE REHACAT+?
Nebenwirkungen oder unerwünschte Wirkungen von Online Befragung oder ähnlicher Studien sind nicht bekannt. Manche der Aufgaben oder Fragen sind möglicherweise schwierig zu beantworten oder umzusetzen. Die Erfahrung, sich Ängsten oder unangenehmen Gedanken zu stellen, ist für die meisten Menschen zunächst nicht leicht, dann aber oft sehr hilfreich. Zusätzlich stehen Ihnen bei Bedarf zuständiges Klinikpersonal Als Ansprechpartner/in zur Verfügung und werden versuchen, Ihnen zu helfen.

FREIWILLIGKEIT:
An dieser Studie nehmen Sie freiwillig teil. Ihr Einverständnis können Sie jederzeit und ohne Angabe von Gründen widerrufen, dann werden alle bis dahin studienbedingt erhobenen personenbezogenen Daten gelöscht. Dieser eventuelle Widerruf hat keine Auswirkungen für Sie. Zur Löschung der Daten müssen Sie dem Forschungsteam Ihre Reha-ID mitteilen. Dafür können Sie sich jederzeit an die Supportmail Adresse (RehaCAT@uni-ulm.de) wenden, sowie während ihres Aufenthalts in der Klinik das Anliegen an Klinikmitarbeitende herantragen, welche wiederum die Reha-ID an das Forschungsteam weiterleiten. Es können nur alle Daten gelöscht werden. Das Löschen einzelner Fragebögen ist nicht möglich.

ERREICHBARKEIT DER STUDIENMITARBEITER:
Sollten während des Verlaufes der Studie Fragen auftauchen, so können Sie jederzeit folgende Ansprechpartner erreichen:

Yannik Terhorst
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32820
E-Mail: yannik.terhorst@uni-ulm.de

Johannes Knauer
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm

Telefon: +49 731/50 32805
E-Mail: Johannes.knauer@uni-ulm.de

VERSICHERUNG:

Während der Teilnahme an der Studie genießen Sie Versicherungsschutz. Die an der Studie mitwirkenden Mitarbeitenden sind über die Universität Ulm beim Land Baden-Württemberg haftpflichtversichert für den Fall, dass Sie durch deren Verschulden einen Schaden erleiden.

Einen Schaden, der Ihrer Meinung nach auf diese Studie zurückzuführen ist, melden Sie bitte unverzüglich dem Studienleiter.

SCHWEIGEPFLICHT/DATENSCHUTZ:

Alle Personen, welche Sie im Rahmen dieser Studie betreuen, unterliegen der beruflichen Schweigepflicht und sind auf das Datengeheimnis verpflichtet. Die studienbezogenen Untersuchungsergebnisse sollen in anonymisierter Form in wissenschaftlichen Veröffentlichungen verwendet werden. Soweit es zur Kontrolle der korrekten Datenerhebung erforderlich ist, dürfen autorisierte Personen (z.B.: des Auftraggebers, der Universität) Einsicht in die studienrelevanten Teile der Akte nehmen. Sofern zur Einsichtnahme autorisierte Personen nicht der obengenannten beruflichen Schweigepflicht unterliegen, stellen personenbezogene Daten, von denen sie bei der Kontrolle Kenntnis erlangen, Betriebsgeheimnisse dar, die geheim zu halten sind.

Die in dieser Studie für die Datenverarbeitung verantwortliche Personen (Studienleiter selbst bzw. von ihm beauftragte Mitarbeitende; jedoch nicht Datenschutzbeauftragter) sind:

Yannik Terhorst
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32820
E-Mail: yannik.terhorst@uni-ulm.de

Johannes Knauer
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32805
E-Mail: Johannes.knauer@uni-ulm.de

Bei Fragen zur Nutzung oder Verarbeitung Ihrer Daten wenden Sie sich bitte an den/die:

- Datenschutzbeauftragte/n des lokalen Studienzentrums
  (a) Universität Ulm: *Universität Ulm, Helmholtzstr. 16, 89081 Ulm, Tel.Nr.: 07542 / 949 21 09,*
  E-Mail: *dsb@uni-ulm.de*

Falls Sie Bedenken oder Beschwerden hinsichtlich der Verarbeitung Ihrer Daten haben, wenden Sie sich bitte an die Datenschutz-Aufsichtsbehörde Ihres Studienzentrums: Die entsprechenden Kontaktdaten finden Sie auf der Internetseite des Landesbeauftragten für Datenschutz und Informationsfreiheit Baden-Württemberg: *https://www.baden-wuerttemberg.datenschutz.de/dsb-online-melden/*

ulm university universität
uulm

Faculty of Engineering, Computer Science and Psychology
Institute of Psychology and Education
Department. of Clinical Psychology and Psychotherapy

Prof. Dr. Harald Baumeister

Lise-Meitner-Str. 16,
89081 Ulm

Tel: +49 731 50-32814
Fax: +49 731 50-32809
harald.baumeister@uni-ulm.de

EINWILLIGUNGSERKLÄRUNG

Titel der Studie: RehaCAT+

Inhalt, Vorgehensweise, Risiken und Ziel der obengenannten Studie sowie die Befugnis zur Einsichtnahme in die erhobenen Daten wurden mir durch die online Informationsmaterialien ausreichend erklärt.
Falls Sie Fragen haben, können Sie sich an folgende Stellen wenden:

- Klinikmitarbeitende
- E-Mail: RehaCAT@uni-ulm.de
- Telefon: +49 731/50 32820 oder +49 731/50 32805

Ich hatte Gelegenheit Fragen zu stellen und alle eventuellen Fragen wurden geklärt.
☐ Ja ☐ Nein

Ich hatte ausreichend Zeit, mich für oder gegen die Teilnahme an der Studie zu entscheiden.
☐ Ja ☐ Nein

E-Mail-Adresse:
Zur Untersuchung des Langzeiteffekts dieser Studie würden wir sie gerne 6 und 12 Monate nach Abschluss ihrer Reha kontaktieren. Dies ist eine Voraussetzung für die Studienteilnahme. Ihre E-Mail-Adresse wird hierbei separat von allen anderen Daten gespeichert.

_____

Kontaktaufnahmen im Rahmen dieser Studie
Ich gebe mein Einverständnis, dass ich im Rahmen der Studie unter der oben angegebenen E-Mail-Adresse kontaktiert werden darf.
☐ JA ☐ NEIN

Elektronische Erfassung der Bankverbindung zur Aufwandsentschädigung
Die Aufwandsentschädigung nach der 6 und 12 Monatsbefragung kann ausschließlich über eine elektronische Überweisung erfolgen. Dazu ist es notwendig, dass Sie im Anschluss an diese Befragungen Ihre Bankdaten angeben und der damit verbundenen Datenverarbeitung zustimmen. Wir klären Sie zu den Zeitpunkten jeweils erneut über die Verarbeitung auf. Die Angabe der Bankdaten ist zu beiden Zeitpunkten freiwillig.
Ich habe dies zur Kenntnis genommen.
☐ JA ☐ NEIN

Mir ist bewusst, dass die Einwilligungen freiwillig sind und ohne Nachteile (auch einzeln) verweigert oder jederzeit auch ohne Angaben von Gründen widerrufen werden können. Ich weiß, dass im Falle eines Widerrufs die Rechtmäßigkeit der aufgrund der Einwilligung bis zum Widerruf erfolgten Verarbeitung nicht berührt wird. Ich habe verstanden, dass ich mich für einen Widerruf einfach an die in den Informationen genannte Kontaktperson wenden kann und dass aus der Verweigerung der Einwilligung oder ihrem Widerruf keine Nachteile entstehen.
Mir wurden die Informationen zur Erhebung personenbezogener Daten in der Studie RehaCAT+ mitgeteilt

und zur Verfügung gestellt. Eine Kopie dieser Einwilligungserklärung können Sie jederzeit über den Menüpunkt „Informationen“ herunterladen oder vom Personal Ihrer Rehabilitationsklinik erhalten.

Ich habe die allgemeinen Informationen zur Studie „RehaCAT+“ gelesen und willige in die Teilnahme an der Studie und die damit verbundene Datenverarbeitung ein.
☐ JA ☐ NEIN

[Weiter Button erscheint erst, nach aktiver Bestätigung dieses und der Bestätigung zur Datenverarbeitung – die Einwilligung ist rein digital]

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, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		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	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	4
Funding	#4	Sources and types of financial, material, and other support	23
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 23

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	23
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	23
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)	19
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
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
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)	8
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	9
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	9

		eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
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)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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	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)	8,9
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9
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	10

		enrol participants or assign interventions	
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	10
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
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	n/a
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 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	19
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	10
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	19
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	20

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
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)	20
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	19
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	n/a
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	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	22
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)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if	n/a

		applicable	
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	19
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
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	19
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	n/a
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	23
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	supplement
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	n/a

BMJ Open

Effectiveness and cost-effectiveness of a web-based routine assessment with integrated recommendations for action for depression and anxiety (RehaCAT+): protocol for a cluster randomized controlled trial for patients with elevated depressive symptoms in rehabilitation facilities

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-061259.R1
Article Type:	Protocol
Date Submitted by the Author:	24-May-2022
Complete List of Authors:	Knauer, Johannes; Ulm University, Department of Clinical Psychology and Psychotherapy Terhorst, Yannik; Ulm University, Department of Clincial Psychology and Psychotherapy Philippi, Paula; Ulm University, Department of Clinical Psychology and Psychotherapy Kallinger, Selina; Ulm University, Department of Clinical Psychology and Psychotherapy Eiler, Sandro; Ulm University, Department of Clinical Psychology and Psychotherapy Kilian, Reinhold; Ulm University, Department of Psychiatry and Psychotherapy II Waldmann, Tamara; Ulm University, Department of Psychiatry and Psychotherapy II Moshagen , Morten ; Ulm University, Department of Psychological Research Methods Bader, Martina; Ulm University, Department of Psychological Research Methods Baumeister, Harald; Universitat Ulm, Department of Clinical Psychology and Psychotherapy
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Diagnostics, Health economics, Rehabilitation medicine, Health informatics
Keywords:	Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, HEALTH ECONOMICS, MENTAL HEALTH, PRIMARY CARE, REHABILITATION MEDICINE

Effectiveness and cost-effectiveness of a web-based routine assessment with integrated recommendations for action for depression and anxiety (RehaCAT+): protocol for a cluster randomized controlled trial for patients with elevated depressive symptoms in rehabilitation facilities

Johannes Knauer[1], Yannik Terhorst[1], Paula Philippi[1], Selina Kallinger[1], Sandro Eiler[1], Reinhold Kilian[2], Tamara Waldmann[2], Morten Moshagen[3], Martina Bader[3], Harald Baumeister[1]

[1]Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University, Germany

[2]Section Health Economics and Health Services Research, Department of Psychiatry and Psychotherapy II, Ulm University, Germany

[3]Department of Psychological Research Methods, Institute of Psychology and Education, Ulm University, Germany

Correspondence to: Johannes Knauer (Lise-Meitner-Straße 16, D-89081 Ulm, johannes.knauer@uni-ulm.de, +49 731/50 32805)

Email addresses of co-authors:

Yannik Terhorst (yannik.terhorst@uni-ulm.de)

Paula Philippi (paula.philippi@uni-ulm.de)

Selina Kallinger (selina.kallinger@uni-ulm.de)

Sandro Eiler (sandro.eiler@uni-ulm.de)

Reinhold Kilian (reinhold.kilian@uni-ulm.de)

Tamara Waldmann (tamara.waldmann@uni-ulm.de)

Morten Moshagen (morten.moshagen@uni-ulm.de)

Martina Bader (martina.bader@uni-ulm.de)

Harald Baumeister (harald.baumeister@uni-ulm.de)

Abstract

Introduction The integration of a web-based computer-adaptive patient reported outcome test (CAT) platform with persuasive design optimized features including recommendations for action into routine health care could provide a promising way to translate reliable diagnostic results into action. The present study aims to evaluate the effectiveness and cost-effectiveness of such a platform for depression and anxiety (RehaCAT+) compared to the standard diagnostic system (RehaCAT) in cardiological and orthopedic health clinics in routine care.

Methods and analysis A two-arm, pragmatic, cluster-randomized controlled trial (cRCT) will be conducted. Twelve participating rehabilitation clinics in Germany will be randomly assigned to a control (RehaCAT) or experimental group (RehaCAT+) in a 1:1 design. A total sample of 1,848 participants will be recruited across all clinics. The primary outcome, depression severity at 12-months follow up (T3), will be assessed using the CAT PROMIS Emotional Distress – Depression Item set. Secondary outcomes are depression at discharge (T1) and 6 months follow-up (T2) as well as anxiety, satisfaction with participation in social roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy, physical functioning, alcohol, personality, and health economic specific general quality of life and socioeconomic cost and benefits at T1-3. User behavior, acceptance, facilitating and hindering factors will be assessed with semi-structured qualitative interviews. Additionally, a smart sensing sub-study will be conducted, with daily ecological momentary assessments and passive collection of smartphone usage variables. Data analysis will follow the intention-to-treat principle with additional per-protocol analyses. Cost-effectiveness analyses will be conducted from a societal perspective and the perspective of the statutory pension insurance.

Ethics and dissemination The study will be conducted according to the Declaration of Helsinki. The Ethics Committee of Ulm University, has approved the study (on 24 February

2021 ref. 509/20). Written informed consent will be obtained for all participants. Results will be published via peer reviewed journals.

Trial registration number German Clinical Trials Register, DRKS00027447 (11.01.2022).

Keywords: cluster randomized controlled trial, patient reported outcome, depression, computer adaptive testing, routine care

Strengths and limitations of this study

- Large pragmatic, cluster-randomized controlled trial conducted in orthopedic and cardiologic rehabilitation care in Germany.
- Comprehensive observer-masked effectiveness, cost-effectiveness, and feasibility analyses of a web-based computer-adaptive PROM platform with action recommendations regarding depression and anxiety.
- Fine granular disease and treatment trajectories modeling using smart sensing data.
- Cluster randomization and implementation of intervention or control condition on clinic level without blinding of clinical personnel.
- Limited generalizability to other health care settings and countries.

Introduction

Bio-psycho-social health care in patients with somatic diseases such as musculoskeletal or cardiovascular diseases is faced with the challenge of designing the initiation and implementation of medical and psycho-social measures in a needs-based manner (1–4). Patient reported outcome measures (PROMs) could become important means to achieve this goal in somatic health care (5–8). For instance, they can serve as a basis for screening mental health comorbidities, quality of life and functioning in daily living. Based on these test results, treatment planning, process and outcome measurement and quality assurance can take place (5,7).

To promote acceptance and to optimize the quality of psychodiagnostics, there is a demand for an economic, resource-saving assessment that minimizes the burden on patients (measurement efficiency) and facilitates evaluation and interpretation of results (usefulness) (1). Besides, a reliable assessment of differences between patients (measurement precision) and changes in the condition of patients during and after treatment (change sensitivity of the assessment) is a necessary prerequisite (1). Paper-and-pencil testing procedures are most commonly used, but have crucial limitations, such as the limited scope or the test load as well as difficulties in collecting these measures before, during, and after the treatment process (1,9–13).

A computer-based implementation of PROM assessments is considered as a possible solution for an equally precise and time-efficient, user-friendly and useful assessment (1,5,14). Furthermore, a likewise web-based implementation of such an assessment removes time- and location dependencies. Hence, assessments of patients before and after the end of treatment could be implemented more easily in routine care settings.

However, PROMs are often static and non-adaptive to the user's responses, resulting in limited accuracy, presentation of inappropriate items for the individual, and an overall long assessment

duration (15–17). Computer-adaptive testing (CAT), which is based on item response theory models, is a promising option in this context to substantially reduce the burden on patients (personalized testing) and health care institutions (e.g., immediate test evaluations) (10,18–23). In CAT, the items providing the maximum information about the respective patient are selected and assessed during test administration based on the previous answers of a patient (24). In this way, besides a considerable reduction in test duration, an estimation accuracy that is equally good or sometimes even better compared to non-adaptive procedures can be achieved (18,23,25–27).

Whereas PROMs are often used in clinical research, the usefulness and effectiveness of routine PROM assessment in somatic health care is still controversially discussed (8,28–33). On the one hand, routine PROMs allow for real-time monitoring. Moreover, PROMs have been shown to lead to improved communication between clinician and patient, decision-making and patient satisfaction with care, and improved health outcome and detection of symptoms and mental comorbidities. On the other hand, there are barriers such as limited ability of clinicians for score interpretation, unfamiliarity with PROM software usage and less time for controlling (8,23,31–42). Additionally one of the central challenges is the implementation of further evidence-based measures on the basis of the assessment results (43). Action plans directly derivable from assessment results are regarded as a prerequisite to implement PROMs beneficially (31,33,44,45). However, there is still an insufficient linkage between assessment results and implementation of existing evidence-based guidelines and recommendations for action in everyday clinical practice (33,46).

One way to promote the desired probability of action following diagnostic results could be persuasive design components, such as reminder features that are automatically triggered depending on the test environment (47–49). Persuasive designed technological approaches are defined as interactive systems that purposefully influence the user, aiming to change behavior

or attitudes (50). The provision of computer-based databases and concrete decision-making aids and recommendations for action is seen as one way of reducing these existing barriers (51,52). In this context, it could be useful to link the individual test results with therapy standards as well as recommendations for action and guideline knowledge. These have been formulated in particular for the areas of comorbid depression and anxiety in patient populations with somatic diseases (53–57). Such a combination could offer the practitioner a) background knowledge, b) recommendations for action as well as c) documentation aids. Ideally, such elements should be directly integrated into testing systems (e.g., web- and CAT-based) to provide a comprehensive platform from screening to action.

Hence, the aim of the present trial is to examine a persuasive design optimized CAT system (RehaCAT+) providing background knowledge, recommendations for action as well as documentation aids against a standard CAT system (RehaCAT). This will be exemplified with a focus on depression as the primary outcome and anxiety as major mental health comorbidities in cardiological and orthopedic care. The following research questions will be addressed:

1) Does RehaCAT+ improve rehabilitation patients' depression after one year (T3)?

2) Does RehaCAT+ improve depression, anxiety, satisfaction with participation in social roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy, physical function, and alcohol use at discharge (T1) and six months follow-up (T2) as well as one year later regarding all the secondary outcomes (T3)?

3) Does RehaCAT+ lead to improved documentation and improved follow-up and post-rehabilitation recommendations?

4) Does RehaCAT+ lead to improved utilization of rehabilitation therapy standard and guideline compliant health care services during and after rehabilitation?

5) What is the cost-effectiveness of RehaCAT+ compared to RehaCAT?

6) What is the acceptance and feasibility of RehaCAT?

7) What are facilitators, hindering factors, mediators and potential risks associated with RehaCAT+?

A web-based CAT system provides a powerful way to assess PROM, however, it is still subject to limitations: 1) it requires active input of the patient – even if reduced through computer adaptive testing, 2) the assessment is limited to fixed time points, which may lead to long unassessed time intervals in which significant symptom change may occur, and 3) due to the nature of self-report the answers by patients may be biased (e.g., social desirability or recall bias) (58–61).

One solution to this could be the addition of ecological momentary assessment and smart sensing to allow for digital phenotyping (62,63). Digital phenotyping is defined as the moment-by-moment quantification of the individual health in situ through digital variables and data generated by personal devices (e.g., smartphone or smart-watch) (62,63). First studies show promising results highlighting the potential of this method to complement PROM assessments for monitoring and predicting symptoms with minimal added patient burden (64–70). In future the combination of high quality PROM at fixed timepoints combined with continuous monitoring through smart sensing and information from the clinical information system could become a promising data base, which could be used to 1) predict symptom trajectories, 2) build early-detection of adverse events systems (RED-flag) or 3) personalized treatment recommendation systems (71–74).

Hence, the present study additionally investigates the extent to which smart sensing is suitable for assessing mental health in a routine care setting. In the context of this exploratory study, we will focus on the following research questions:

8) What are the associations between digital markers and health-related variables?

9) Are digital markers suitable for predicting health-related variables and disease or disorder status?

10) What is patient acceptance, adherence, and perceived usefulness of smart sensing?

Methods and analysis

Study design

A two-arm, pragmatic, cluster-randomized controlled trial (cRCT) will be conducted, comparing the experimental group receiving an enhanced version of a PROM system called "RehaCAT+" to the control group receiving the basic version of the PROM system called "RehaCAT" in a 1:1 design (Figure 1). See below for detailed description of the experimental and control group.

----------insert Figure 1 about here----------

This cRCT has been approved by the ethics committee of Ulm University (509/20 – FSt/Sta) and will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) Statement 2010 and the extensions for reporting pragmatic trials and cluster randomized trials (75–77). Cost-effectiveness analyses will be reported following the Consolidated Health Economic Evaluation Reporting Standards statement (CHEERS) (78) and the guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (79). This trial protocol was created according to SPIRIT guidelines (80). The trial has been registered in the German clinical trial register under DRKS00027447. The expected timeline for trial completion is September 2024 with first patient enrolment in July 2022.

Procedure and recruitment

The testing systems RehaCAT (control group) and RehaCAT+ (experimental group) will be implemented in the clinic routine of 12 clinics offering cardiological or orthopedic rehabilitation treatment in Germany. Included clinics pursue medical and occupational oriented stationary rehabilitation according to German ICF diagnosis-based rehabilitation guidelines (81). With a psycho-social approach rehabilitation is focused on patients' impairments (e.g., body functions & structure), restoration of activities and removing restrictions of participation (82). Accordingly, the treatment in clinics often contains diagnostics, pharmacotherapy, physiotherapy, and psychotherapy. Standard stationary stay usually lasts for three weeks. The treatment as well as the duration of treatment is expected to vary across patients and between clinics. Treatment will be further described post-hoc using the results from the cost-effectiveness questionnaires (see 2.5). Neither the control condition nor the experimental condition will interfere with clinical treatment (see 2.3.).

For the study, one of two versions of a web-based computer-adaptive diagnostic platform will be implemented within the clinics (see 2.3). Clinic personnel will be trained in an on-site workshop during the implementation phase. The training will cover technical functions of the platform (e.g., how new patients can be registered, how patients' results can be received, etc.) as well as recommendations and guidelines for clinical practice (e.g., how results should be interpreted, information about national treatment guidelines for mental health, etc.). Lastly, clinicians will also be trained in the communication with patients and procedures for patients. After the training, written manuals providing a summary of the workshop will be available in the system for the clinic personnel. Qualification level of clinic personnel operating the system will vary across clinics (e.g., nurses, medical doctors, clinical psychologists, etc.). This will be monitored and reported (se 2.5.5). Furthermore, the technical administrator has direct contact options (e.g., e-mail) to the research team. The platform is designed so patients can go through

the respective version of the testing system to deliver patient-reported outcomes at various points in time. A subset of patients in routine care fulfilling the inclusion criteria (see 2.1.1) will be included in the present study. Study participants will receive all questionnaires from routine care and additional research questionnaires. Routine patients will go through the diagnostic measures at admission (T0) and before discharge (T1), as well as at six months (T2) follow-up as part of their clinical routine. Study participants will additionally be assessed at twelve-months (T3) follow up.

Data collection will be digital. Due to the web-based character of the platform, in- and outpatient assessments are possible. Clinics are free to implement the admission and discharge assessments as in- or outpatient assessments. Data for follow-up will be assessed solely in an outpatient setting. Assessment procedures (e.g., in- or outpatient assessment at admission) are expected to vary across clinics and will be further described post-hoc. For an explanatory illustration of the assessment procedures see Figure 2.

----------insert Figure 2 about here----------

Inclusion and exclusion criteria

Since this is a cRCT, inclusion and exclusion are differentiated at two levels a) cluster level (i.e., eligibility of clinics) and b) patient level: To be eligible, rehabilitation clinics must be located in Germany, provide cardiological or orthopedic rehabilitation and sign a cooperation agreement with Ulm University. There are no further exclusion criteria for clinics. Within each cluster (i.e., rehabilitation clinic) patients who exhibit elevated depression scores (PROMIS Emotional Distress Depression: T-value $\geq$ 65.2) (15) at the initial assessment will be informed about the study and consecutively asked for their participation consent (Supplemental Material: SPIRIT Supplement Informed Consent). To be eligible, patients with elevated depression scores must a) be 18 years or older, b) have sufficient German language skills, c) provide an e-mail

address, d) agree to the data privacy and processing procedures according to the European General Data Protection Regulation, and e) sign the informed consent. There are no further exclusion criteria for patients.

Randomization, allocation, and masking

Randomization and allocation regarding the control (RehaCAT) and experimental group (RehaCAT+) of the 12 participating rehabilitation clinics will be performed by an independent researcher to avoid selection bias. Randomization will be done on cluster-level.

Researchers responsible for randomization will be obscured to the rehabilitation clinic names and agencies. Randomization will be done using an automatically created randomization list.

For the outcome analyses the conducting analyst will be obscured to group allocation. Patients will remain obscured to their study arm assignment. Neither the clinics (clinic personnel) nor the research team will be obscured to assigned study condition.

Conditions

RehaCAT-Control Group: RehaCAT is a server- and web-based, device-independent test system, which allows the use of classical test procedures as well as Computer-adaptive procedures. RehaCAT does not interfere with the (clinic specific) standard treatment and patients have unrestricted access to treatment as usual (TAU). RehaCAT is divided into four user areas: 1) patient, 2) staff, 3) administrator, 4) researcher. The platform allows system administrators to upload and manage patients. Patients go through the diagnostic measures. Clinicians can view the test results of their patients immediately after completion of each assessment point (T0, T1 and T2). Test results consist of a traffic light feedback (green = normal severity, yellow = elevated severity based on clinical cut-off values, red = high severity 2.5 SDs above mean (15,83)), patients' test results expressed in T-values combined with clinical cut-off

values, and a line graph visualizing the results and change over assessment times. For a full overview of the assessment see 2.5.1 and 2.5.2.

RehaCAT+-Experimental Group: In addition to the structure and features of RehaCAT, RehaCAT+ follows a persuasive design optimized technology (e.g., motivation, ability, and automatic trigger considering test environment) (47,48) to increase the desired probability of action. RehaCAT+ offers additional (1) system features (automated e-mail reminders for patients), (2) clinician features (stored recommendations for action for depression and anxiety based on respective patient results, call to action plans, individualized documentation aids and supporting information material for depression and anxiety), and (3) patient features (individual symptomatic information at discharge and T2/3, possible points of contact/help).

The urgency of the recommendation for action (i.e., need for in-depth psychodiagnostics) varies depending on screening severity. Additionally, material on handling of psychological burden can be accessed. The material is based on: a) the rehabilitation therapy standards and framework concepts (84–87), b) the practice recommendations for orthopedic and cardiological rehabilitation (54,55), c) the recommendations for psychodiagnostics in somatic rehabilitation (53), and e) the national S3 guidelines for depression (56) and anxiety (57). A summary of the two conditions is provided in Figure 3.

----------insert Figure 3 about here----------

The clinics will be compensated with 100€ per recruited patient for the resulting hospital expenses in the context of participant recruitment, data collection, study documentation as well as provision of the discharge reports. Study patients will receive an expense allowance of 20€ each for their participation in the T2 and T3 measurements.

RehaCAT(+) is developed as an open-source platform. It is currently in the certification process according to the medical device regulation. The platform is developed according to the requirements of the German Medical Devices Act and the Medical Device Regulation (MDR). Hence, the software development and validation process is taking the IEC 62304 (safety class B), the GAMP5 (category 4), the General Principles of Software Validation of the FDA as well as the Pharmaceutical Inspection Cooperation Scheme (PIC/S) 11-3 into account. Furthermore, technical requirements and standards for the interoperability between different medical devices (e.g. HL7 FHIR) are under development. The certification process of the platform is planned to be completed in 2022.

Sample size and study power

The sample size calculation is based on the primary outcome, depression severity 12 months after the end of rehabilitation. It is assumed that the experimental group is superior to the control group in the way that patients will show fewer depressive symptoms at twelve-months follow-up. In view of the additive study design testing for incremental benefit of RehaCAT+ over RehaCAT and the distal outcome, a small additional effect of d = .24 compared to the standard condition is regarded as clinically significant following the recommendation of Cuijpers et al. (88). With 2*6 cluster-randomized rehabilitation clinics, each clinic requires a sample of 110 (SD = 25) participating rehabilitants with elevated depression scores to achieve a test power of 80% given an alpha error (two-sided) of .05, an estimated ICC of .02 (89,90), and an assumed correlation with baseline depression scores of .50. With an estimated drop-out rate (rehabilitation start-end) of 20% (91) and the assumption of a doubling drop-out rate by T3, a total sample of N=1,848 rehabilitants is required.

Assessments

Quantitative outcome assessment will be performed at baseline/ beginning of rehabilitation (T0), at discharge/ end of rehabilitation (T1), and at 6 and 12 months (T2, T3). Primary outcome is the depression severity score twelve months after rehabilitation (T3). An overview is provided in Table 1.

Table 1. Assessments

Variable	Instrument	CAT	Time of measurement			
			T0	T1	T2	T3
Depression	PROMIS® Emotional Distress – Depression	✓	✓	✓	✓	✓
Anxiety	PROMIS® Emotional Distress – Anxiety	✓	✓	✓	✓	✓
Satisfaction with Participation in Social Roles and Activities	PROMIS® Satisfaction with Social Roles and Activities	✓	✓	✓	✓	✓
Pain impairment	PROMIS® Pain Interference	✓	✓	✓	✓	✓
Fatigue	PROMIS® Fatigue	✓	✓	✓	✓	✓
Sleep	PROMIS® Sleep Disturbance	✓	✓	✓	✓	✓
Health-related quality of life	PROMIS® Global Health		✓	✓	✓	✓
Self-Efficacy	PROMIS® Self-Efficacy General		✓	✓	✓	✓
Physical Function	PROMIS® Physical Function	✓	✓	✓	✓	✓
Alcohol use	AUDIT-10		✓	✓	✓	✓
Personality	BFI-10		✓			
Generic quality of life	EQ5D-5L		✓		✓	✓

Health and social services use and costs	CSSRI	✓		✓	✓
Medical record data	Provided by clinicians (e.g. discharge reports)		✓		

CAT: Computer-Adaptive Patient Reported Outcome Test; T0: Baseline; T1: Discharge; T2: 6-month follow-up; T3: 12-month follow-up; PROMIS: Patient Reported Outcome Measurement Information System; AUDIT-10: Alcohol Use Disorders Identification Test; BFI-10: 10 item Big Five Inventory; EQ5D-5L: European Quality of Life 5 Dimension - 5 Level Questionnaire; CSSRI: Client Sociodemographic and Service Receipt Inventory.

Primary outcome

Depression severity will be assessed with the computer-adaptive PROMIS Emotional Distress - Depression Item Set including an item bank with 28 items that capture negative mood, decrease in positive emotions, cognitive deficits, as well as negative self-image and negative social cognition (92). All items are rated on a five-point response scale asking respondents to rate the frequency of their symptoms in the past seven days (never, rarely, often, sometimes, always). A Cronbach's Alpha of 0.99 was found for the internal consistency of the item set (93).

Secondary outcomes

Anxiety will be assessed with the computer-adaptive PROMIS Emotional Distress - Anxiety Item Set including 29 items that assess emotional distress caused by hypersensitivity, anxiety, and stress, as well as associated somatic symptoms (92). All items are rated on a five-point response scale asking respondents to rate the frequency of their symptoms in the past seven days (never, rarely, often, sometimes, always). The internal consistency of the item set was found to be good (92).

The computer-adaptive PROMIS Satisfaction with Participation in Social Roles and Activities Item Set comprising 14 items will be used to assess the perceived ability to perform usual social

roles and participate in social activities. All items are phrased in terms of perceived limitations and answered using a five-point response scale. Reliability was estimated to be $\alpha > 0.90$ (94).

Pain impairment will be assessed with the computer-adaptive PROMIS Pain Interference Item Set including 40 items that capture self-assessment of the consequences of pain in one's life. This includes the extent to which pain interferes with engagement in social, cognitive, emotional, physical, as well as leisure activities (95). The items refer to the past seven days and are rated on three different five-point Likert scales. The internal consistency of the item set was found to be good (95).

Fatigue will be assessed with the computer-adaptive PROMIS Fatigue Scale comprising 95 items and measures both fatigue experience and the impact of fatigue on daily life and functionality. The intensity, frequency, and duration of fatigue were graded on a five-point response scale. Reliability was estimated to be $\alpha > 0.90$ (96).

Sleep will be assessed with the computer-adaptive PROMIS Sleep Dimension that measures subjective sleep quality and quantity and sleep-related impairment in daily functioning. The scale comprises 27 items and is rated on a response scale from 1 (not at all or never) to 5 (very much or always). It is a validated instrument and has good psychometric properties with $\alpha > 0.90$ (97,98).

Health-related quality of life will be assessed with the PROMIS scale on global health aspects (Global Health) is used. The scale includes 10 items that capture global physical health (physical health, physical functioning, fatigue, pain), and global mental health (general quality of life, mental health, satisfaction with social activities and relationships, and emotional distress) (99). Nine items are scored on a response scale of 1 to 5, and the item assessing pain is scored from 0 to 10. Internal consistency was estimated to be good with $\alpha > 0.82$ (Katzan & Lapin, 2018).

Self-efficacy will be assessed with the short scale of the PROMIS General Self-Efficacy Scale which contains 4 items. It can be used to assess how much confidence one has in one's own abilities to master tasks and situations. Items are rated on a response scale from 1 (I am not at all confident) to 5 (I am very confident). Internal consistency was estimated to be high (α = 0.96) (100,101).

Physical function will be assessed using the computer-adaptive PROMIS Physical Function Item Set that measures the ability to perform daily life activities that require physical activity such as walking or lifting objects. It comprises 164 items that are assessed on a 5-point scale ranging from 1 (Without any difficulty) to 5 (Unable to do). Internal consistency was found to be very good with $\alpha > 0.88$ (102).

Alcohol use will be assessed with the AUDIT-10 (Alcohol Use Disorders Identification Test) which is a 10-item questionnaire developed by the WHO as a screening tool for hazardous and harmful alcohol use. Responses to each question are scored from 0 to 4, allowing a maximum of 40 points. Reliability has been investigated in some studies and is considered good with a median of $\alpha = 0.80$ (103).

Discharge reports will be analyzed regarding a) frequency of documented screening results, b) therapy standard and guideline appropriate therapeutic services (documented services / therapy standard recommendations as a function of depression and anxiety results), c) therapy standard and guideline appropriate follow-up and post-rehabilitation recommendations (documented recommendations / therapy standard/guideline recommendations as a function of depression and anxiety results).

Moderators

As potential moderators, socio-demographic data (age, gender, nationality) and personality will be recorded at admission (T0). Personality will be assessed with the BFI-10 (Big Five Inventory

– 10), a short version of the Big Five Inventory that has good psychometric properties and a retest-reliability of α = 0.73 (104). Additionally, data from medical records will be used as moderators (e.g. indication area orthopedic or cardiologic, chronic conditions, rehabilitation duration, etc.).

Health economics

Generic quality of life will be assessed with the EQ5D-5L (European Quality of Life 5 Dimension - 5 Level Questionnaire) from the EuroQol foundation (www.euroqol.org) (105). The five dimensions surveyed are mobility, self-care, general activities, pain/physical discomfort, and anxiety/dejection. Each of the five areas is ranked on a five-point scale. Based on the answers, the respective health status is recorded (106).

Health and social services use and costs will be assessed with the CSSRI (Client Sociodemographic and Service Receipt Inventory) which is a standardized but adaptable inventory. Five domains are queried, including sociodemographic information, usual living situation, income and employment status, use of mental health services, and medication treatment (107).

Usage behavior, acceptance, facilitating and hindering factors

Questions about usage behavior, potential risks of the platforms, as well as barriers and facilitators to implementation, will be elicited based on qualitative semi-structured interviews conducted with both patients and clinic staff centrally involved in the implementation of RehaCAT and RehaCAT+. The semi-structured interviews will be conducted with the help of an interview guide based on existing instruments of previous studies (53,108).

Smart sensing sub-study

Smart sensing data will be collected actively and passively via the mobile application AWARE for smartphones. The AWARE Framework is an open-source framework that allows to passively collect digital behavioural data via an app as well as to send ecological momentary assessments (e.g., short questions: "how are you feeling right now?") to the app user for answering (109). The AWARE framework has been tested in previous studies (64,68,109,110) without technical, privacy or ethical issues. All collected data will be stored pseudonymized and personal data (e.g., contact numbers) will be anonymized using a cryptographic hash function (SHA-256) (109).

After completing the diagnostic measures at T0, T1 and T2, all patients will be informed in the RehaCAT(+) system about the optional mobile sensing sub-study. If interested, they can provide an e-mail address to receive further information on the study and a study invitation. This is independent from study participation in the cRCT. Therefore, both routine care patients and patients partaking in the cRCT will be able to participate. Participants who provide their informed consent will be instructed to install the research application on their personal smartphones. After installation participants will be able to choose which data points will be collected over the next six months.

Active Assessment

Gender, age, and personality with the BFI-10 (The Big Five Inventory – 10) will be assessed (104) once after installing the application.

Furthermore, acceptance of and satisfaction with smart sensing will be measured using the UTAUT (Unified Theory of Acceptance and Use of Technology) questionnaire (111,112), satisfaction with the research application will be measured with the User Version of the Mobile

Application Rating Scale (uMARS) (113). Both questionnaires will be assessed once after 6 months before deinstalling the application.

The following clinical questionnaires will be assessed every two weeks: Depression (dimensional and categorical) with the PHQ-8 (if PHQ-2 score > 2) (114–116); anxiety with the GAD-7 (117); stress with the PSS-10 (118); sleep with the ISI-7 (119); loneliness with the UCLA 3 item version (120).

Every morning, participants will be asked short questions about mood (valence), drive (arousal), control, unpredictability, stress and sleep, at midday about mood (valence), drive (arousal), control, unpredictability, and stress, and in the evening, participants are again asked about mood (valence), drive (arousal), control, unpredictability, stress, and activity during the day. This assessment is based on previous studies (65,68,121,122).

Passive outcomes

The research app allows to track a broad range of sensors (accelerometer, application usage, barometer, battery, Bluetooth, communication, gravity, gyroscope, light, locations, magnetometer, network, proximity, rotation, screen sensor). However, each user will be able to freely decide which sensors are activated and access permissions can always be activated and deactivated without giving reasons. In addition, sensible location data (e.g., GPS coordinates) will be obscured, so pseudonymization can be upheld all the time.

The following digital markers can be collected (depending on permissions of user): frequency and duration of smartphone and individual app usage, frequency and duration/length of calls and text messages, randomly distorted GPS, and type of movement.

Data management and data sharing plan

Data collection will be completed online using the server-based system RehaCAT(+) and the research application in pseudonymized form. Retrieved data will be stored encrypted by responsible employees. All data will be anonymized after completion of the trial. Furthermore, an independent Data Safety and Monitoring Board (DSMB) with long-standing experience in clinical trials has been established. The function of the DSMB is to monitor the course of the study and, if necessary, give recommendations to the steering committee for discontinuation, modification or continuation of the study.

Individual participant data will be made available on request after de-identification beginning 12 months following article publication of the effectiveness paper. Data will be made available to researchers who provide a methodologically sound proposal, not already covered by others. Proposals should be directed to HB. Data requestors will need to sign a data access agreement. Provision of data is subject to data security regulations. Investigator support depends on available resources.

Measures to reduce methodological sources of error

Selection bias: Randomization and allocation regarding the group allocation (RehaCAT/ RehaCAT+) of the participating rehabilitation clinics will be done by an independent researcher. Performance bias: Rehabilitation staff centrally involved in the implementation will be trained along training materials, as well as continuously supervised regarding the training materials. RehaCAT(+) and its application will be described in detail in a test manual. Deviations from the test manual will be recorded and formatively reduced during the implementation process of RehaCAT(+) in the individual clinics. Contamination bias: Cluster randomization is used to avoid study arm contamination. Detection bias: rating procedures (analysis of discharge reports) are performed by independent raters who are obscured to the study arm affiliation of the clinics and thus the patients. Patients also remain obscured to their study arm assignment, as the differentiation between RehaCAT and RehaCAT(+) is not obvious

to them. Obscuring will not be realized for clinic personnel only. Reporting bias: A detailed definition of all methodological aspects of the present clinical study is provided in this study protocol, submitted for publication prior to randomization start. Evaluating representativeness: To assess the representativeness of the results, quantitative and qualitative analyses will be performed regarding the reasons that may lead to a non-existent 100% exhaustion in the routine assessment.

Statistical analyses

Clinical analyses

Study data will be centrally processed and analyzed by an independent researcher. Missing values and missingness patterns will be explored and analysis will be adjusted accordingly using multiple imputation strategies (based on heteroscedastic two-level linear models considering the metric of outcome). The analysis will follow the intention-to-treat principle. In addition, per-protocol analyses will be conducted. The primary outcome as well as all other continuous outcomes will be analyzed based on Hierarchical Linear Models (HLM) considering cluster structure and baseline values. Binary outcomes will be analyzed using Mixed Logistic Regression Models. Moderator and mediator analyses will be performed to determine differential effects with respect to key sociodemographic and medical variables.

The effect of study participation will also be measured (participation rate at T1-3) in order to be able to make statements about the transferability of the results from the present randomized study to routine care without research support.

Health economic evaluation

In the health economic evaluation, an incremental cost-utility analysis (ICUA) will be performed from the societal perspective, as well as from the perspective of the German statutory pension insurance (SPI) according to the net benefit approach (78,123). The necessary

maximum willingness to pay (MWTP) for a clinical improvement of depressive symptoms by 50% (= response) and for the gain of a quality-adjusted life year (QALY) will be determined. The estimation of the stochastic uncertainty will be done by means of nonparametric bootstrapping, the interpretation of the results is based on cost-effectiveness acceptance curves (124). These provide information on how high the MWTP must be to be judged cost-effective with a probability of 95%, or with what probability a pre-determined MWTP is judged to be cost-effective (123). Following international guidelines, a value range of the MWTP between 0 and 1250,000 € is chosen (125,126). The analysis of the health economic relevance of moderator and mediator variables will be performed by means of net benefit regression models for net benefit ratios between 0 and 1250,000€ (127–130). The analysis from the macroeconomic perspective will consider all direct and indirect disease costs (131), the analysis from the perspective of the SPI will take the disease costs to be borne by the SPI (e.g. for medical rehabilitation services) as well as the costs for the testing platform to be borne by the SPI into account.

Qualitative data analysis

Qualitative interviews of patients and clinic staff will be conducted and analyzed. The analysis of qualitative data will be based on qualitative content analysis. An inductive-deductive approach will be applied along the theory-based interview guide. Reliability of results will be established (indicated by intercoder agreement) with two independent raters coding all transcripts on the basis of coding guide and rules. This coding guide will be developed in an iterative process with consensus finding.

Smart sensing

Identification of prognostic factors

Correlation analysis and multilevel regression models will be used to identify bivariate relationships between PROMs, digital markers, disease-free survival, and postoperative complications. The presence of missing values and missingness patterns will be investigated and analysis will be adjusted accordingly (e.g., multiple imputation) (132).

Prediction modelling

Significance test-based methods as well as machine learning models will be used. In case of nested data structure (e.g., development of quality of life over time with repeated measures) multilevel regression models will also be used for prediction (133–135). For continuous outcomes (e.g., depression severity) linear models will be used, while logistic models will be applied for dichotomous outcomes (e.g., depression state yes or no).

In addition to these significance test-based methods, machine learning models will be used. Machine learning is an iterative process and several modeling approaches will be tested (e.g., K-Nearest Neighbor algorithm (136) or gradient-boosted trees (137,138)). However, since the field is rapidly developing, we cannot a-priori define the exact approaches that will be used. Hyperparameter optimization will be conducted using grid-search.

Patient and public involvement

Patient and public involvement (PPI) representatives have provided input to the present study in several stages. Results of previous projects including patient feedback, were used to further develop and optimize study design and procedures. PPI representatives (e.g. as members of an advisory board) are included to improve usability, design and comprehensibility but have no influence on the outcomes, data analysis methods or study design.

Ethics and dissemination

Ethical approval has been obtained from Ulm University on 24 February 2021 (ref. 509/20). The study is conducted according to the Declaration of Helsinki. Informed consent will be obtained from all participants.

Results will be published in peer-reviewed journals. They will also be made known through local conferences and research seminars, national and international scientific congresses, and through direct and indirect contacts with clinicians, public health managers and other healthcare professionals.

Contributors

HB is principle investigator of RehaCAT+. HB, RK, MM obtained funding for this study. HB, JK, YT, PP, SK, MM, MB, RK, TW contributed to the study design. HB, SE, JK, YT, PP, SK developed the platform RehaCAT(+). MM and RK contributed to the design of the effectiveness and health-economic evaluation. JK drafted the manuscript. All authors contributed to the article and approved the submitted version.

Funding

This work was supported by the Federal Ministry of Education and Research (BMBF, 01GX1901). BMBF had no role in study design, decision to publish or preparation of this manuscript. BMBF will not be involved in data collection, analyses, decision to publish or preparation of future papers regarding this study.

Competing interests

Authors of the manuscript were partly involved in the development of RehaCAT(+). HB has been the beneficiary of study support (third party funding) from several public funding organizations in the context of research on Computer-adaptive Testing and Patient Reported Outcome Systems.

Acknowledgments

Authors would like to thank the project members Carolin von Gottberg, Minh Duc Duong, Erce Rodopman, Tobias Sterns, Aydin Spieler, Rebecca Knoll and Robin Kraft for their technical support and development of RehaCAT.

References

1. Baumeister H, Lin J, Ebert DD. Internet- and mobile-based approaches: Psycho-social diagnostics and treatment in medical rehabilitation. Bundesgesundheitsblatt - Gesundheitsforsch - Gesundheitsschutz. 2017;60(4):436–44.

2. Haywood KL. Patient-reported outcome I: Measuring what matters in musculoskeletal care. Musculoskeletal Care [Internet]. 2006;4(4):187–203. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/msc.94

3. Kelkar AA, Spertus J, Pang P, Pierson RF, Cody RJ, Pina IL, et al. Utility of Patient-Reported Outcome Instruments in Heart Failure. JACC Hear Fail. 2016;4(3):165–75.

4. Algurén B, Coenen M, Malm D, Fridlund B, Mårtensson J, Årestedt K. A scoping review and mapping exercise comparing the content of patient-reported outcome measures (PROMs) across heart disease-specific scales. J Patient-Reported Outcomes. 2020;4(1).

5. Calvert M, Kyte D, Price G, Valderas JM, Hjollund NH. Maximising the impact of

patient reported outcome assessment for patients and society. BMJ [Internet]. 2019;364. Available from: https://www.bmj.com/content/364/bmj.k5267

6. Klag MJ, MacKenzie EJ, Carswell CI, Bridges JFP. The Role of The Patient in Promoting Patient-Centered Outcomes Research. Patient Patient-Centered Outcomes Res [Internet]. 2008 Jan;1(1):1–3. Available from: http://link.springer.com/10.2165/01312067-200801010-00001

7. Nelson EC, Eftimovska E, Lind C, Hager A, Wasson JH, Lindblad S. Patient reported outcome measures in practice. BMJ [Internet]. 2015 Feb 10;g7818. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.g7818

8. Field J, Holmes MM, Newell D. PROMs data: can it be used to make decisions for individual patients? A narrative review . Patient Relat Outcome Meas. 2019;Volume 10:233–41.

9. Gibbons RD, Weiss DJ, Kupfer DJ, Frank E, Fagiolini A, Grochocinski VJ, et al. Using computerized adaptive testing to reduce the burden of mental health assessment. Psychiatr Serv. 2008;59(4):361–8.

10. Gamper EM, Martini C, Petersen MA, Virgolini I, Holzner B, Giesinger JM. Do patients consider computer-adaptive measures more appropriate than static questionnaires? J Patient-Reported Outcomes. 2019;3(1).

11. Forkmann T, Boecker M, Wirtz M, Glaesmer H, Brähler E, Norra C, et al. Validation of the Rasch-based depression screening in a large scale German general population sample. Health Qual Life Outcomes. 2010;8:105–12.

12. Abberger B, Haschke A, Tully PJ, Forkmann T, Berger J, Wirtz M, et al. Development and validation of parallel short forms PaSA-cardio for the assessment of general

anxiety in cardiovascular rehabilitation patients using Rasch analysis. Clin Rehabil. 2017;31(1):104–14.

13. Sharpe JP, Gilbert DG, Patrick J, Gilbert DG. Effects of repeated administration of the Beck Depression Inventory and other measures of negative mood states. Pers Individ Dif [Internet]. 1998;24(4):457–63. Available from: file:///S:/Projekte/CAT/Literatur/Citavi 5/Projects/Literatur CAT Projekte/Citavi Attachments/Sharpe 1998 - Effects Repeated Administration Beck Depression and Other.pdf

14. Sehlen S, Ott M, Marten-Mittag B, Haimerl W, Dinkel A, Duehmke E, et al. Machbarkeit und Akzeptanz Computer-gestützter Indikationsdiagnostik (CgID) zur Identifizierung psychosozial belasteter Patienten im klinischen Alltag. PPmP - Psychother · Psychosom · Medizinische Psychol. 2012 Jul;62(07):276–83.

15. Wahl I, Löwe B, Bjorner JB, Fischer F, Langs G, Voderholzer U, et al. Standardization of depression measurement: a common metric was developed for 11 self-report depression measures. J Clin Epidemiol [Internet]. 2014 Jan 1 [cited 2020 Jan 9];67(1):73–86. Available from: https://www.sciencedirect.com/science/article/pii/S0895435613003168?via%3Dihub

16. Embretson, S., & Yang X. Item Response Theory. In: J L Green, G Camilli, & P B Elmore (Eds), Handbook of complementary methods in education research. Lawrence Erlbaum Associates Publishers; 2006. p. 385–409.

17. Rose M, Wahl I, Löwe B. Computer Adaptive Tests in der Medizin. PPmP - Psychother · Psychosom · Medizinische Psychol [Internet]. 2013 Jan 22;63(01):48–54. Available from: http://www.thieme-connect.de/DOI/DOI?10.1055/s-0032-1329976

18. Abberger B, Haschke A, Wirtz M, Kroehne U, Bengel J, Baumeister H. Development and Evaluation of a Computer Adaptive Test to Assess Anxiety in Cardiovascular Rehabilitation Patients. Arch Phys Med Rehabil. 2013 Dec;94(12):2433–9.

19. Forkmann T, Kroehne U, Wirtz M, Norra C, Baumeister H, Gauggel S, et al. Adaptive screening for depression — Recalibration of an item bank for the assessment of depression in persons with mental and somatic diseases and evaluation in a simulated computer-adaptive test environment. J Psychosom Res. 2013;75(5):437–43.

20. Fischer HF, Klug C, Roeper K, Blozik E, Edelmann F, Eisele M, et al. Screening for mental disorders in heart failure patients using computer-adaptive tests. Qual Life Res. 2014;23(5):1609–18.

21. Papuga MO, Dasilva C, McIntyre A, Mitten D, Kates S, Baumhauer JF. Large-scale clinical implementation of PROMIS computer adaptive testing with direct incorporation into the electronic medical record. Heal Syst. 2018 Jan;7(1):1–12.

22. Ling G, Attali Y, Finn B, Stone EA. Is a Computerized Adaptive Test More Motivating Than a Fixed-Item Test? Appl Psychol Meas. 2017;41(7):495–511.

23. Cella D, Gershon R, Lai JS, Choi S. The future of outcomes measurement: Item banking, tailored short-forms, and computerized adaptive assessment. Qual Life Res. 2007;16(SUPPL. 1):133–41.

24. Gorin JS, Dodd BG, Fitzpatrick SJ, Shieh YY. Computerized adaptive testing with the partial credit model. Appl Psychol Meas. 2005;29(6):433–56.

25. Forkmann T, Böcker M, Norra C, Eberle N, Kircher T, Schauerte P, et al. Development of an item bank for the assessment of depression in persons with mental illnesses and physical diseases using Rasch analysis. Rehabil Psychol. 2009;54(2):186–97.

26. Linacre JM. Computer-Adaptive Testing : A Methodology Whose Time Has Come . By J ohn Michael Linacr e , Ph . D . MESA Psychometr ic Labor ator y Univer sity of Chicago. Test [Internet]. 2000;(69):27. Available from: https://www.cehd.umn.edu/EdPsych/C-Bas-R/Docs/Linacre2000_CAT.pdf.

27. Bjorner JB, Chang CH, Thissen D, Reeve BB. Developing tailored instruments: Item banking and computerized adaptive assessment. Qual Life Res. 2007;16(SUPPL. 1):95–108.

28. Vodicka E, Kim K, Devine EB, Gnanasakthy A, Scoggins JF, Patrick DL. Inclusion of patient-reported outcome measures in registered clinical trials: Evidence from ClinicalTrials.gov (2007-2013). Contemp Clin Trials [Internet]. 2015;43:1–9. Available from: http://dx.doi.org/10.1016/j.cct.2015.04.004

29. Rivera SC, Kyte DG, Aiyegbusi OL, Slade AL, McMullan C, Calvert MJ. The impact of patient-reported outcome (PRO) data from clinical trials: A systematic review and critical analysis. Health Qual Life Outcomes. 2019;17(1):1–19.

30. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. BMJ [Internet]. 2010;340. Available from: https://www.bmj.com/content/340/bmj.c186

31. Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, et al. Patient-reported outcomes in routine cancer clinical practice: A scoping review of use, impact on health outcomes, and implementation factors. Vol. 26, Annals of Oncology. Oxford University Press; 2015. p. 1846–58.

32. Turner GM, Litchfield I, Finnikin S, Aiyegbusi OL, Calvert M. General practitioners' views on use of patient reported outcome measures in primary care: A cross-sectional

survey and qualitative study. BMC Fam Pract. 2020;21(1):1–10.

33. Porter I, Gonçalves-Bradley D, Ricci-Cabello I, Gibbons C, Gangannagaripalli J, Fitzpatrick R, et al. Framework and guidance for implementing patient-reported outcomes in clinical practice: Evidence, challenges and opportunities. J Comp Eff Res. 2016;5(5):507–19.

34. Gilbody SM. Routinely administered questionnaires for depression and anxiety: systematic review. BMJ [Internet]. 2001 Feb 17;322(7283):406–9. Available from: https://www.bmj.com/lookup/doi/10.1136/bmj.322.7283.406

35. Härter, Katrin Reuter, Katrin Gross M. Screening for anxiety, depressive and somatoform disorders in rehabilitation󒀔validity of HADS and GHQ-12 in patients with musculoskeletal disease. Disabil Rehabil. 2001 Jan;23(16):737–44.

36. Härter M, Woll S, Reuter K, Wunsch A, Bengel J. Recognition of psychiatric disorders in musculoskeletal and cardiovascular rehabilitation patients. Arch Phys Med Rehabil [Internet]. 2004 Jul;85(7):1192–7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0003999303011808

37. Härter M, Reuter K, Weisser B, Schretzmann B, Aschenbrenner A, Bengel J. A descriptive study of psychiatric disorders and psychosocial burden in rehabilitation patients with musculoskeletal diseases. Arch Phys Med Rehabil. 2002 Apr;83(4):461–8.

38. Tirosh O, Tran P, Renouf J, Pergaminelis N, Purdie CN, Ho A, et al. PROMsBase: Web-based repository portal for patient-reported outcome measures in orthopaedics. Health Informatics J. 2019;25(3):867–77.

39. Santana MJ, Feeny D. Framework to assess the effects of using patient-reported

outcome measures in chronic care management. Qual Life Res. 2014;23(5):1505–13.

40. Munoz RF, Cuijpers P, Smit F, Barrera AZ, Leykin Y. Prevention of major depression. Annu Rev Clin Psychol. 2010;6(1):181–212.

41. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. JAMA [Internet]. 2017 Jul 11;318(2):197. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2017.7156

42. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. J Clin Oncol [Internet]. 2016 Feb 20;34(6):557–65. Available from: https://ascopubs.org/doi/10.1200/JCO.2015.63.0830

43. Siu AL, Bibbins-Domingo K, Grossman DC, Baumann LC, Davidson KW, Ebell M, et al. Screening for Depression in Adults. JAMA [Internet]. 2016 Jan 26;315(4):380. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2015.18392

44. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer settings: 10 lessons from 40 years of primary-care research. Psychooncology [Internet]. 2011 Jun;20(6):572–84. Available from: http://doi.wiley.com/10.1002/pon.1943

45. Haverman L, Van Oers HA, Van Muilekom MM, Grootenhuis MA. Options for the Interpretation of and Recommendations for Acting on Different PROMs in Daily Clinical Practice Using KLIK. Med Care. 2019;57(5):S52–8.

46. Farin E, Glattacker M, Jäckel WH. Leitlinien und Leitlinienforschung. Bundesgesundheitsblatt - Gesundheitsforsch - Gesundheitsschutz [Internet]. 2011 Apr 1;54(4):429–35. Available from: http://link.springer.com/10.1007/s00103-011-1238-9

47. Marcus A. Mobile Persuasion Design: Changing Behaviour by Combining Persuasion Design with Information Design. Human–Computer Interaction. London: Springer-Verlag; 2015.

48. Fogg B. A behavior model for persuasive design. Proc 4th Int Conf Persuas Technol - Persuas '09 [Internet]. 2009;1. Available from: http://portal.acm.org/citation.cfm?doid=1541948.1541999

49. Baumeister H, Kraft R, Baumel A, Pryss R, Messner E-M. Persuasive e-health design for behavior change. In: Baumeister H, Montag C, editors. Mobile sensing and digital phenotyping: new developments in psychoinformatics. Berlin: Springer; 2019.

50. Fogg B. Persuasive Computers: Perspectives and Research Directions. Proc SIGCHI Conf Hum Factors Comput Syst - CHI '98. 1998;(April):225–32.

51. Imison C, Castle-Clarke S, Watson R, & Edwards N. Delivering the benefits of digital health care. London; 2016.

52. Sucher JF, Moore FA, Todd SR, Sailors RM, McKinley BA. Computerized Clinical Decision Support: A Technology to Implement and Validate Evidence Based Guidelines. J Trauma Inj Infect Crit Care [Internet]. 2008 Feb;64(2):520–37. Available from: https://journals.lww.com/00005373-200802000-00049

53. Baumeister H, Jahed J, Vogel B, Härter M, Barth J, Bengel J. Diagnostik, Indikation und Behandlung von psychischen Störungen in der medizinischen Rehabilitation (DIBpS): Ein Leitfaden zur Implementierung eines psychodiagnostischen Stufenplans

in der medizinischen Rehabilitation. Berlin: DRV M4 - Citavi; 2011.

54. Reese C, Mittag O. Psychologische Interventionen. Praxisempfehlungen für psychologische Interventionen in der Rehabilitation: Chronische Rückenschmerzen und Koronare Herzerkrankung. Berlin: Deutsche Rentenversicherung M4 - Citavi; 2013.

55. Reese C, Spieser A, Mittag O. Psychologische Interventionen in der Rehabilitation von Patienten mit koronarer Herzerkrankung: Zusammenfassung der Evidenz und der Empfehlungen aus systematischen Übersichtsarbeiten und Leitlinien. Rehabil. 06.06.2012. 2012;51(06):405–14.

56. DGPPN, BÄK, KBV, AWMF, AkdÄ, BPtK DAGSHG, DEGAM, DGPM, DGPS, DGRW Ba. S3-Leitlinie/Nationale VersorgungsLeitlinie Unipolare Depression. Langfassung. 2015.

57. Bandelow B, Wiltinkt J, Alpers GW, Benecke C, Deckert J, Eckhardt-Henn A, et al. Deutsche S3-Leitlinie Behandlung von Angststörungen. 2014;

58. Ben-Zeev D, Young MA. Accuracy of hospitalized depressed patients' and healthy controls' retrospective symptom reports: an experience sampling study. J Nerv Ment Dis. 2010 Apr;198(4):280–5.

59. Gorzelitz J, Peppard PE, Malecki K, Gennuso K, Nieto FJ, Cadmus-Bertram L. Predictors of discordance in self-report versus device-measured physical activity measurement. Ann Epidemiol. 2018 Jul;28(7):427–31.

60. Paulhus DL. Socially Desirable Responding on Self-Reports. In: Encyclopedia of Personality and Individual Differences. Springer International Publishing; 2017. p. 1–5.

61. Stone AA, Shiffman S. Capturing momentary, self-report data: A proposal for

reporting guidelines. Ann Behav Med. 2002 Aug;24(3):236–43.

62. Baumeister H, Montag C. Digital Phenotyping and Mobile Sensing [Internet]. Baumeister H, Montag C, editors. Cham: Springer International Publishing; 2019. 291 p. (Studies in Neuroscience, Psychology and Behavioral Economics). Available from: http://link.springer.com/10.1007/978-3-030-31620-4

63. Onnela J-P, Rauch SL. Harnessing Smartphone-Based Digital Phenotyping to Enhance Behavioral and Mental Health. Neuropsychopharmacology [Internet]. 2016 Jun 28;41(7):1691–6. Available from: http://dx.doi.org/10.1038/npp.2016.7

64. Low CA, Dey AK, Ferreira D, Kamarck T, Sun W, Bae S, et al. Estimation of Symptom Severity During Chemotherapy From Passively Sensed Data: Exploratory Study. J Med Internet Res [Internet]. 2017 Dec 19;19(12):e420. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29258977

65. Messner E-M, Sariyska R, Mayer B, Montag C, Kannen C, Schwerdtfeger A, et al. Insights: Future implications of passive smartphone sensing in the therapeutic context. Verhaltenstherapie [Internet]. 2019;1–11. Available from: https://www.karger.com/Article/FullText/501735

66. Mohr DC, Zhang M, Schueller SM. Personal Sensing: Understanding Mental Health Using Ubiquitous Sensors and Machine Learning. Annu Rev Clin Psychol [Internet]. 2017 May 8;13(1):23–47. Available from: http://www.annualreviews.org/doi/10.1146/annurev-clinpsy-032816-044949

67. Montag C, Baumeister H, Kannen C, Sariyska R, Meßner E-M, Brand M. Concept, Possibilities and Pilot-Testing of a New Smartphone Application for the Social and Life Sciences to Study Human Behavior Including Validation Data from Personality

Psychology. J [Internet]. 2019 Mar 27;2(2):102–15. Available from: https://www.mdpi.com/2571-8800/2/2/8

68. Moshe I, Terhorst Y, Opoku Asare K, Sander LB, Ferreira D, Baumeister H, et al. Predicting Symptoms of Depression and Anxiety Using Smartphone and Wearable Data. Front Psychiatry. 2021 Jan;12:625247.

69. Rohani DA, Faurholt-Jepsen M, Kessing LV, Bardram JE. Correlations Between Objective Behavioral Features Collected From Mobile and Wearable Devices and Depressive Mood Symptoms in Patients With Affective Disorders: Systematic Review. JMIR mHealth uHealth [Internet]. 2018 Aug 13;6(8):e165. Available from: http://mhealth.jmir.org/2018/8/e165/

70. Umbricht D, Cheng W-Y, Lipsmeier F, Bamdadian A, Lindemann M. Deep Learning-Based Human Activity Recognition for Continuous Activity and Gesture Monitoring for Schizophrenia Patients With Negative Symptoms. Front Psychiatry. 2020 Sep;11:574375.

71. Alyass A, Turcotte M, Meyre D. From big data analysis to personalized medicine for all: challenges and opportunities. BMC Med Genomics. 2015 Dec;8(1):33.

72. Hamburg MA, Collins FS. The Path to Personalized Medicine. N Engl J Med [Internet]. 2010 Jul 22 [cited 2019 May 15];363(4):301–4. Available from: http://www.nejm.org/doi/abs/10.1056/NEJMp1006304

73. Obermeyer Z, Emanuel EJ. Predicting the Future — Big Data, Machine Learning, and Clinical Medicine. N Engl J Med. 2016;375(13):1216.

74. Wang F, Casalino LP, Khullar D. Deep Learning in Medicine—Promise, Progress, and Challenges. JAMA Intern Med. 2019 Mar;179(3):293.

75. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ (Clinical Res ed. 2012;345:e5661.

76. Zwarenstein M, Treweek S, Gagnier J, D.G. A, Tunis S, Haynes B, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390.

77. Montgomery P, Grant S, Mayo-Wilson E, Macdonald G, Michie S, Hopewell S, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension. Trials [Internet]. 2018 Dec 31;19(1):407. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2733-1

78. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. Value Heal J Int Soc Pharmacoeconomics Outcomes Res. 2013;16(2):e1-5.

79. Ramsey SD, Willke RJ, Glick H, Reed SD, Augustovski F, Jonsson B, et al. Cost-Effectiveness Analysis Alongside Clinical Trials II—An ISPOR Good Research Practices Task Force Report. Value Heal [Internet]. 2015 Mar;18(2):161–72. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1098301515000169

80. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Ann Intern Med [Internet]. 2013 Feb 5;158(3):200. Available from: http://annals.org/article.aspx?doi=10.7326/0003-4819-158-3-201302050-00583

81. Rauch A, Cieza A, Stucki G. How to apply the International Classification of Functioning, Disability and Health (ICF) for rehabilitation management in clinical practice. Eur J Phys Rehabil Med [Internet]. 2008 Sep;44(3):329–42. Available from:

http://www.ncbi.nlm.nih.gov/pubmed/18762742

82. Word Health Organization. Internationale Klassifikation der Funktonsfähigkeit, Behinderung und Gesundheit (ICF). Handb der Neuro-und Biopsychologie. 2005;615–25.

83. van Muilekom MM, Luijten MAJ, van Oers HA, Terwee CB, van Litsenburg RRL, Roorda LD, et al. From statistics to clinics: the visual feedback of PROMIS® CATs. J Patient-Reported Outcomes [Internet]. 2021 Dec 10;5(1):55. Available from: https://jpro.springeropen.com/articles/10.1186/s41687-021-00324-y

84. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Depressive Störungen - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

85. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Chronischer Rückenschmerz - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

86. Deutsche Rentenversicherung Bund. Reha-Therapiestandards Koronare Herzkrankheit - für die medizinische Rehabilitation der Rentenversicherung. Geschäftsbereich Sozialmedizin und Rehabil. 2016;

87. Deutsche Rentenversicherung Bund. Rahmenkonzept zur Nachsorge - für medizinische Rehabilitation nach §15 SGB VI. Geschäftsbereich Sozialmedizin und Rehabil. 2015;

88. Cuijpers P, Turner EH, Koole SL, van Dijke A, Smit F. What is the threshold for a clinically relevant effect? The case of major depressive disorders. Depress Anxiety. 2014 May;31(5):374–8.

89. Bell ML, McKenzie JE. Designing psycho-oncology randomised trials and cluster randomised trials: variance components and intra-cluster correlation of commonly used psychosocial measures. Psychooncology. 2013 Aug;22(8):1738–47.

90. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ. Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol. 2004 Aug;57(8):785–94.

91. Baumeister H, Kallinger S, Scharm H, Böcker M, Forkmann T, Wirtz M, et al. Sachbericht zum Zwischenverwendungsnachweis 2017 - Implementierung einer Computer-adaptiven Erst- und Verlaufsdiagnostik zur Erfassung der funktionalen Gesundheit in der orthopädischen und kardiologischen Rehabilitation (DRV-Bund gefördert). 2018.

92. Pilkonis PA, Choi SW, Reise SP, Stover AM, Riley WT, Cella D. Item banks for measuring emotional distress from the patient-reported outcomes measurement information system (PROMIS®): Depression, anxiety, and anger. Assessment. 2011 Sep;18(3):263–83.

93. Nolte S, Coon C, Hudgens S, Verdam MGE. Psychometric evaluation of the PROMIS® Depression Item Bank: an illustration of classical test theory methods. J Patient-Reported Outcomes. 2019 Dec;3(1):46.

94. Terwee CB, Crins MHP, Boers M, de Vet HCW, Roorda LD. Validation of two PROMIS item banks for measuring social participation in the Dutch general population. Qual Life Res. 2019 Jan;28(1):211–20.

95. Crins MHP, Terwee CB, Ogreden O, Schuller W, Dekker P, Flens G, et al. Differential item functioning of the PROMIS physical function, pain interference, and pain

behavior item banks across patients with different musculoskeletal disorders and persons from the general population. Qual Life Res. 2019 May;28(5):1231–43.

96. Cella D, Lai JS, Jensen SE, Christodoulou C, Junghaenel DU, Reeve BB, et al. PROMIS Fatigue Item Bank had Clinical Validity across Diverse Chronic Conditions. J Clin Epidemiol. 2016 May;73:128–34.

97. van Kooten JAMC, Terwee CB, Luijten MAJ, Steur LMH, Pillen S, Wolters NGJ, et al. Psychometric properties of the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance and Sleep-Related Impairment item banks in adolescents. J Sleep Res. 2020;(February):1–12.

98. Wesselius HM, Van Den Ende ES, Alsma J, Ter Maaten JC, Schuit SCE, Stassen PM, et al. Quality and quantity of sleep and factors associated with sleep disturbance in hospitalized patients. JAMA Intern Med. 2018 Sep;178(9):1165–71.

99. Katzan IL, Lapin B. PROMIS GH (Patient-reported outcomes measurement information system global health) scale in stroke a validation study. Stroke [Internet]. 2018 Jan;49(1):147–54. Available from: https://www.ahajournals.org/doi/10.1161/STROKEAHA.117.018766

100. Gruber-Baldini AL, Velozo C, Romero S, Shulman LM. Validation of the PROMIS® measures of self-efficacy for managing chronic conditions. Qual Life Res. 2017 Jul;26(7):1915–24.

101. Salsman JM, Schalet BD, Merluzzi T V, Park CL, Hahn EA, Snyder MA, et al. Calibration and initial validation of a general self-efficacy item bank and short form for the NIH PROMIS®. Qual Life Res [Internet]. 2019 Sep;28(9):2513–23. Available from: https://pubmed.ncbi.nlm.nih.gov/31140041/

102. Liegl G, Rose M, Correia H, Fischer HF, Kanlidere S, Mierke A, et al. An initial psychometric evaluation of the German PROMIS v1.2 Physical Function item bank in patients with a wide range of health conditions. Clin Rehabil [Internet]. 2018 Jan 11;32(1):84–93. Available from: http://journals.sagepub.com/doi/10.1177/0269215517714297

103. Reinert DF, Allen JP. The Alcohol Use Disorders Identification Test (AUDIT): A Review of Recent Research. Alcohol Clin Exp Res [Internet]. 2002 Feb [cited 2020 Nov 5];26(2):272–9. Available from: http://doi.wiley.com/10.1111/j.1530-0277.2002.tb02534.x

104. Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short version of the Big Five Inventory in English and German. J Res Pers [Internet]. 2007;41:203–12. Available from: www.elsevier.com/locate/jrp

105. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011 Dec;20(10):1727–36.

106. Ludwig K, Graf von der Schulenburg JM, Greiner W. German Value Set for the EQ-5D-5L. Pharmacoeconomics [Internet]. 2018 Jun;36(6):663–74. Available from: https://doi.org/10.1007/s40273-018-0615-8

107. Chisholm D, Knapp MRJ, Knudsen HC, Amaddeo F, Gaite L, van Wijngaarden B, et al. Client Socio-Demographic and Service Receipt Inventory – European Version: development of an instrument for international research. Br J Psychiatry [Internet]. 2000 Jul;177(S39):s28--s33. Available from: https://www.cambridge.org/core/product/identifier/S0007125000227736/type/journal_article

108. Baumeister H, Bengel J, Forkmann T, Böcker M, Wirtz M, (2015-2018). Implementierung einer Computer-adaptiven Erst- und Verlaufsdiagnostik zur Erfassung der funktionalen Gesundheit in der orthopädischen und kardiologischen Rehabilitation. Drittmittelprojekt, DRV-Bund. 2015;

109. Ferreira D, Kostakos V, Dey AK. AWARE: Mobile Context Instrumentation Framework. Front ICT [Internet]. 2015 Apr 20;2(APR):1–9. Available from: http://journal.frontiersin.org/article/10.3389/fict.2015.00006/abstract

110. Bae S, Chung T, Ferreira D, Dey AK, Suffoletto B. Mobile phone sensors and supervised machine learning to identify alcohol use events in young adults: Implications for just-in-time adaptive interventions. Addict Behav [Internet]. 2018 Aug;83:42–7. Available from: https://linkinghub.elsevier.com/retrieve/pii/S030646031730446X

111. Philippi P, Baumeister H, Apolinário-Hagen J, Ebert DD, Hennemann S, Kott L, et al. Acceptance towards digital health interventions – Model validation and further development of the Unified Theory of Acceptance and Use of Technology. Internet Interv [Internet]. 2021 Dec;26:100459. Available from: https://linkinghub.elsevier.com/retrieve/pii/S2214782921000993

112. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Q [Internet]. 2003;27(3):425–78. Available from: http://www.jstor.org/stable/30036540

113. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS). JMIR mHealth uHealth [Internet]. 2016 Jun 10;4(2):e72. Available from: http://mhealth.jmir.org/2016/2/e72/

114. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord. 2009;114(1–3):163–73.

115. Löwe B, Spitzer RL, Zipfel S, Herzog W. Komplettversion und Kurzform Autorisierte deutsche Version des. Nervenarzt. 2002;2–11.

116. Löwe B, Kroenke K, Herzog W, Grafe K, Gräfe K. Measuring depression outcome with a brief self-report instrument: Sensitivity to change of the Patient Health Questionnaire (PHQ-9). 2004;81(1):61–6.

117. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166:1092–7.

118. Klein EM, Brähler E, Dreier M, Reinecke L, Müller KW, Schmutzer G, et al. The German version of the Perceived Stress Scale – psychometric characteristics in a representative German community sample. BMC Psychiatry [Internet]. 2016;16(1):159. Available from: http://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-016-0875-9

119. Gerber M, Lang C, Lemola S, Colledge F, Kalak N, Holsboer-Trachsler E, et al. Validation of the German version of the insomnia severity index in adolescents, young adults and adult workers: results from three cross-sectional studies. BMC Psychiatry [Internet]. 2016;16(1):174. Available from: http://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-016-0876-8

120. Hughes ME, Waite LJ, Hawkley LC, Cacioppo JT. A Short Scale for Measuring Loneliness in Large Surveys: Results From Two Population-Based Studies. Res Aging. 2004;26(6):655–72.

121. Rathner E-M, Terhorst Y, Cummins N, Schuller B, Baumeister H. State of Mind: Classification through Self-reported Affect and Word Use in Speech. In: Interspeech 2018 [Internet]. ISCA: ISCA; 2018. p. 267–71. Available from: https://www.isca-speech.org/archive/interspeech_2018/rathner18b_interspeech.html

122. Fontaine JRJ, Scherer KR, Roesch EB, Ellsworth PC. The world of emotions is not two-dimensional. Psychol Sci. 2007;18(12):1050–7.

123. Glick HA, Doshi JA, Sonnad SS, Polsky D. Economic Evaluation in Clinical Trials - Handbooks in Health Economic Evaluation Series. Oxford: Oxford University Press; 2014.

124. Willan AR, Briggs AH. Statistical Analysis of Cost-Effectiveness Data. Statistical Analysis of Cost-Effectiveness Data. 2006. 1–196 p.

125. Marseille E, Larson B, Kazi DS, Kahn JG, Rosen S. Thresholds for the cost–effectiveness of interventions: alternative approaches. Bull World Health Organ. 2015 Feb;93(2):118–24.

126. Woods B, Revill P, Sculpher M, Claxton K. Country-Level Cost-Effectiveness Thresholds: Initial Estimates and the Need for Further Research. Value Heal. 2016 Dec;19(8):929–35.

127. Willan AR, Briggs AH, Hoch JS. Regression methods for covariate adjustment and subgroup analysis for non-censored cost-effectiveness data. Health Econ [Internet]. 2004 May [cited 2019 Jan 24];13(5):461–75. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15127426

128. Kilian R, Becker T, Frasch K. Effectiveness and cost-effectiveness of home treatment compared with inpatient care for patients with acute mental disorders in a rural

catchment area in Germany. Neurol Psychiatry Brain Res. 2016 Jun;22(2):81–6.

129. Kilian R, Frasch K, Steinert T, Schepp W, Weiser P, Jaeger S, et al. Cost-effectiveness of psychotropic polypharmacy in routine schizophrenia care. Results of the ELAN prospective observational trial. Neurol Psychiatry Brain Res. 2018 Dec;30:47–55.

130. Hoch JS, Briggs AH, Willan AR. Something old, something new, something borrowed, something blue: a framework for the marriage of health econometrics and cost-effectiveness analysis. Health Econ [Internet]. 2002 Jul [cited 2019 Jan 24];11(5):415–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12112491

131. Salize HJ, Kilian R. Gesundheitsökonomie in der Psychiatrie - Konzepte, Methoden und Analysen. Stuttgart: Kohlhammer; 2010.

132. van Buuren S, Groothuis-Oudshoorn K. mice : Multivariate Imputation by Chained Equations in R. J Stat Softw [Internet]. 2011;45(3). Available from: http://www.jstatsoft.org/v45/i03/

133. Goldstein H. Multi-level statistical models. New York: Halsted; 1995. 64–88 p.

134. MacCallum RC, Cheongtan K, Malarkey WB. Studying multivariate change using multilevel models and latent curve models. Vol. 32, Multivariate Behavioral Research1. MacCallum RC, Cheongtan K, Malarkey WB. Studying multivariate change using multilevel models and latent curve models. Multivariate Behav Res. 1997;32(3):215-253. doi:10.1207/s15327906mbr3203_1. 1997. p. 215–53.

135. Nezlek JB. Multilevel modeling for psychologists. APA Handb Res methods Psychol Vol 3 Data Anal Res Publ. 2012;3:219–41.

136. Hastie T, Tibshirani R, Friedman J. Prototype Methods and Nearest-Neighbors. In

2009.

137. Freund, Yoav and LM. The alternating decision tree learning algorithm. Int Conf Mach Learn. 1999;

138. Freund Y, Schapire RE. A decision-theoretic generalization of on-line learning and an application to boosting. In: Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics). 1995.

Figures titles

Figure 1. Flow chart

Figure 2. Procedure

Figure 3. Features

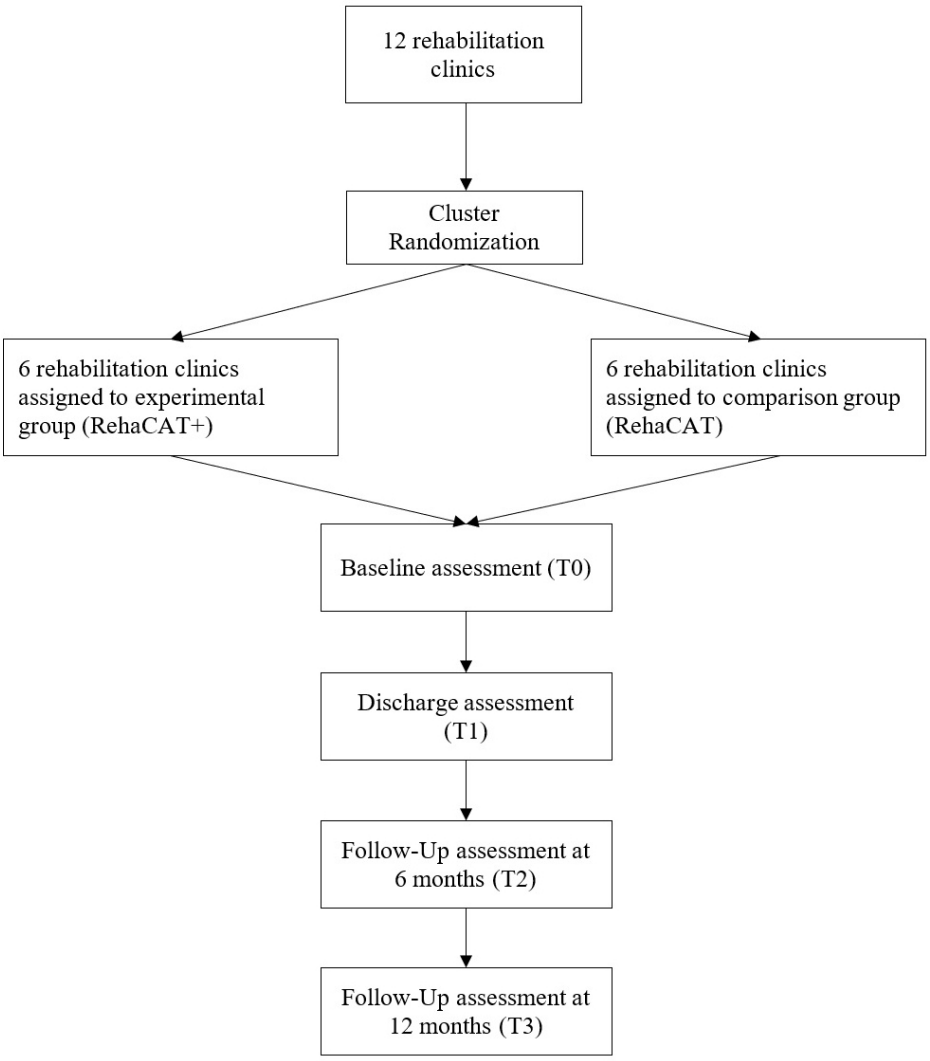

Figure 1. Flow chart

89x95mm (300 x 300 DPI)

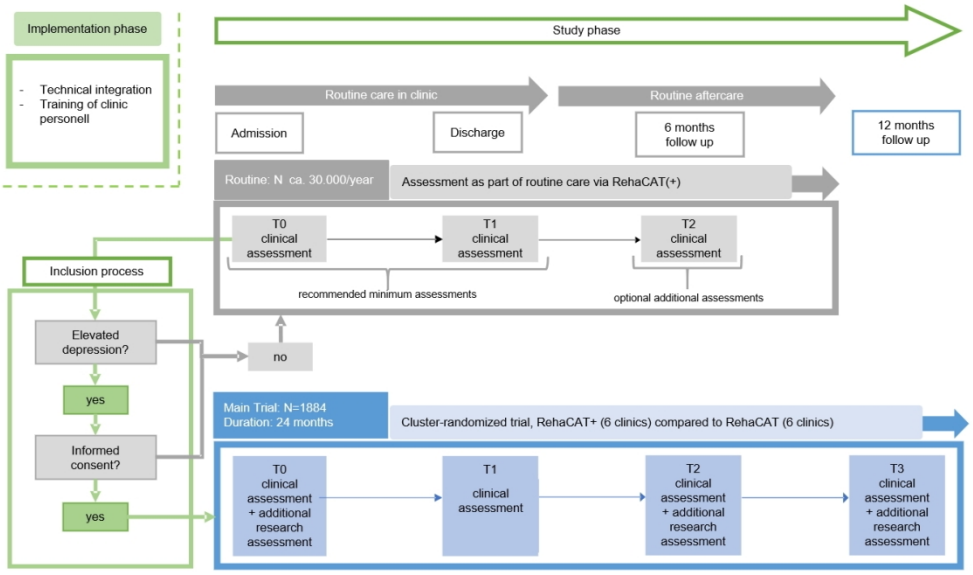

Figure 2. Procedure

116x68mm (300 x 300 DPI)

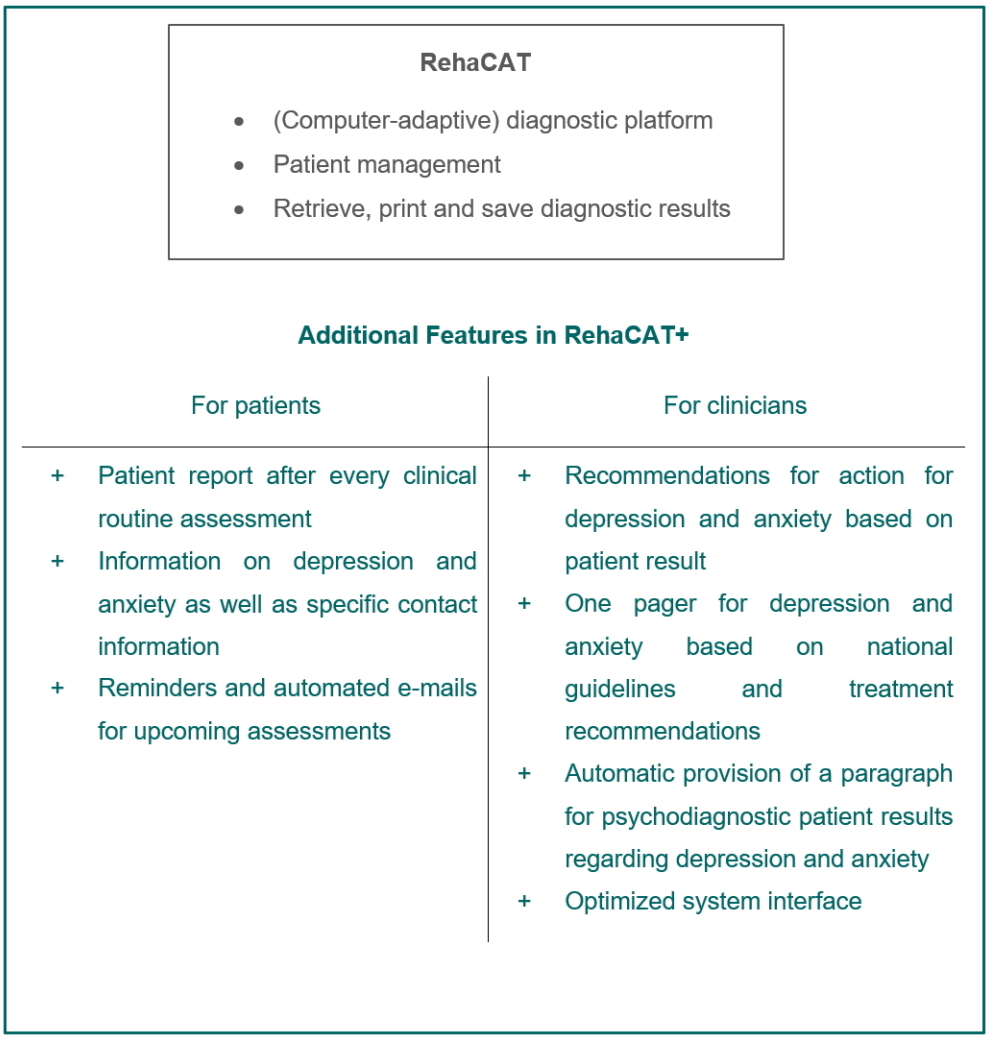

Figure 3. Features

88x92mm (300 x 300 DPI)

ulm university universität
uulm

Faculty of Engineering, Computer Science and Psychology
Institute of Psychology and Education
Department. of Clinical Psychology and Psychotherapy

Prof. Dr. Harald Baumeister

Lise-Meitner-Str. 16,
89081 Ulm

Tel: +49 731 50-32814
Fax: +49 731 50-32809
harald.baumeister@uni-ulm.de

TEILNEHMENDEN-INFORMATION

Titel der Studie: RehaCAT+

Sehr geehrte Probandin, sehr geehrter Proband,

Herzlich willkommen zu unserer Studie RehaCAT+, wir danken Ihnen für Ihr Interesse!
Wir sind ein Studienteam der Abteilung für Klinische Psychologie und Psychotherapie des Instituts für Psychologie und Pädagogik an der Universität Ulm. Im Voraus möchten wir Sie darüber informieren, dass jede Teilnahme an einer wissenschaftlichen Studie freiwillig ist und wir aus diesem Grund für die Teilnahme ihre Einwilligung benötigen. Falls Sie nicht an der Studie teilnehmen möchten oder eine mögliche Teilnahme frühzeitig beenden möchten, entstehen Ihnen keine Nachteile. Mit diesem Schreiben möchten wir Sie umfassend zur Studie informieren und bitten Sie, den folgenden Text sorgfältig zu lesen. Sollten Sie im Nachhinein noch offene Fragen haben, können Sie uns telefonisch oder per Mail erreichen oder das Klinikpersonal fragen!

WARUM WIRD DIESE STUDIE DURCHGEFÜHRT?

Die medizinische Rehabilitation sieht sich der Herausforderung gegenüber, medizinische Maßnahmen bedarfsgerecht einzuleiten und zu gestalten sowie die Nachhaltigkeit von Behandlungseffekten zu sichern. Nicht selten treten bei Menschen, die aufgrund von schwerwiegenden medizinischen Problemen eine Rehabilitation durchlaufen Symptome psychischer Belastungen auf. Eine umfassende psychosoziale Diagnostik erfordert viel Zeit und Ressourcen und ist aufgrund dessen in der Rehabilitationsroutine für die Klinik nur schwer umsetzbar und auch für Sie als Rehabilitand:in sehr zeitaufwändig.
Um Sie und ihre Rehabilitationseinrichtung bei einer umfangreichen und fundierten Diagnostik zu unterstützen, haben wir RehaCAT+ entwickelt. RehaCAT+ ist ein Computer- und Web-basiertes Testsystem, das adaptive Testverfahren verwendet. Das bedeutet, dass das System basierend auf den gegebenen Antworten die relevanten Fragen heraussucht, sodass nicht mehr jede einzelne Frage durchlaufen werden muss. Das ist insbesondere auch für Sie als Rehabilitand:in von Vorteil, da sich die Zeit zum Ausfüllen von Fragebögen stark verkürzt, bei gleichbleibend hoher Genauigkeit des Testergebnisses.
Basierend auf Ihren Testergebnissen erhält Ihr behandelnder Arzt oder Ihre behandelnde Ärztin in der Rehabilitationsklinik Rückmeldung über mögliche psychosoziale Belastungen. Diese Ergebnisse können Ihrem Arzt:Ihrer Ärztin dabei helfen, die bestmögliche Behandlung für Sie einzuleiten.
Ziel der Studie ist es, zu untersuchen, ob es 12 Monate nach Entlassung aus der Rehabilitation einen Unterschied im Wohlbefinden der Rehabilitand:innen im Vergleich zu anderen Kliniken gibt.

ABLAUF DER STUDIE

Sie erhalten diese Informationen, da sie für eine Studienteilnahme in Frage kommen. Sofern Sie sich für eine Teilnahme entscheiden, bitten wir Sie der Einwilligungserklärung, welche im nächsten Teil folgen wird, zuzustimmen.
Im Rahmen der normalen Rehabilitationsmaßnahmen in Ihrer Klinik haben Sie bereits an der computer-adaptiven Befragung teilgenommen. Dies hilft dem Klinikpersonal, für Sie passende Behandlungsmaßnahmen einzuleiten. Im Zuge Ihrer Rehabilitation werden Sie bei Aufnahme, Entlassung sowie 6 Monate nach der Entlassung befragt, um festzustellen, wie es Ihnen geht und ob sich Ihre Symptome verbessert haben. Insgesamt durchlaufen Sie also routinemäßig 3 Befragungen.
Sollten Sie sich entscheiden an dieser Studie teilzunehmen, werden Ihnen zu jedem Befragungszeitpunkt noch einige zusätzliche Fragen gestellt, mit deren Beantwortung Sie einen wertvollen Beitrag zur Forschung leisten

und dabei helfen, künftige Behandlungen für Rehabilitand:innen wie Sie effektiver zu gestalten. Dabei werden sensible Daten zu Ihrer Gesundheit erfasst.
Basierend auf unseren Erfahrungen schätzen wir den zeitlichen Mehraufwand für Sie auf ca. 20 Minuten je Befragung. Zusätzlich befragen wir Sie 12 Monate nach der Rehabilitation, womit insgesamt vier Befragungen auf Sie zukommen.

ENTGELT
Das vollständige Ausfüllen der Onlinebefragungen wird mit einer finanziellen Aufwandsentschädigung vergütet. Für die Befragungen 6 und 12 Monate nach ihrem Rehabilitationsaufenthalt haben Sie die Möglichkeit jeweils 20 Euro elektronisch überwiesen zu bekommen.

UMGANG MIT IHREN DATEN
Im Rahmen der Studie werden Ihre Daten von der Abteilung Klinische Psychologie und Psychotherapie am Institut für Psychologie und Pädagogik Universität Ulm verwendet. Es haben nur diejenigen Personen innerhalb der Universität Zugriff auf Ihre pseudonymisierten Daten, die dies für einen ordnungsgemäßen Ablauf der Studie benötigen. Nach Abschluss der Studie wird die Kodierliste, welche Ihren Namen zu ihrer Reha-ID zuordnen und nur in ihrer Klinik vorliegt, gelöscht. Danach sind die Daten anonymisiert und es kann kein Personenbezug mehr hergestellt werden. Wissenschaftliche Veröffentlichungen erfolgen mit diesen anonymisierten Daten über viele Studienteilnehmende hinweg. Eine mögliche Weitergabe der anonymisierten Daten an Dritte beschränkt sich auf wissenschaftliche Nutzungszwecke. Zu keinem Zeitpunkt können Krankenversicherungen/ Leistungserbringer oder Arbeitgeber individualisierte Studiendaten einsehen. Nach der 6 und 12 Monatsbefragung möchten wir Ihnen jeweils eine Aufwandentschädigung elektronisch überweisen.

Dazu werden wir nach Abschluss der Befragung Ihre IBAN, Name und Reha-ID erfassen. Ihre Bankdaten werden nicht mit den Gesundheitsdaten verknüpft und abgespeichert. Ihre Bankdaten Daten werden nach der elektronischen Überweisung der Vergütung unmittelbar gelöscht. Die Angabe Ihrer Bankdaten ist freiwillig. Sollten Sie keine Aufwandsentschädigung erhalten möchten, brauchen Sie Ihre Daten nicht angeben.

GIBT ES RISIKEN DURCH DIE TEILNAHME AN DER STUDIE REHACAT+?
Nebenwirkungen oder unerwünschte Wirkungen von Online Befragung oder ähnlicher Studien sind nicht bekannt. Manche der Aufgaben oder Fragen sind möglicherweise schwierig zu beantworten oder umzusetzen. Die Erfahrung, sich Ängsten oder unangenehmen Gedanken zu stellen, ist für die meisten Menschen zunächst nicht leicht, dann aber oft sehr hilfreich. Zusätzlich stehen Ihnen bei Bedarf zuständiges Klinikpersonal Als Ansprechpartner/in zur Verfügung und werden versuchen, Ihnen zu helfen.

FREIWILLIGKEIT:
An dieser Studie nehmen Sie freiwillig teil. Ihr Einverständnis können Sie jederzeit und ohne Angabe von Gründen widerrufen, dann werden alle bis dahin studienbedingt erhobenen personenbezogenen Daten gelöscht. Dieser eventuelle Widerruf hat keine Auswirkungen für Sie. Zur Löschung der Daten müssen Sie dem Forschungsteam Ihre Reha-ID mitteilen. Dafür können Sie sich jederzeit an die Supportmail Adresse (RehaCAT@uni-ulm.de) wenden, sowie während ihres Aufenthalts in der Klinik das Anliegen an Klinikmitarbeitende herantragen, welche wiederum die Reha-ID an das Forschungsteam weiterleiten. Es können nur alle Daten gelöscht werden. Das Löschen einzelner Fragebögen ist nicht möglich.

ERREICHBARKEIT DER STUDIENMITARBEITER:
Sollten während des Verlaufes der Studie Fragen auftauchen, so können Sie jederzeit folgende Ansprechpartner erreichen:

Yannik Terhorst
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32820
E-Mail: yannik.terhorst@uni-ulm.de

Johannes Knauer
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm

Telefon: +49 731/50 32805
E-Mail: Johannes.knauer@uni-ulm.de

VERSICHERUNG:

Während der Teilnahme an der Studie genießen Sie Versicherungsschutz. Die an der Studie mitwirkenden Mitarbeitenden sind über die Universität Ulm beim Land Baden-Württemberg haftpflichtversichert für den Fall, dass Sie durch deren Verschulden einen Schaden erleiden.

Einen Schaden, der Ihrer Meinung nach auf diese Studie zurückzuführen ist, melden Sie bitte unverzüglich dem Studienleiter.

SCHWEIGEPFLICHT/DATENSCHUTZ:

Alle Personen, welche Sie im Rahmen dieser Studie betreuen, unterliegen der beruflichen Schweigepflicht und sind auf das Datengeheimnis verpflichtet. Die studienbezogenen Untersuchungsergebnisse sollen in anonymisierter Form in wissenschaftlichen Veröffentlichungen verwendet werden. Soweit es zur Kontrolle der korrekten Datenerhebung erforderlich ist, dürfen autorisierte Personen (z.B.: des Auftraggebers, der Universität) Einsicht in die studienrelevanten Teile der Akte nehmen. Sofern zur Einsichtnahme autorisierte Personen nicht der obengenannten beruflichen Schweigepflicht unterliegen, stellen personenbezogene Daten, von denen sie bei der Kontrolle Kenntnis erlangen, Betriebsgeheimnisse dar, die geheim zu halten sind.

Die in dieser Studie für die Datenverarbeitung verantwortliche Personen (Studienleiter selbst bzw. von ihm beauftragte Mitarbeitende; jedoch nicht Datenschutzbeauftragter) sind:

Yannik Terhorst
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32820
E-Mail: yannik.terhorst@uni-ulm.de

Johannes Knauer
Universität Ulm
Institut für Psychologie und Pädagogik
Abteilung für Klinische Psychologie und Psychotherapie
Lise-Meitner-Straße 16, D-89081 Ulm
Telefon: +49 731/50 32805
E-Mail: Johannes.knauer@uni-ulm.de

Bei Fragen zur Nutzung oder Verarbeitung Ihrer Daten wenden Sie sich bitte an den/die:

- Datenschutzbeauftragte/n des lokalen Studienzentrums
  (a) *Universität Ulm*: *Universität Ulm, Helmholtzstr. 16, 89081 Ulm, Tel.Nr.: 07542 / 949 21 09,*
  E-Mail: *dsb@uni-ulm.de*

Falls Sie Bedenken oder Beschwerden hinsichtlich der Verarbeitung Ihrer Daten haben, wenden Sie sich bitte an die Datenschutz-Aufsichtsbehörde Ihres Studienzentrums: Die entsprechenden Kontaktdaten finden Sie auf der Internetseite des Landesbeauftragten für Datenschutz und Informationsfreiheit Baden-Württemberg: *https://www.baden-wuerttemberg.datenschutz.de/dsb-online-melden/*

Faculty of Engineering, Computer Science and Psychology
Institute of Psychology and Education
Department. of Clinical Psychology and Psychotherapy

Prof. Dr. Harald Baumeister

Lise-Meitner-Str. 16,
89081 Ulm

Tel: +49 731 50-32814
Fax: +49 731 50-32809
harald.baumeister@uni-ulm.de

EINWILLIGUNGSERKLÄRUNG

Titel der Studie: RehaCAT+

Inhalt, Vorgehensweise, Risiken und Ziel der obengenannten Studie sowie die Befugnis zur Einsichtnahme in die erhobenen Daten wurden mir durch die online Informationsmaterialien ausreichend erklärt.
Falls Sie Fragen haben, können Sie sich an folgende Stellen wenden:

- Klinikmitarbeitende
- E-Mail: RehaCAT@uni-ulm.de
- Telefon: +49 731/50 32820 oder +49 731/50 32805

Ich hatte Gelegenheit Fragen zu stellen und alle eventuellen Fragen wurden geklärt.
☐ Ja ☐ Nein

Ich hatte ausreichend Zeit, mich für oder gegen die Teilnahme an der Studie zu entscheiden.
☐ Ja ☐ Nein

E-Mail-Adresse:
Zur Untersuchung des Langzeiteffekts dieser Studie würden wir sie gerne 6 und 12 Monate nach Abschluss ihrer Reha kontaktieren. Dies ist eine Voraussetzung für die Studienteilnahme. Ihre E-Mail-Adresse wird hierbei separat von allen anderen Daten gespeichert.

_____

Kontaktaufnahmen im Rahmen dieser Studie
Ich gebe mein Einverständnis, dass ich im Rahmen der Studie unter der oben angegebenen E-Mail-Adresse kontaktiert werden darf.
☐ JA ☐ NEIN

Elektronische Erfassung der Bankverbindung zur Aufwandsentschädigung
Die Aufwandsentschädigung nach der 6 und 12 Monatsbefragung kann ausschließlich über eine elektronische Überweisung erfolgen. Dazu ist es notwendig, dass Sie im Anschluss an diese Befragungen Ihre Bankdaten angeben und der damit verbundenen Datenverarbeitung zustimmen. Wir klären Sie zu den Zeitpunkten jeweils erneut über die Verarbeitung auf. Die Angabe der Bankdaten ist zu beiden Zeitpunkten freiwillig.
Ich habe dies zur Kenntnis genommen.
☐ JA ☐ NEIN

Mir ist bewusst, dass die Einwilligungen freiwillig sind und ohne Nachteile (auch einzeln) verweigert oder jederzeit auch ohne Angaben von Gründen widerrufen werden können. Ich weiß, dass im Falle eines Widerrufs die Rechtmäßigkeit der aufgrund der Einwilligung bis zum Widerruf erfolgten Verarbeitung nicht berührt wird. Ich habe verstanden, dass ich mich für einen Widerruf einfach an die in den Informationen genannte Kontaktperson wenden kann und dass aus der Verweigerung der Einwilligung oder ihrem Widerruf keine Nachteile entstehen.
Mir wurden die Informationen zur Erhebung personenbezogener Daten in der Studie RehaCAT+ mitgeteilt

und zur Verfügung gestellt. Eine Kopie dieser Einwilligungserklärung können Sie jederzeit über den Menüpunkt „Informationen“ herunterladen oder vom Personal Ihrer Rehabilitationsklinik erhalten.

Ich habe die allgemeinen Informationen zur Studie „RehaCAT+“ gelesen und willige in die Teilnahme an der Studie und die damit verbundene Datenverarbeitung ein.
☐ JA ☐ NEIN

[Weiter Button erscheint erst, nach aktiver Bestätigung dieses und der Bestätigung zur Datenverarbeitung – die Einwilligung ist rein digital]

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, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		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	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	4
Funding	#4	Sources and types of financial, material, and other support	23
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 23

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	23
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	23
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)	19
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
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
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)	8
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	9
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	9

		eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	10
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)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	10
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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	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)	8,9
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	9
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	10

		enrol participants or assign interventions	
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	10
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10
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	n/a
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 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	19
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	10
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	19
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	20

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21
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)	20
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	19
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	n/a
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	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	22
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)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if	n/a

		applicable	
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	19
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	23
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	19
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	n/a
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	23
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	supplement
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	n/a