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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.

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Manuscripts

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

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3 2021 ref. 509/20). Written informed consent will be obtained. Results will be published via peer
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5 reviewed journals.
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8 **Trial Registration** The trial is registered in the German Clinical Trials Register
9
10 (DRKS00027447, date of registration: 11.01.2022)
11
12

13 **Word Count: 5110**
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17 **Keywords:** cluster randomized controlled trial, patient reported outcome, depression, computer
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19 adaptive testing, routine care
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22 **Strengths and limitations of this study**

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- 25 • Large pragmatic, cluster-randomized controlled trial.
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- 28 • First integration of a computer-adaptive patient reported outcome platform for screening
29
30 with action recommendations regarding depression and anxiety in orthopedic and
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32 cardiologic health care.
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- 35 • Comprehensive effectiveness, cost-effectiveness and feasibility analyses.
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- 38 • Fine granular disease and treatment trajectories by means of smart sensing.
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- 41 • Representative for German rehabilitation health care system.
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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.

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3 However, PROMs are often static and non-adaptive to the user's responses, resulting in limited
4 accuracy, presentation of inappropriate items for the individual, and an overall long assessment
5 duration (15–17). Computer-adaptive testing (CAT), which is based on item response theory
6 models, is a promising option in this context, substantially reducing the burden on patients
7 (personalized testing) and health care institutions (e.g., immediate test evaluations) (10,18–23).
8
9 In CAT, the items providing the maximum information about the respective patient are selected
10 and assessed during test administration based on the previous answers of a patient (24). In this
11 way, besides a considerable reduction in test duration, an estimation accuracy that is equally
12 good or sometimes even better compared to non-adaptive procedures can be achieved
13 (18,23,25–27).
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27 Whereas PROMs are often used in clinical research, the usefulness and effectiveness of routine
28 PROM assessment in somatic health care is still controversially discussed (8,28–33). On the
29 one hand, routine PROMs allow for real-time monitoring. Moreover, PROMs have been shown
30 to lead to improved communication between clinician and patient, decision-making and patient
31 satisfaction with care, and improved health outcome and detection of symptoms and mental
32 comorbidities. On the other hand, there are barriers such as limited ability of clinicians for score
33 interpretation, unfamiliarity with PROM software usage and less time for controlling (8,23,39–
34 42,31–38). Additionally one of the central challenges is the implementation of further evidence-
35 based measures on the basis of the assessment results (43). Action plans directly derivable from
36 assessment results are regarded as a prerequisite to implement PROMs beneficially
37 (31,33,44,45). However, there is still an insufficient linkage between assessment results and
38 implementation of existing evidence-based guidelines and recommendations for action in
39 everyday clinical practice (33,46).
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57 One way to promote the desired probability of action following diagnostic results could be
58 persuasive design components, such as reminder features that are automatically triggered
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3 depending on the test environment (47–49). Persuasive designed technological approaches are
4 defined as interactive systems that purposefully influence the user, aiming to change behavior
5 or attitudes (50). Supplementary, the provision of computer-based databases and concrete
6 decision-making aids and recommendations for action is seen as one way of reducing these
7 existing barriers (51,52). In this context, it could be useful to link the individual test results with
8 therapy standards as well as recommendations for action and guideline knowledge. These have
9 been formulated in particular for the areas of comorbid depression and anxiety in patient
10 populations with somatic diseases (53–57). Such a combination could offer the practitioner a)
11 background knowledge, b) recommendations for action as well as c) documentation aids.
12 Ideally, such elements should be directly integrated into testing systems (e.g., web- and CAT-
13 based) to provide a comprehensive platform from screening to action.
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29 Hence, the aim of the present trial is to examine a persuasive design optimized CAT system
30 (RehaCAT+) providing background knowledge, recommendations for action as well as
31 documentation aids against a standard CAT system (RehaCAT). This will be exemplified with
32 a focus on depression as the primary outcome and anxiety as major mental health comorbidities
33 in cardiological and orthopedic care. The following research questions will be addressed:
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- 42 1) Does RehaCAT+ improve rehabilitation patients' depression after one year (T3)?
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44 45 2) Does RehaCAT+ improve depression, anxiety, satisfaction with participation in social
46 roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy,
47 physical function, and alcohol use at discharge (T1) and six months (T2) as well as one year
48 regarding all the secondary outcomes (T3)?
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50 51 52 53 54 55 3) Does RehaCAT+ lead to improved documentation and improved follow-up and post-
56 rehabilitation recommendations?
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- 3 4) Does RehaCAT+ lead to improved utilization of rehabilitation therapy standard and
- 4 guideline compliant health care services during and after rehabilitation?
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- 8 5) What is the cost-effectiveness of RehaCAT+ compared to RehaCAT?
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- 11 6) What is the acceptance and feasibility of RehaCAT?
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- 15 7) What are facilitators, hindering factors, mediators and potential risks associated with
- 16 RehaCAT+?
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21 A web-based CAT system provides a powerful way to assess PROM, however, it is still subject
22 to limitations: 1) it requires active input of the patient – even if reduced through computer
23 adaptive testing, 2) the assessment is limited to fixed time points, which may lead to long
24 unassessed time intervals in which significant symptom change may occur, and 3) due to the
25 nature of self-report the answers by patients may be biased (e.g., social desirability or recall
26 bias) (58–61).
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35 One solution to this could be the addition of ecological momentary assessment and smart
36 sensing to allow for digital phenotyping (62,63). Digital phenotyping is defined as the moment-
37 by-moment quantification of the individual health in situ through digital variables and data
38 generated by personal devices (e.g., smartphone or smart-watch) (62,63). First studies show
39 promising results highlighting the potential of this method to complement PROM assessments
40 for monitoring and predicting symptoms with minimal added patient burden (64–70). In future
41 the combination of high quality PROM at fixed timepoints combined with continuous
42 monitoring through smart sensing and information from the clinical information system could
43 become a promising data base, which could be used to 1) predict symptom trajectories, 2) build
44 early-detection of adverse events systems (RED-flag) or 3) personalized treatment
45 recommendation systems (71–74).
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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 ≥ 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

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3 Randomization and allocation regarding the control (RehaCAT) and experimental group
4 (RehaCAT+) of the participating rehabilitation clinics will be performed by an independent
5 researcher to avoid selection bias. Randomization will be done on cluster-level.
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11 The patients remain obscured to their study arm assignment. Clinics are aware of their
12 condition. For the primary outcome analyses the conducting analyst will be obscured to group
13 allocation. The study flow is presented in Figure 1.
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18 19 **2.3 Conditions**

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22 RehaCAT-Control Group: RehaCAT is a server- and web-based, device-independent test
23 system, which allows the use of classical test procedures as well as Computer-adaptive
24 procedures. RehaCAT does not interfere with the (clinic specific) standard treatment and
25 patients have unrestricted access to treatment as usual (TAU). RehaCAT is divided into four
26 user areas: 1) patient, 2) staff, 3) administrator, 4) researcher. The platform allows system
27 administrators to upload and manage patients. Patients go through the diagnostic measures.
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29 Clinicians can view the test results of the different patient reported health outcomes of their
30 respective patients. For a full overview of the assessment see 2.5.
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42 RehaCAT+-Experimental Group: In addition to the structure of RehaCAT, RehaCAT+ follows
43 a persuasive design optimized technology (e.g., motivation, ability, and automatic trigger
44 considering test environment) (47,48) to increase the desired probability of action. RehaCAT+
45 offers additional (1) system features (reminders), (2) clinician features (stored
46 recommendations for action for depression and anxiety based on respective patient results, call
47 to action plans, individualized documentation aids and supporting information material for the
48 dimensions of depression and anxiety), and (3) patient features (individual symptomatic
49 information at discharge and T2/3, possible points of contact/help). A summary of the two
50 conditions is provided in Figure 3.
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-----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	✓	✓	✓	✓	✓

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3							
4	Fatigue	PROMIS® Fatigue	✓	✓	✓	✓	✓
5							
6	Sleep	PROMIS® Sleep Disturbance	✓	✓	✓	✓	✓
7							
8	Health-related	PROMIS® Global Health		✓	✓	✓	✓
9							
10	quality of life						
11							
12	Self-Efficacy	PROMIS® Self-Efficacy General		✓	✓	✓	✓
13							
14	Physical	PROMIS Physical Function	✓	✓	✓	✓	✓
15							
16	Function						
17							
18	Alcohol use	AUDIT		✓	✓	✓	✓
19							
20	Personality	BFI-10		✓			
21							
22	Generic quality	EQ5D-5L		✓		✓	✓
23							
24	of life						
25							
26	Health and	CSSRI		✓		✓	✓
27							
28	social services						
29							
30	use and costs						
31							
32	Medical record	Provided by clinicians (e.g. discharge reports)				✓	
33							
34	data						
35							
36							

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, 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

1
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3 much or always). It is a validated instrument and has good psychometric properties with
4
5 $\alpha > 0.90$ (94,95).
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9 Health-related quality of life will be assessed with the PROMIS scale on global health aspects
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11 (Global Health) is used. The scale includes 10 items that capture global physical health
12
13 (physical health, physical functioning, fatigue, pain), and global mental health (general quality
14
15 of life, mental health, satisfaction with social activities and relationships, and emotional
16
17 distress) (96). Nine items are scored on a response scale of 1 to 5, and the item assessing pain
18
19 is scored from 0 to 10. Internal consistency was estimated to be good with $\alpha > 0.82$ (Katzan &
20
21 Lapin, 2018).
22
23

24
25 Self-efficacy will be assessed with the short scale of the PROMIS General Self-Efficacy Scale
26
27 which contains 4 items. It can be used to assess how much confidence one has in one's own
28
29 abilities to master tasks and situations. Items are rated on a response scale from 1 (I am not at
30
31 all confident) to 5 (I am very confident). Internal consistency was estimated to be high ($\alpha =$
32
33 0.96) (97,98).
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39 Physical function will be assessed using the computer-adaptive PROMIS Physical Function
40
41 Item Set that measures the ability to perform daily life activities that require physical activity
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43 such as walking or lifting objects. It comprises 164 items that are assessed on a 5-point scale
44
45 ranging from 1 (Without any difficulty) to 5 (Unable to do). Internal consistency was found to
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47 be very good with $\alpha > 0.88$ (99).
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51 Alcohol use will be assessed with the AUDIT (Alcohol Use Disorders Identification Test)
52
53 which is a 10-item questionnaire developed by the WHO as a screening tool for hazardous and
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55 harmful alcohol use. Responses to each question are scored from 0 to 4, allowing a maximum
56
57 of 40 points. Reliability has been investigated in some studies and is considered good with a
58
59 median of $\alpha = 0.80$ (100).
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3 Discharge reports will be analyzed regarding a) frequency of documented screening results, b)
4 therapy standard and guideline appropriate therapeutic services (documented services / therapy
5 standard recommendations as a function of depression and anxiety results), c) therapy standard
6 and guideline appropriate follow-up and post-rehabilitation recommendations (documented
7 recommendations / therapy standard/guideline recommendations as a function of depression
8 and anxiety results).

17 **2.5.3 Moderators**

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19
20 As potential moderators, socio-demographic data (age, gender, nationality) and personality will
21 be recorded at admission (T0). Personality will be assessed with the BFI-10 (Big Five Inventory
22 – 10), a short version of the Big Five Inventory that has good psychometric properties and a
23 retest-reliabilities of $\alpha = 0.73$ (101). Additionally, data from medical records will be used as
24 moderators (e.g. indication area orthopedic or cardiologic, chronic conditions, rehabilitation
25 duration, etc.).

34 **2.5.4 Health economics**

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36
37
38 Generic quality of life will be assessed with the EQ5D-5L (European Quality of Life 5
39 Dimension - 5 Level Questionnaire) from the EuroQol foundation (www.euroqol.org) (102).
40 The five dimensions surveyed are mobility, self-care, general activities, pain/physical
41 discomfort, and anxiety/dejection. Each of the five areas is ranked on a five-point scale. Based
42 on the answers, the respective health status is recorded (103).

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

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3 Furthermore, acceptance of and satisfaction with smart sensing will be measured using the
4
5 UTAUT (Unified Theory of Acceptance and Use of Technology) questionnaire (108,109),
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7 satisfaction with the research application will be measured with the User Version of the Mobile
8
9 Application Rating Scale (uMARS) (110). Both questionnaires will be assessed once after 6
10
11 months before deinstalling the application.
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16 The following clinical questionnaires will be assessed every two weeks: Depression
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18 (dimensional and categorical) with the PHQ-8 (if PHQ-2 score > 2) (111–113); anxiety with
19
20 the GAD-7 (114); stress with the PSS-10 (115); sleep with the ISI-7 (116); loneliness with the
21
22 UCLA 3 item version (117).
23
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26 Every morning, participants will be asked short questions about mood (valence), drive
27
28 (arousal), control, unpredictability, stress experience and sleep, at midday about mood
29
30 (valence), drive (arousal), control, unpredictability, and stress experience, and in the evening,
31
32 participants are again asked about mood (valence), drive (arousal), control, unpredictability,
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34 stress experience, and activity during the day. This assessment is based on previous studies
35
36 (65,68,118,119).
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40 41 **2.5.6.2 Passive Outcomes**

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43 The research app allows to track a broad range of sensors (accelerometer, application usage,
44
45 barometer, battery, Bluetooth, communication, gravity, gyroscope, light, locations,
46
47 magnetometer, network, proximity, rotation, screen sensor). However, each user can freely
48
49 decide which sensors are activated and access permissions can always be activated and
50
51 deactivated without giving reasons. In addition, sensible location data (e.g., GPS coordinates)
52
53 will be obscured, so pseudonymization can be upheld all the time.
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3 The following digital markers can be collected (depending on permissions of user): frequency
4 and duration of smartphone and individual app usage, frequency and duration/length of calls
5 and text messages, randomly distorted GPS, and type of movement.
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10 **2.6 Data management and data sharing plan**

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14 Data collection will be completed online using the server-based system RehaCAT(+) and the
15 research application in pseudonymized form. Retrieved data will be stored encrypted by
16 responsible employees. All data will be anonymized after completion of the trial. Furthermore,
17 an independent Data Safety and Monitoring Board (DSMB) with long-standing experience in
18 clinical trials has been established. The function of the DSMB is to monitor the course of the
19 study and, if necessary, give recommendations to the steering committee for discontinuation,
20 modification or continuation of the study.
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31 Individual participant data will be made available on request after de-identification beginning
32 12 months following article publication of the effectiveness paper. Data will be made available
33 to researchers who provide a methodologically sound proposal, not already covered by others.
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46 **2.7 Measures to reduce methodological sources of error**

49 Selection bias: Randomization and allocation regarding the group allocation (RehaCAT/
50 RehaCAT+) of the participating rehabilitation clinics will be done by an independent
51 researcher. Performance bias: Rehabilitation staff centrally involved in the implementation will
52 be trained along training materials, as well as continuously supervised regarding the training
53 materials. RehaCAT(+) and its application will be described in detail in a test manual.
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3 implementation process of RehaCAT(+) in the individual clinics. Contamination bias: Cluster
4 randomization is used to avoid study arm contamination. Detection bias: rating procedures
5
6 (analysis of discharge reports) are performed by independent raters who are obscured to the
7
8 study arm affiliation of the clinics and thus the patients. Patients also remain obscured to their
9
10 study arm assignment, as the differentiation between RehaCAT and RehaCAT(+) is not obvious
11
12 to them. Only for clinic personnel obscuring cannot be realized. Reporting bias: A detailed
13
14 definition of all methodological aspects of the present clinical study is provided in this study
15
16 protocol, submitted for publication prior to randomization start. Evaluating representativeness:
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18 To assess the representativeness of the results, quantitative and qualitative analyses will be
19
20 performed regarding the reasons that may lead to a non-existent 100% exhaustion in the routine
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22 assessment.
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29 **2.8 Patient and public involvement**

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32 Patient and public involvement (PPI) representatives have provided input to the present study
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34 in several stages. Results of previous projects including patient feedback, were used to further
35
36 develop and optimize study design and procedures. PPI representatives (e.g. as members of an
37
38 advisory board) are included to improve usability, design and comprehensibility but have no
39
40 influence on the outcomes, data analysis methods or study design.
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45 **2.9 Statistical analyses**

48 **2.9.1 Clinical analyses**

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50 Study data will be centrally processed and analyzed by an independent researcher. Missing
51
52 values and missingness patterns will be explored and analysis will be adjusted accordingly
53
54 using multiple imputation strategies (based on heteroscedastic two-level linear models
55
56 considering the metric of outcome). The analysis will follow the intention-to-treat principle. In
57
58 addition, per-protocol analyses will be conducted. The primary outcome as well as all other
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3 continuous outcomes will be analyzed based on Hierarchical Linear Models (HLM) considering
4 cluster structure and baseline values. Binary outcomes will be analyzed using Mixed Logistic
5 Regression Models. Moderator and mediator analyses will be performed to determine
6 differential effects with respect to key sociodemographic and medical variables.
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13 The effect of study participation will also be measured (participation rate at T1-3) in order to
14 be able to make statements about the transferability of the results from the present randomized
15 study to routine care without research support.
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21 **2.9.2 Health economic evaluation**

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23 In the health economic evaluation, an incremental cost-utility analysis (ICUA) is performed
24 from the societal perspective, as well as from the perspective of the German statutory pension
25 insurance (SPI) according to the net benefit approach (78,120). The necessary maximum
26 willingness to pay (MWTP) for a clinical improvement of depressive symptoms by 50% (=
27 response) and for the gain of a quality-adjusted life year (QALY) is determined. The estimation
28 of the stochastic uncertainty is done by means of nonparametric bootstrapping, the
29 interpretation of the results is based on cost-effectiveness acceptance curves (121). These
30 provide information on how high the MWTP must be to be judged cost-effective with a
31 probability of 95%, or with what probability a pre-determined MWTP is judged to be cost-
32 effective (120). Following international guidelines, a value range of the MWTP between 0 and
33 1250,000 € is chosen (122,123). The analysis of the health economic relevance of moderator
34 and mediator variables is performed by means of net benefit regression models for net benefit
35 ratios between 0 and 1250,000€ (124–127). The analysis from the macroeconomic perspective
36 considers all direct and indirect disease costs (128), the analysis from the perspective of the SPI
37 takes into account the disease costs to be borne by the SPI (e.g. for medical rehabilitation
38 services) as well as the costs for the testing platform to be borne by the SPI.
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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.

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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

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3 organizations in the context of research on Computer-adaptive Testing and Patient Reported
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5 Outcome Systems.
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18 **8 Figures**

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21 Figure 1. Flow chart

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24 Figure 2. Procedure

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27 Figure 3. Features

28 **9 Tables**

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31 Table 1. Assessments

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For peer review only

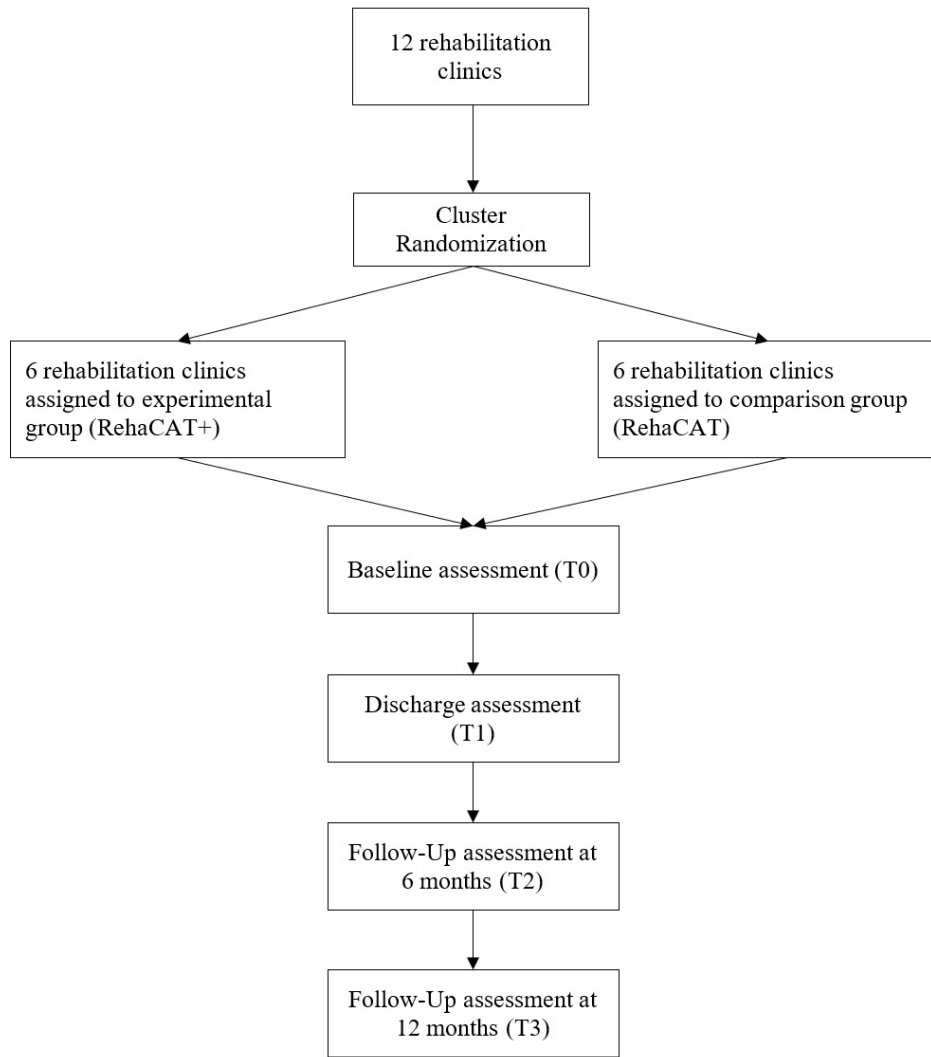


Figure 1. Flow chart

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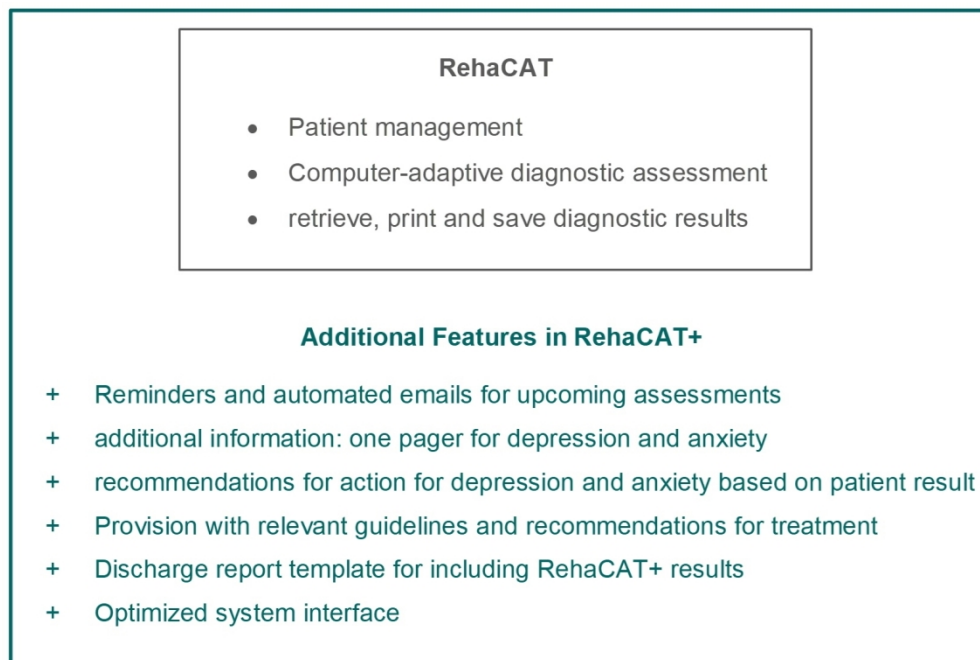


Figure 3. Features

141x94mm (300 x 300 DPI)

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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

1
2 und dabei helfen, künftige Behandlungen für Rehabilitand:innen wie Sie effektiver zu gestalten. Dabei werden
3 sensible Daten zu Ihrer Gesundheit erfasst.

4 Basierend auf unseren Erfahrungen schätzen wir den zeitlichen Mehraufwand für Sie auf ca. 20 Minuten je
5 Befragung. Zusätzlich befragen wir Sie 12 Monate nach der Rehabilitation, womit insgesamt vier Befragungen
6 auf Sie zukommen.
7

8 **ENTGELT**

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

13 **UMGANG MIT IHREN DATEN**

14 Im Rahmen der Studie werden Ihre Daten von der Abteilung Klinische Psychologie und Psychotherapie am
15 Institut für Psychologie und Pädagogik Universität Ulm verwendet. Es haben nur diejenigen Personen innerhalb
16 der Universität Zugriff auf Ihre pseudonymisierten Daten, die dies für einen ordnungsgemäßen Ablauf der Stu-
17 die benötigen. Nach Abschluss der Studie wird die Kodierliste, welche Ihren Namen zu ihrer Reha-ID zuordnen
18 und nur in ihrer Klinik vorliegt, gelöscht. Danach sind die Daten anonymisiert und es kann kein Personenbezug
19 mehr hergestellt werden. Wissenschaftliche Veröffentlichungen erfolgen mit diesen anonymisierten Daten über
20 viele Studienteilnehmende hinweg. Eine mögliche Weitergabe der anonymisierten Daten an Dritte beschränkt
21 sich auf wissenschaftliche Nutzungszwecke. Zu keinem Zeitpunkt können Krankenversicherungen/ Leistungs-
22 erbringer oder Arbeitgeber individualisierte Studiendaten einsehen. Nach der 6 und 12 Monatsbefragung möch-
23 ten wir Ihnen jeweils eine Aufwandsentschädigung elektronisch überweisen.
24

25 Dazu werden wir nach Abschluss der Befragung Ihre IBAN, Name und Reha-ID erfassen. Ihre Bankdaten wer-
26 den nicht mit den Gesundheitsdaten verknüpft und abgespeichert. Ihre Bankdaten Daten werden nach der
27 elektronischen Überweisung der Vergütung unmittelbar gelöscht. Die Angabe Ihrer Bankdaten ist freiwillig. Soll-
28 ten Sie keine Aufwandsentschädigung erhalten möchten, brauchen Sie Ihre Daten nicht angeben.
29

30 **GIBT ES RISIKEN DURCH DIE TEILNAHME AN DER STUDIE REHACAT+?**

31 Nebenwirkungen oder unerwünschte Wirkungen von Online Befragung oder ähnlicher Studien sind nicht be-
32 kannt. Manche der Aufgaben oder Fragen sind möglicherweise schwierig zu beantworten oder umzusetzen.
33 Die Erfahrung, sich Ängsten oder unangenehmen Gedanken zu stellen, ist für die meisten Menschen zunächst
34 nicht leicht, dann aber oft sehr hilfreich. Zusätzlich stehen Ihnen bei Bedarf zuständiges Klinikpersonal Als
35 Ansprechpartner/in zur Verfügung und werden versuchen, Ihnen zu helfen.
36

37 **FREIWILLIGKEIT:**

38 An dieser Studie nehmen Sie freiwillig teil. Ihr Einverständnis können Sie jederzeit und ohne Angabe von Grün-
39 den widerrufen, dann werden alle bis dahin studienbedingt erhobenen personenbezogenen Daten gelöscht.
40 Dieser eventuelle Widerruf hat keine Auswirkungen für Sie. Zur Löschung der Daten müssen Sie dem For-
41 schungsteam Ihre Reha-ID mitteilen. Dafür können Sie sich jederzeit an die Supportmail Adresse
42 (RehaCAT@uni-ulm.de) wenden, sowie während ihres Aufenthalts in der Klinik das Anliegen an Klinikmitarbei-
43 tende herantragen, welche wiederum die Reha-ID an das Forschungsteam weiterleiten. Es können nur alle
44 Daten gelöscht werden. Das Löschen einzelner Fragebögen ist nicht möglich.
45

46 **ERREICHBARKEIT DER STUDIENMITARBEITER:**

47 Sollten während des Verlaufes der Studie Fragen auftauchen, so können Sie jederzeit folgende Ansprechpartner
48 erreichen:
49

50 Yannik Terhorst
51 Universität Ulm
52 Institut für Psychologie und Pädagogik
53 Abteilung für Klinische Psychologie und Psychotherapie
54 Lise-Meitner-Straße 16, D-89081 Ulm
55 Telefon: +49 731/50 32820
56 E-Mail: yannik.terhorst@uni-ulm.de
57

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

1
2 Telefon: +49 731/50 32805
3 E-Mail: Johannes.knauer@uni-ulm.de
4

5 **VERSICHERUNG:**

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

9 Einen Schaden, der Ihrer Meinung nach auf diese Studie zurückzuführen ist, melden Sie bitte unverzüglich dem
10 Studienleiter.
11

12 **SCHWEIGEPFLICHT/DATENSCHUTZ:**

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

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

22 Yannik Terhorst
23 Universität Ulm
24 Institut für Psychologie und Pädagogik
25 Abteilung für Klinische Psychologie und Psychotherapie
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27 Telefon: +49 731/50 32820
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36 E-Mail: Johannes.knauer@uni-ulm.de
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38
39 Bei Fragen zur Nutzung oder Verarbeitung Ihrer Daten wenden Sie sich bitte an den/die:

- 40 • Datenschutzbeauftragte/n des lokalen Studienzentrums
41 (a) *Universität Ulm: Universität Ulm, Helmholtzstr. 16, 89081 Ulm, Tel.Nr.: 07542 / 949 21 09,*
42 E-Mail: dsb@uni-ulm.de
43

44 Falls Sie Bedenken oder Beschwerden hinsichtlich der Verarbeitung Ihrer Daten haben, wenden Sie sich bitte
45 an die Datenschutz-Aufsichtsbehörde Ihres Studienzentrums: Die entsprechenden Kontaktdaten finden Sie auf
46 der Internetseite des Landesbeauftragten für Datenschutz und Informationsfreiheit Baden-Württemberg:
47 <https://www.baden-wuerttemberg.datenschutz.de/dsb-online-melden/>
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Faculty of Engineering, Computer Science and Psychology
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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

1
2 und zur Verfügung gestellt. Eine Kopie dieser Einwilligungserklärung können Sie jederzeit über den Menü-
3 punkt „Informationen“ herunterladen oder vom Personal Ihrer Rehabilitationsklinik erhalten.
4

5 Ich habe die allgemeinen Informationen zur Studie „RehaCAT+“ gelesen und willige in die Teilnahme an der
6 Studie und die damit verbundene Datenverarbeitung ein.
7

8 JA NEIN
9

10
11 **[Weiter Button erscheint erst, nach aktiver Bestätigung dieses und der Bestätigung zur Datenverarbeitung**
12 **– die Einwilligung ist rein digital]**
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For peer review only

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 SPIRIT reporting 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

1	Roles and	#5b	Name and contact information for the trial sponsor	23
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	23
8	responsibilities:		collection, management, analysis, and interpretation of data;	
9	sponsor and funder		writing of the report; and the decision to submit the report for	
10			publication, including whether they will have ultimate authority	
11			over any of these activities	
12				
13				
14				
15	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	19
16	responsibilities:		centre, steering committee, endpoint adjudication committee,	
17	committees		data management team, and other individuals or groups	
18			overseeing the trial, if applicable (see Item 21a for data	
19			monitoring committee)	
20				
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23				
24	Introduction			
25				
26	Background and	#6a	Description of research question and justification for undertaking	4
27	rationale		the trial, including summary of relevant studies (published and	
28			unpublished) examining benefits and harms for each intervention	
29				
30				
31	Background and	#6b	Explanation for choice of comparators	6
32	rationale: choice of			
33	comparators			
34				
35				
36	Objectives	#7	Specific objectives or hypotheses	6
37				
38				
39	Trial design	#8	Description of trial design including type of trial (eg, parallel	8
40			group, crossover, factorial, single group), allocation ratio, and	
41			framework (eg, superiority, equivalence, non-inferiority,	
42			exploratory)	
43				
44				
45				
46	Methods:			
47	Participants,			
48	interventions, and			
49	outcomes			
50				
51				
52	Study setting	#9	Description of study settings (eg, community clinic, academic	9
53			hospital) and list of countries where data will be collected.	
54			Reference to where list of study sites can be obtained	
55				
56				
57				
58	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	9
59				
60				

eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

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3			
4	Interventions:	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
5	description		10
6			
7			
8	Interventions:	#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)
9	modifications		n/a
10			
11			
12			
13	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)
14	adherence		10
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18	Interventions:	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
19	concomitant care		9
20			
21			
22	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
23			13
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32	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)
33			8,9
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37	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
38			11
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43	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size
44			9
45			
46			
47	Methods: Assignment		
48	of interventions (for		
49	controlled trials)		
50			
51			
52	Allocation: sequence	#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
53	generation		10
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		enrol participants or assign interventions	
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2	Allocation	#16b Mechanism of implementing the allocation sequence (eg, central	10
3	concealment	telephone; sequentially numbered, opaque, sealed envelopes),	
4	mechanism	describing any steps to conceal the sequence until interventions	
5		are assigned	
6			
7			
8	Allocation:	#16c Who will generate the allocation sequence, who will enrol	10
9	implementation	participants, and who will assign participants to interventions	
10			
11	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg, trial	10
12		participants, care providers, outcome assessors, data analysts),	
13		and how	
14			
15	Blinding (masking):	#17b If blinded, circumstances under which unblinding is permissible,	n/a
16	emergency unblinding	and procedure for revealing a participant's allocated intervention	
17		during the trial	
18			
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23	Methods: Data		
24	collection,		
25	management, and		
26	analysis		
27			
28	Data collection plan	#18a Plans for assessment and collection of outcome, baseline, and	19
29		other trial data, including any related processes to promote data	
30		quality (eg, duplicate measurements, training of assessors) and a	
31		description of study instruments (eg, questionnaires, laboratory	
32		tests) along with their reliability and validity, if known.	
33		Reference to where data collection forms can be found, if not in	
34		the protocol	
35			
36	Data collection plan:	#18b Plans to promote participant retention and complete follow-up,	10
37	retention	including list of any outcome data to be collected for participants	
38		who discontinue or deviate from intervention protocols	
39			
40			
41	Data management	#19 Plans for data entry, coding, security, and storage, including any	19
42		related processes to promote data quality (eg, double data entry;	
43		range checks for data values). Reference to where details of data	
44		management procedures can be found, if not in the protocol	
45			
46			
47	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	20
48		outcomes. Reference to where other details of the statistical	
49		analysis plan can be found, if not in the protocol	
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1	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and adjusted	21
2	analyses		analyses)	
3				
4	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	20
5	population and missing		adherence (eg, as randomised analysis), and any statistical	
6	data		methods to handle missing data (eg, multiple imputation)	
7				
8				
9				
10	Methods: Monitoring			
11				
12	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary of	19
13	formal committee		its role and reporting structure; statement of whether it is	
14			independent from the sponsor and competing interests; and	
15			reference to where further details about its charter can be found,	
16			if not in the protocol. Alternatively, an explanation of why a	
17			DMC is not needed	
18				
19				
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21				
22	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines,	n/a
23	interim analysis		including who will have access to these interim results and make	
24			the final decision to terminate the trial	
25				
26				
27	Harms	#22	Plans for collecting, assessing, reporting, and managing solicited	n/a
28			and spontaneously reported adverse events and other unintended	
29			effects of trial interventions or trial conduct	
30				
31				
32				
33	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	n/a
34			whether the process will be independent from investigators and	
35			the sponsor	
36				
37				
38	Ethics and			
39	dissemination			
40				
41				
42	Research ethics	#24	Plans for seeking research ethics committee / institutional review	22
43	approval		board (REC / IRB) approval	
44				
45				
46	Protocol amendments	#25	Plans for communicating important protocol modifications (eg,	n/a
47			changes to eligibility criteria, outcomes, analyses) to relevant	
48			parties (eg, investigators, REC / IRBs, trial participants, trial	
49			registries, journals, regulators)	
50				
51				
52				
53	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial	9
54			participants or authorised surrogates, and how (see Item 32)	
55				
56				
57	Consent or assent:	#26b	Additional consent provisions for collection and use of	n/a
58	ancillary studies		participant data and biological specimens in ancillary studies, if	
59				
60				

		applicable	
1			
2	Confidentiality	#27 How personal information about potential and enrolled	19
3		participants will be collected, shared, and maintained in order to	
4		protect confidentiality before, during, and after the trial	
5			
6			
7	Declaration of interests	#28 Financial and other competing interests for principal	23
8		investigators for the overall trial and each study site	
9			
10			
11	Data access	#29 Statement of who will have access to the final trial dataset, and	19
12		disclosure of contractual agreements that limit such access for	
13		investigators	
14			
15			
16	Ancillary and post trial	#30 Provisions, if any, for ancillary and post-trial care, and for	n/a
17	care	compensation to those who suffer harm from trial participation	
18			
19			
20	Dissemination policy:	#31a Plans for investigators and sponsor to communicate trial results	23
21	trial results	to participants, healthcare professionals, the public, and other	
22		relevant groups (eg, via publication, reporting in results	
23		databases, or other data sharing arrangements), including any	
24		publication restrictions	
25			
26			
27			
28	Dissemination policy:	#31b Authorship eligibility guidelines and any intended use of	n/a
29	authorship	professional writers	
30			
31			
32	Dissemination policy:	#31c Plans, if any, for granting public access to the full protocol,	19
33	reproducible research	participant-level dataset, and statistical code	
34			
35			
36			
37	Appendices		
38			
39	Informed consent	#32 Model consent form and other related documentation given to	supplement
40	materials	participants and authorised surrogates	
41			
42			
43	Biological specimens	#33 Plans for collection, laboratory evaluation, and storage of	n/a
44		biological specimens for genetic or molecular analysis in the	
45		current trial and for future use in ancillary studies, if applicable	
46			
47			

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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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-061259.R1
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4 **Effectiveness and cost-effectiveness of a web-based routine**
5 **assessment with integrated recommendations for action for**
6 **depression and anxiety (RehaCAT+): protocol for a cluster**
7 **randomized controlled trial for patients with elevated depressive**
8 **symptoms in rehabilitation facilities**
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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

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3 2021 ref. 509/20). Written informed consent will be obtained for all participants. Results will
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5 be published via peer reviewed journals.
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8 **Trial registration number** German Clinical Trials Register, DRKS00027447 (11.01.2022).
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14 **Keywords:** cluster randomized controlled trial, patient reported outcome, depression, computer
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16 adaptive testing, routine care
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19 20 21 22 **Strengths and limitations of this study** 23

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

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3 duration (15–17). Computer-adaptive testing (CAT), which is based on item response theory
4 models, is a promising option in this context to substantially reduce the burden on patients
5 (personalized testing) and health care institutions (e.g., immediate test evaluations) (10,18–23).
6
7 In CAT, the items providing the maximum information about the respective patient are selected
8 and assessed during test administration based on the previous answers of a patient (24). In this
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10 way, besides a considerable reduction in test duration, an estimation accuracy that is equally
11 good or sometimes even better compared to non-adaptive procedures can be achieved
12 (18,23,25–27).
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22 Whereas PROMs are often used in clinical research, the usefulness and effectiveness of routine
23 PROM assessment in somatic health care is still controversially discussed (8,28–33). On the
24 one hand, routine PROMs allow for real-time monitoring. Moreover, PROMs have been shown
25 to lead to improved communication between clinician and patient, decision-making and patient
26 satisfaction with care, and improved health outcome and detection of symptoms and mental
27 comorbidities. On the other hand, there are barriers such as limited ability of clinicians for score
28 interpretation, unfamiliarity with PROM software usage and less time for controlling (8,23,31–
29 42). Additionally one of the central challenges is the implementation of further evidence-based
30 measures on the basis of the assessment results (43). Action plans directly derivable from
31 assessment results are regarded as a prerequisite to implement PROMs beneficially
32 (31,33,44,45). However, there is still an insufficient linkage between assessment results and
33 implementation of existing evidence-based guidelines and recommendations for action in
34 everyday clinical practice (33,46).
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52 One way to promote the desired probability of action following diagnostic results could be
53 persuasive design components, such as reminder features that are automatically triggered
54 depending on the test environment (47–49). Persuasive designed technological approaches are
55 defined as interactive systems that purposefully influence the user, aiming to change behavior
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3 or attitudes (50). The provision of computer-based databases and concrete decision-making aids
4 and recommendations for action is seen as one way of reducing these existing barriers (51,52).
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6 In this context, it could be useful to link the individual test results with therapy standards as
7
8 well as recommendations for action and guideline knowledge. These have been formulated in
9
10 particular for the areas of comorbid depression and anxiety in patient populations with somatic
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12 diseases (53–57). Such a combination could offer the practitioner a) background knowledge, b)
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14 recommendations for action as well as c) documentation aids. Ideally, such elements should be
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16 directly integrated into testing systems (e.g., web- and CAT-based) to provide a comprehensive
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18 platform from screening to action.
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24 Hence, the aim of the present trial is to examine a persuasive design optimized CAT system
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26 (RehaCAT+) providing background knowledge, recommendations for action as well as
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28 documentation aids against a standard CAT system (RehaCAT). This will be exemplified with
29
30 a focus on depression as the primary outcome and anxiety as major mental health comorbidities
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32 in cardiological and orthopedic care. The following research questions will be addressed:
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37 1) Does RehaCAT+ improve rehabilitation patients' depression after one year (T3)?
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40 2) Does RehaCAT+ improve depression, anxiety, satisfaction with participation in social
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42 roles and activities, pain impairment, fatigue, sleep, health-related quality of life, self-efficacy,
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44 physical function, and alcohol use at discharge (T1) and six months follow-up (T2) as well as
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46 one year later regarding all the secondary outcomes (T3)?
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50 3) Does RehaCAT+ lead to improved documentation and improved follow-up and post-
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52 rehabilitation recommendations?
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56 4) Does RehaCAT+ lead to improved utilization of rehabilitation therapy standard and
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58 guideline compliant health care services during and after rehabilitation?
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- 3 5) What is the cost-effectiveness of RehaCAT+ compared to RehaCAT?
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- 6 6) What is the acceptance and feasibility of RehaCAT?
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- 10 7) What are facilitators, hindering factors, mediators and potential risks associated with
- 11 RehaCAT+?
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15 A web-based CAT system provides a powerful way to assess PROM, however, it is still subject
16 to limitations: 1) it requires active input of the patient – even if reduced through computer
17 adaptive testing, 2) the assessment is limited to fixed time points, which may lead to long
18 unassessed time intervals in which significant symptom change may occur, and 3) due to the
19 nature of self-report the answers by patients may be biased (e.g., social desirability or recall
20 bias) (58–61).
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30 One solution to this could be the addition of ecological momentary assessment and smart
31 sensing to allow for digital phenotyping (62,63). Digital phenotyping is defined as the moment-
32 by-moment quantification of the individual health in situ through digital variables and data
33 generated by personal devices (e.g., smartphone or smart-watch) (62,63). First studies show
34 promising results highlighting the potential of this method to complement PROM assessments
35 for monitoring and predicting symptoms with minimal added patient burden (64–70). In future
36 the combination of high quality PROM at fixed timepoints combined with continuous
37 monitoring through smart sensing and information from the clinical information system could
38 become a promising data base, which could be used to 1) predict symptom trajectories, 2) build
39 early-detection of adverse events systems (RED-flag) or 3) personalized treatment
40 recommendation systems (71–74).
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55 Hence, the present study additionally investigates the extent to which smart sensing is suitable
56 for assessing mental health in a routine care setting. In the context of this exploratory study, we
57 will focus on the following research questions:
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3 8) What are the associations between digital markers and health-related variables?
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6 9) Are digital markers suitable for predicting health-related variables and disease or
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8 disorder status?
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12 10) What is patient acceptance, adherence, and perceived usefulness of smart sensing?
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15 **Methods and analysis**

16 **Study design**

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21 A two-arm, pragmatic, cluster-randomized controlled trial (cRCT) will be conducted,
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23 comparing the experimental group receiving an enhanced version of a PROM system called
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25 "RehaCAT+" to the control group receiving the basic version of the PROM system called
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27 "RehaCAT" in a 1:1 design (Figure 1). See below for detailed description of the experimental
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29 and control group.
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34 -----insert Figure 1 about here-----
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37 This cRCT has been approved by the ethics committee of Ulm University (509/20 – FSt/Sta)
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39 and will be reported in accordance with the Consolidated Standards of Reporting Trials
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41 (CONSORT) Statement 2010 and the extensions for reporting pragmatic trials and cluster
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43 randomized trials (75–77). Cost-effectiveness analyses will be reported following the
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45 Consolidated Health Economic Evaluation Reporting Standards statement (CHEERS) (78) and
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47 the guidelines from the International Society for Pharmacoeconomics and Outcomes Research
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49 (ISPOR) (79). This trial protocol was created according to SPIRIT guidelines (80). The trial
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51 has been registered in the German clinical trial register under DRKS00027447. The expected
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53 timeline for trial completion is September 2024 with first patient enrolment in July 2022.
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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 (see 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

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3 the respective version of the testing system to deliver patient-reported outcomes at various
4 points in time. A subset of patients in routine care fulfilling the inclusion criteria (see 2.1.1)
5 will be included in the present study. Study participants will receive all questionnaires from
6 routine care and additional research questionnaires. Routine patients will go through the
7 diagnostic measures at admission (T0) and before discharge (T1), as well as at six months (T2)
8 follow-up as part of their clinical routine. Study participants will additionally be assessed at
9 twelve-months (T3) follow up.
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20 Data collection will be digital. Due to the web-based character of the platform, in- and
21 outpatient assessments are possible. Clinics are free to implement the admission and discharge
22 assessments as in- or outpatient assessments. Data for follow-up will be assessed solely in an
23 outpatient setting. Assessment procedures (e.g., in- or outpatient assessment at admission) are
24 expected to vary across clinics and will be further described post-hoc. For an explanatory
25 illustration of the assessment procedures see Figure 2.
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35 -----insert Figure 2 about here-----
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38 **Inclusion and exclusion criteria**

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41 Since this is a cRCT, inclusion and exclusion are differentiated at two levels a) cluster level
42 (i.e., eligibility of clinics) and b) patient level: To be eligible, rehabilitation clinics must be
43 located in Germany, provide cardiological or orthopedic rehabilitation and sign a cooperation
44 agreement with Ulm University. There are no further exclusion criteria for clinics. Within each
45 cluster (i.e., rehabilitation clinic) patients who exhibit elevated depression scores (PROMIS
46 Emotional Distress Depression: T-value ≥ 65.2) (15) at the initial assessment will be informed
47 about the study and consecutively asked for their participation consent (Supplemental Material:
48 SPIRIT Supplement Informed Consent). To be eligible, patients with elevated depression scores
49 must a) be 18 years or older, b) have sufficient German language skills, c) provide an e-mail
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3 address, d) agree to the data privacy and processing procedures according to the European
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5 General Data Protection Regulation, and e) sign the informed consent. There are no further
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7 exclusion criteria for patients.
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10 11 **Randomization, allocation, and masking**

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14 Randomization and allocation regarding the control (RehaCAT) and experimental group
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16 (RehaCAT+) of the 12 participating rehabilitation clinics will be performed by an independent
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18 researcher to avoid selection bias. Randomization will be done on cluster-level.
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22 Researchers responsible for randomization will be obscured to the rehabilitation clinic names
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24 and agencies. Randomization will be done using an automatically created randomization list.
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28 For the outcome analyses the conducting analyst will be obscured to group allocation. Patients
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30 will remain obscured to their study arm assignment. Neither the clinics (clinic personnel) nor
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32 the research team will be obscured to assigned study condition.
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34 35 **Conditions**

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38 RehaCAT-Control Group: RehaCAT is a server- and web-based, device-independent test
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40 system, which allows the use of classical test procedures as well as Computer-adaptive
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42 procedures. RehaCAT does not interfere with the (clinic specific) standard treatment and
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44 patients have unrestricted access to treatment as usual (TAU). RehaCAT is divided into four
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46 user areas: 1) patient, 2) staff, 3) administrator, 4) researcher. The platform allows system
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48 administrators to upload and manage patients. Patients go through the diagnostic measures.
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50 Clinicians can view the test results of their patients immediately after completion of each
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52 assessment point (T0, T1 and T2). Test results consist of a traffic light feedback (green = normal
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54 severity, yellow = elevated severity based on clinical cut-off values, red = high severity 2.5 SDs
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56 above mean (15,83)), patients' test results expressed in T-values combined with clinical cut-off
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3 values, and a line graph visualizing the results and change over assessment times. For a full
4
5 overview of the assessment see 2.5.1 and 2.5.2.
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9 RehaCAT+-Experimental Group: In addition to the structure and features of RehaCAT,
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11 RehaCAT+ follows a persuasive design optimized technology (e.g., motivation, ability, and
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13 automatic trigger considering test environment) (47,48) to increase the desired probability of
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15 action. RehaCAT+ offers additional (1) system features (automated e-mail reminders for
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17 patients), (2) clinician features (stored recommendations for action for depression and anxiety
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19 based on respective patient results, call to action plans, individualized documentation aids and
20
21 supporting information material for depression and anxiety), and (3) patient features (individual
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23 symptomatic information at discharge and T2/3, possible points of contact/help).
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28 The urgency of the recommendation for action (i.e., need for in-depth psychodiagnostics) varies
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30 depending on screening severity. Additionally, material on handling of psychological burden
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32 can be accessed. The material is based on: a) the rehabilitation therapy standards and framework
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34 concepts (84–87), b) the practice recommendations for orthopedic and cardiological
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36 rehabilitation (54,55), c) the recommendations for psychodiagnostics in somatic rehabilitation
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38 (53), and e) the national S3 guidelines for depression (56) and anxiety (57). A summary of the
39
40 two conditions is provided in Figure 3.
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51 The clinics will be compensated with 100€ per recruited patient for the resulting hospital
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53 expenses in the context of participant recruitment, data collection, study documentation as well
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55 as provision of the discharge reports. Study patients will receive an expense allowance of 20€
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57 each for their participation in the T2 and T3 measurements.
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3 RehaCAT(+) is developed as an open-source platform. It is currently in the certification process
4 according to the medical device regulation. The platform is developed according to the
5 requirements of the German Medical Devices Act and the Medical Device Regulation (MDR).
6 Hence, the software development and validation process is taking the IEC 62304 (safety class
7 B), the GAMP5 (category 4), the General Principles of Software Validation of the FDA as well
8 as the Pharmaceutical Inspection Cooperation Scheme (PIC/S) 11-3 into account. Furthermore,
9 technical requirements and standards for the interoperability between different medical devices
10 (e.g. HL7 FHIR) are under development. The certification process of the platform is planned to
11 be completed in 2022.
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25 **Sample size and study power**

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28 The sample size calculation is based on the primary outcome, depression severity 12 months
29 after the end of rehabilitation. It is assumed that the experimental group is superior to the control
30 group in the way that patients will show fewer depressive symptoms at twelve-months follow-
31 up. In view of the additive study design testing for incremental benefit of RehaCAT+ over
32 RehaCAT and the distal outcome, a small additional effect of $d = .24$ compared to the standard
33 condition is regarded as clinically significant following the recommendation of Cuijpers et al.
34 (88). With 2*6 cluster-randomized rehabilitation clinics, each clinic requires a sample of 110
35 (SD = 25) participating rehabilitants with elevated depression scores to achieve a test power of
36 80% given an alpha error (two-sided) of .05, an estimated ICC of .02 (89,90), and an assumed
37 correlation with baseline depression scores of .50. With an estimated drop-out rate
38 (rehabilitation start-end) of 20% (91) and the assumption of a doubling drop-out rate by T3, a
39 total sample of $N=1,848$ rehabilitants is required.
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55 **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

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3 roles and participate in social activities. All items are phrased in terms of perceived limitations
4 and answered using a five-point response scale. Reliability was estimated to be $\alpha > 0.90$ (94).
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8 Pain impairment will be assessed with the computer-adaptive PROMIS Pain Interference Item
9 Set including 40 items that capture self-assessment of the consequences of pain in one's life.
10 This includes the extent to which pain interferes with engagement in social, cognitive,
11 emotional, physical, as well as leisure activities (95). The items refer to the past seven days and
12 are rated on three different five-point Likert scales. The internal consistency of the item set was
13 found to be good (95).
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23 Fatigue will be assessed with the computer-adaptive PROMIS Fatigue Scale comprising 95
24 items and measures both fatigue experience and the impact of fatigue on daily life and
25 functionality. The intensity, frequency, and duration of fatigue were graded on a five-point
26 response scale. Reliability was estimated to be $\alpha > 0.90$ (96).
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33 Sleep will be assessed with the computer-adaptive PROMIS Sleep Dimension that measures
34 subjective sleep quality and quantity and sleep-related impairment in daily functioning. The
35 scale comprises 27 items and is rated on a response scale from 1 (not at all or never) to 5 (very
36 much or always). It is a validated instrument and has good psychometric properties with
37 $\alpha > 0.90$ (97,98).
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46 Health-related quality of life will be assessed with the PROMIS scale on global health aspects
47 (Global Health) is used. The scale includes 10 items that capture global physical health
48 (physical health, physical functioning, fatigue, pain), and global mental health (general quality
49 of life, mental health, satisfaction with social activities and relationships, and emotional
50 distress) (99). Nine items are scored on a response scale of 1 to 5, and the item assessing pain
51 is scored from 0 to 10. Internal consistency was estimated to be good with $\alpha > 0.82$ (Katzan &
52 Lapin, 2018).
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3 Self-efficacy will be assessed with the short scale of the PROMIS General Self-Efficacy Scale
4 which contains 4 items. It can be used to assess how much confidence one has in one's own
5 abilities to master tasks and situations. Items are rated on a response scale from 1 (I am not at
6 all confident) to 5 (I am very confident). Internal consistency was estimated to be high ($\alpha =$
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12 0.96) (100,101).

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14
15 Physical function will be assessed using the computer-adaptive PROMIS Physical Function
16 Item Set that measures the ability to perform daily life activities that require physical activity
17 such as walking or lifting objects. It comprises 164 items that are assessed on a 5-point scale
18 ranging from 1 (Without any difficulty) to 5 (Unable to do). Internal consistency was found to
19 be very good with $\alpha > 0.88$ (102).

20
21
22 Alcohol use will be assessed with the AUDIT-10 (Alcohol Use Disorders Identification Test)
23 which is a 10-item questionnaire developed by the WHO as a screening tool for hazardous and
24 harmful alcohol use. Responses to each question are scored from 0 to 4, allowing a maximum
25 of 40 points. Reliability has been investigated in some studies and is considered good with a
26 median of $\alpha = 0.80$ (103).

27
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29 Discharge reports will be analyzed regarding a) frequency of documented screening results, b)
30 therapy standard and guideline appropriate therapeutic services (documented services / therapy
31 standard recommendations as a function of depression and anxiety results), c) therapy standard
32 and guideline appropriate follow-up and post-rehabilitation recommendations (documented
33 recommendations / therapy standard/guideline recommendations as a function of depression
34 and anxiety results).

54 55 **Moderators**

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58 As potential moderators, socio-demographic data (age, gender, nationality) and personality will
59 be recorded at admission (T0). Personality will be assessed with the BFI-10 (Big Five Inventory
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3 – 10), a short version of the Big Five Inventory that has good psychometric properties and a
4
5 retest-reliability of $\alpha = 0.73$ (104). Additionally, data from medical records will be used as
6
7 moderators (e.g. indication area orthopedic or cardiologic, chronic conditions, rehabilitation
8
9 duration, etc.).
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11

12 13 **Health economics** 14

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16 Generic quality of life will be assessed with the EQ5D-5L (European Quality of Life 5
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18 Dimension - 5 Level Questionnaire) from the EuroQol foundation (www.euroqol.org) (105).
19
20 The five dimensions surveyed are mobility, self-care, general activities, pain/physical
21
22 discomfort, and anxiety/dejection. Each of the five areas is ranked on a five-point scale. Based
23
24 on the answers, the respective health status is recorded (106).
25
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28 Health and social services use and costs will be assessed with the CSSRI (Client
29
30 Sociodemographic and Service Receipt Inventory) which is a standardized but adaptable
31
32 inventory. Five domains are queried, including sociodemographic information, usual living
33
34 situation, income and employment status, use of mental health services, and medication
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36 treatment (107).
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39 40 41 **Usage behavior, acceptance, facilitating and hindering factors** 42

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44 Questions about usage behavior, potential risks of the platforms, as well as barriers and
45
46 facilitators to implementation, will be elicited based on qualitative semi-structured interviews
47
48 conducted with both patients and clinic staff centrally involved in the implementation of
49
50 RehaCAT and RehaCAT+. The semi-structured interviews will be conducted with the help of
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52 an interview guide based on existing instruments of previous studies (53,108).
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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

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3 Application Rating Scale (uMARS) (113). Both questionnaires will be assessed once after 6
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5 months before deinstalling the application.
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9 The following clinical questionnaires will be assessed every two weeks: Depression
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11 (dimensional and categorical) with the PHQ-8 (if PHQ-2 score > 2) (114–116); anxiety with
12
13 the GAD-7 (117); stress with the PSS-10 (118); sleep with the ISI-7 (119); loneliness with the
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15 UCLA 3 item version (120).
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19 Every morning, participants will be asked short questions about mood (valence), drive
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21 (arousal), control, unpredictability, stress and sleep, at midday about mood (valence), drive
22
23 (arousal), control, unpredictability, and stress, and in the evening, participants are again asked
24
25 about mood (valence), drive (arousal), control, unpredictability, stress, and activity during the
26
27 day. This assessment is based on previous studies (65,68,121,122).
28
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30 31 **Passive outcomes** 32 33

34 The research app allows to track a broad range of sensors (accelerometer, application usage,
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36 barometer, battery, Bluetooth, communication, gravity, gyroscope, light, locations,
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38 magnetometer, network, proximity, rotation, screen sensor). However, each user will be able to
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40 freely decide which sensors are activated and access permissions can always be activated and
41
42 deactivated without giving reasons. In addition, sensible location data (e.g., GPS coordinates)
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44 will be obscured, so pseudonymization can be upheld all the time.
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49 The following digital markers can be collected (depending on permissions of user): frequency
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51 and duration of smartphone and individual app usage, frequency and duration/length of calls
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53 and text messages, randomly distorted GPS, and type of movement.
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57 **Data management and data sharing plan** 58 59 60

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3 Data collection will be completed online using the server-based system RehaCAT(+) and the
4 research application in pseudonymized form. Retrieved data will be stored encrypted by
5 responsible employees. All data will be anonymized after completion of the trial. Furthermore,
6 an independent Data Safety and Monitoring Board (DSMB) with long-standing experience in
7 clinical trials has been established. The function of the DSMB is to monitor the course of the
8 study and, if necessary, give recommendations to the steering committee for discontinuation,
9 modification or continuation of the study.
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20 Individual participant data will be made available on request after de-identification beginning
21 12 months following article publication of the effectiveness paper. Data will be made available
22 to researchers who provide a methodologically sound proposal, not already covered by others.
23 Proposals should be directed to HB. Data requestors will need to sign a data access agreement.
24 Provision of data is subject to data security regulations. Investigator support depends on
25 available resources.
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35 **Measures to reduce methodological sources of error**

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38 Selection bias: Randomization and allocation regarding the group allocation (RehaCAT/
39 RehaCAT+) of the participating rehabilitation clinics will be done by an independent
40 researcher. Performance bias: Rehabilitation staff centrally involved in the implementation will
41 be trained along training materials, as well as continuously supervised regarding the training
42 materials. RehaCAT(+) and its application will be described in detail in a test manual.
43 Deviations from the test manual will be recorded and formatively reduced during the
44 implementation process of RehaCAT(+) in the individual clinics. Contamination bias: Cluster
45 randomization is used to avoid study arm contamination. Detection bias: rating procedures
46 (analysis of discharge reports) are performed by independent raters who are obscured to the
47 study arm affiliation of the clinics and thus the patients. Patients also remain obscured to their
48 study arm assignment, as the differentiation between RehaCAT and RehaCAT(+) is not obvious
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3 to them. Obscuring will not be realized for clinic personnel only. Reporting bias: A detailed
4 definition of all methodological aspects of the present clinical study is provided in this study
5 protocol, submitted for publication prior to randomization start. Evaluating representativeness:
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7 To assess the representativeness of the results, quantitative and qualitative analyses will be
8 performed regarding the reasons that may lead to a non-existent 100% exhaustion in the routine
9 assessment.
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18 **Statistical analyses**

19 **Clinical analyses**

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22 Study data will be centrally processed and analyzed by an independent researcher. Missing
23 values and missingness patterns will be explored and analysis will be adjusted accordingly
24 using multiple imputation strategies (based on heteroscedastic two-level linear models
25 considering the metric of outcome). The analysis will follow the intention-to-treat principle. In
26 addition, per-protocol analyses will be conducted. The primary outcome as well as all other
27 continuous outcomes will be analyzed based on Hierarchical Linear Models (HLM) considering
28 cluster structure and baseline values. Binary outcomes will be analyzed using Mixed Logistic
29 Regression Models. Moderator and mediator analyses will be performed to determine
30 differential effects with respect to key sociodemographic and medical variables.
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45 The effect of study participation will also be measured (participation rate at T1-3) in order to
46 be able to make statements about the transferability of the results from the present randomized
47 study to routine care without research support.
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53 **Health economic evaluation**

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56 In the health economic evaluation, an incremental cost-utility analysis (ICUA) will be
57 performed from the societal perspective, as well as from the perspective of the German statutory
58 pension insurance (SPI) according to the net benefit approach (78,123). The necessary
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3 maximum willingness to pay (MWTP) for a clinical improvement of depressive symptoms by
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5 50% (= response) and for the gain of a quality-adjusted life year (QALY) will be determined.
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7 The estimation of the stochastic uncertainty will be done by means of nonparametric
8
9 bootstrapping, the interpretation of the results is based on cost-effectiveness acceptance curves
10
11 (124). These provide information on how high the MWTP must be to be judged cost-effective
12
13 with a probability of 95%, or with what probability a pre-determined MWTP is judged to be
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15 cost-effective (123). Following international guidelines, a value range of the MWTP between
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17 0 and 1250,000 € is chosen (125,126). The analysis of the health economic relevance of
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19 moderator and mediator variables will be performed by means of net benefit regression models
20
21 for net benefit ratios between 0 and 1250,000€ (127–130). The analysis from the
22
23 macroeconomic perspective will consider all direct and indirect disease costs (131), the analysis
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25 from the perspective of the SPI will take the disease costs to be borne by the SPI (e.g. for
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27 medical rehabilitation services) as well as the costs for the testing platform to be borne by the
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29 SPI into account.
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36 **Qualitative data analysis**

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

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Competing interests

1
2
3 Authors of the manuscript were partly involved in the development of RehaCAT(+). HB has
4
5 been the beneficiary of study support (third party funding) from several public funding
6
7 organizations in the context of research on Computer-adaptive Testing and Patient Reported
8
9 Outcome Systems.
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19
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20 **Figures titles**

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23 **Figure 1. Flow chart**

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25 **Figure 2. Procedure**

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28 **Figure 3. Features**
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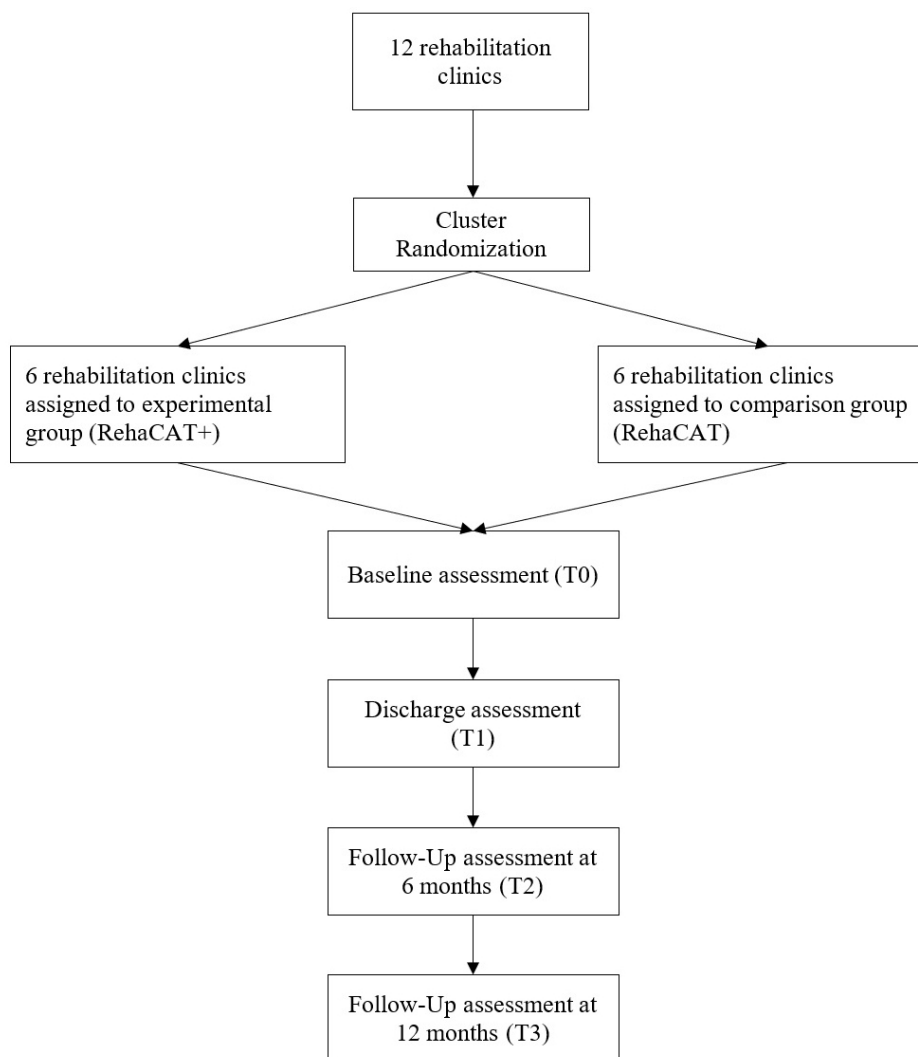


Figure 1. Flow chart

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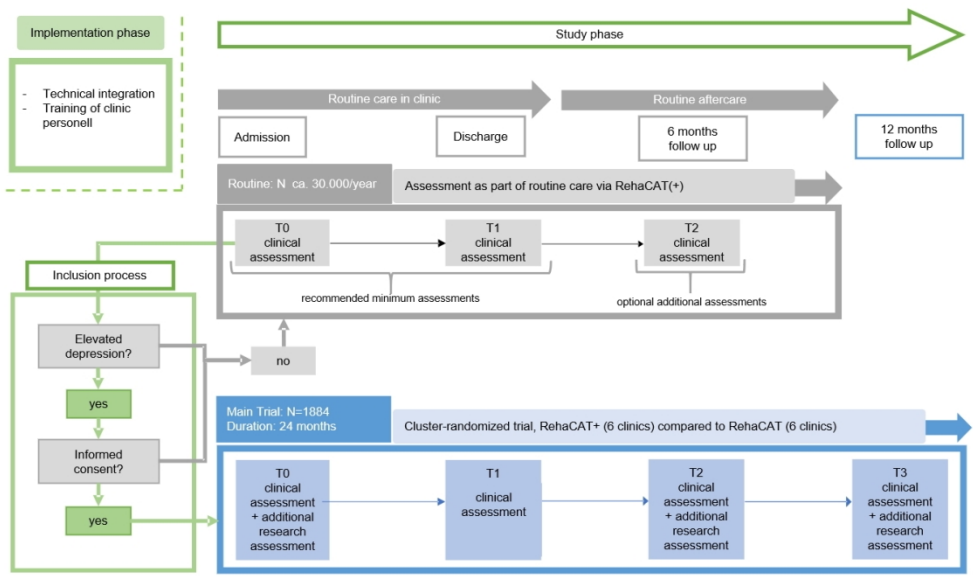


Figure 2. Procedure

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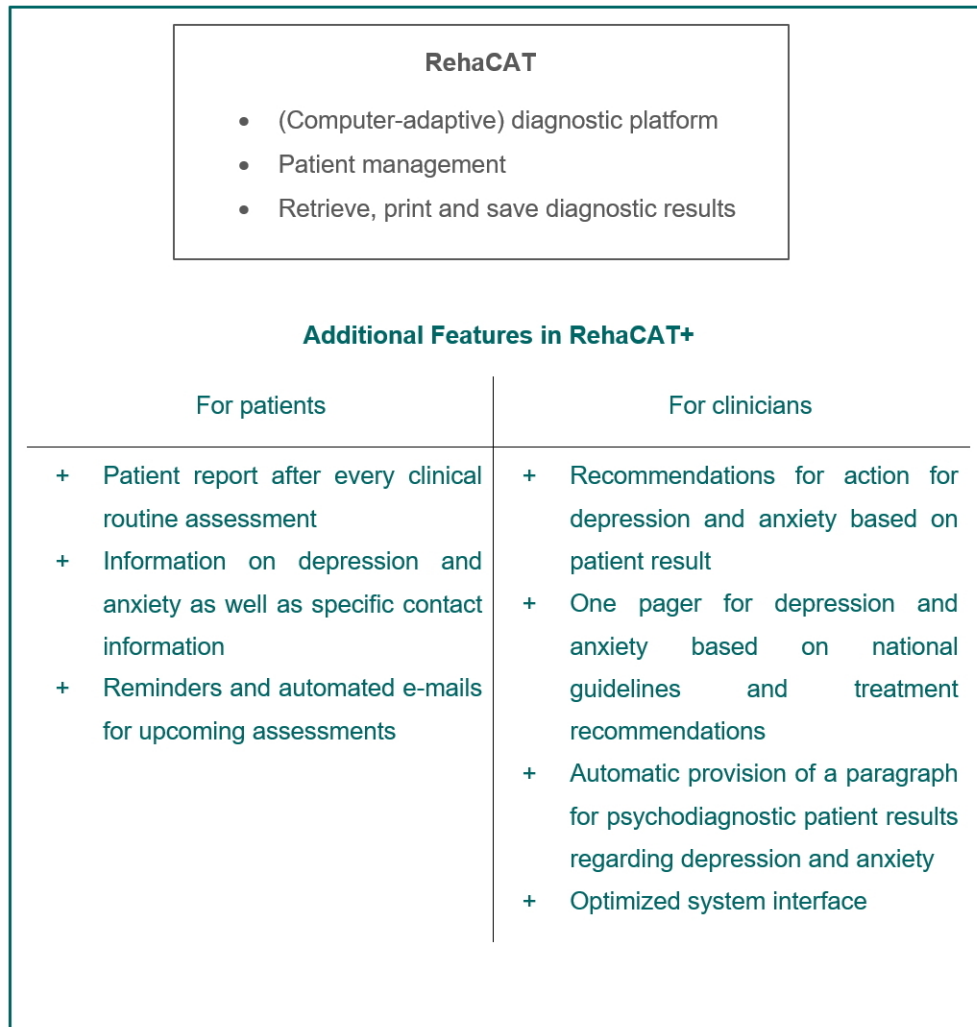


Figure 3. Features

88x92mm (300 x 300 DPI)

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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

1
2 und dabei helfen, künftige Behandlungen für Rehabilitand:innen wie Sie effektiver zu gestalten. Dabei werden
3 sensible Daten zu Ihrer Gesundheit erfasst.

4 Basierend auf unseren Erfahrungen schätzen wir den zeitlichen Mehraufwand für Sie auf ca. 20 Minuten je
5 Befragung. Zusätzlich befragen wir Sie 12 Monate nach der Rehabilitation, womit insgesamt vier Befragungen
6 auf Sie zukommen.

8 **ENTGELT**

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

13 **UMGANG MIT IHREN DATEN**

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

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

31 **GIBT ES RISIKEN DURCH DIE TEILNAHME AN DER STUDIE REHACAT+?**

32 Nebenwirkungen oder unerwünschte Wirkungen von Online Befragung oder ähnlicher Studien sind nicht be-
33 kannt. Manche der Aufgaben oder Fragen sind möglicherweise schwierig zu beantworten oder umzusetzen.
34 Die Erfahrung, sich Ängsten oder unangenehmen Gedanken zu stellen, ist für die meisten Menschen zunächst
35 nicht leicht, dann aber oft sehr hilfreich. Zusätzlich stehen Ihnen bei Bedarf zuständiges Klinikpersonal Als
36 Ansprechpartner/in zur Verfügung und werden versuchen, Ihnen zu helfen.

37 **FREIWILLIGKEIT:**

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

46 **ERREICHBARKEIT DER STUDIENMITARBEITER:**

47 Sollten während des Verlaufes der Studie Fragen auftauchen, so können Sie jederzeit folgende Ansprechpartner
48 erreichen:

49
50 Yannik Terhorst
51 Universität Ulm
52 Institut für Psychologie und Pädagogik
53 Abteilung für Klinische Psychologie und Psychotherapie
54 Lise-Meitner-Straße 16, D-89081 Ulm
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58 Johannes Knauer
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1
2 Telefon: +49 731/50 32805
3 E-Mail: Johannes.knauer@uni-ulm.de

4
5 **VERSICHERUNG:**

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

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

11
12 **SCHWEIGEPFLICHT/DATENSCHUTZ:**

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

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

22 Yannik Terhorst
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29
30 Johannes Knauer
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32 Institut für Psychologie und Pädagogik
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36 E-Mail: Johannes.knauer@uni-ulm.de

37
38
39 Bei Fragen zur Nutzung oder Verarbeitung Ihrer Daten wenden Sie sich bitte an den/die:

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

43
44 Falls Sie Bedenken oder Beschwerden hinsichtlich der Verarbeitung Ihrer Daten haben, wenden Sie sich bitte
45 an die Datenschutz-Aufsichtsbehörde Ihres Studienzentrums: Die entsprechenden Kontaktdaten finden Sie auf
46 der Internetseite des Landesbeauftragten für Datenschutz und Informationsfreiheit Baden-Württemberg:
47 <https://www.baden-wuerttemberg.datenschutz.de/dsb-online-melden/>

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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

1
2 und zur Verfügung gestellt. Eine Kopie dieser Einwilligungserklärung können Sie jederzeit über den Menü-
3 punkt „Informationen“ herunterladen oder vom Personal Ihrer Rehabilitationsklinik erhalten.
4

5 Ich habe die allgemeinen Informationen zur Studie „RehaCAT+“ gelesen und willige in die Teilnahme an der
6 Studie und die damit verbundene Datenverarbeitung ein.
7

8 JA NEIN
9

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11 **[Weiter Button erscheint erst, nach aktiver Bestätigung dieses und der Bestätigung zur Datenverarbeitung**
12 **– die Einwilligung ist rein digital]**
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For peer review only

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.

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

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		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

1	Roles and	#5b	Name and contact information for the trial sponsor	23
2	responsibilities:			
3	sponsor contact			
4	information			
5				
6				
7	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	23
8	responsibilities:		collection, management, analysis, and interpretation of data;	
9	sponsor and funder		writing of the report; and the decision to submit the report for	
10			publication, including whether they will have ultimate authority	
11			over any of these activities	
12				
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14				
15	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	19
16	responsibilities:		centre, steering committee, endpoint adjudication committee,	
17	committees		data management team, and other individuals or groups	
18			overseeing the trial, if applicable (see Item 21a for data	
19			monitoring committee)	
20				
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23				
24	Introduction			
25				
26	Background and	#6a	Description of research question and justification for undertaking	4
27	rationale		the trial, including summary of relevant studies (published and	
28			unpublished) examining benefits and harms for each intervention	
29				
30				
31	Background and	#6b	Explanation for choice of comparators	6
32	rationale: choice of			
33	comparators			
34				
35	Objectives	#7	Specific objectives or hypotheses	6
36				
37	Trial design	#8	Description of trial design including type of trial (eg, parallel	8
38			group, crossover, factorial, single group), allocation ratio, and	
39			framework (eg, superiority, equivalence, non-inferiority,	
40			exploratory)	
41				
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43				
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45				
46	Methods:			
47	Participants,			
48	interventions, and			
49	outcomes			
50				
51	Study setting	#9	Description of study settings (eg, community clinic, academic	9
52			hospital) and list of countries where data will be collected.	
53			Reference to where list of study sites can be obtained	
54				
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56				
57	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	9
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		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: adherence	#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	
1			
2	Allocation	#16b Mechanism of implementing the allocation sequence (eg, central	10
3	concealment	telephone; sequentially numbered, opaque, sealed envelopes),	
4	mechanism	describing any steps to conceal the sequence until interventions	
5		are assigned	
6			
7			
8			
9	Allocation:	#16c Who will generate the allocation sequence, who will enrol	10
10	implementation	participants, and who will assign participants to interventions	
11			
12			
13	Blinding (masking)	#17a Who will be blinded after assignment to interventions (eg, trial	10
14		participants, care providers, outcome assessors, data analysts),	
15		and how	
16			
17			
18	Blinding (masking):	#17b If blinded, circumstances under which unblinding is permissible,	n/a
19	emergency unblinding	and procedure for revealing a participant's allocated intervention	
20		during the trial	
21			
22			
23			
24	Methods: Data		
25	collection,		
26	management, and		
27	analysis		
28			
29			
30	Data collection plan	#18a Plans for assessment and collection of outcome, baseline, and	19
31		other trial data, including any related processes to promote data	
32		quality (eg, duplicate measurements, training of assessors) and a	
33		description of study instruments (eg, questionnaires, laboratory	
34		tests) along with their reliability and validity, if known.	
35		Reference to where data collection forms can be found, if not in	
36		the protocol	
37			
38			
39			
40			
41	Data collection plan:	#18b Plans to promote participant retention and complete follow-up,	10
42	retention	including list of any outcome data to be collected for participants	
43		who discontinue or deviate from intervention protocols	
44			
45			
46			
47	Data management	#19 Plans for data entry, coding, security, and storage, including any	19
48		related processes to promote data quality (eg, double data entry;	
49		range checks for data values). Reference to where details of data	
50		management procedures can be found, if not in the protocol	
51			
52			
53			
54	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	20
55		outcomes. Reference to where other details of the statistical	
56		analysis plan can be found, if not in the protocol	
57			
58			
59			

1	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and adjusted	21
2	analyses		analyses)	
3				
4	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	20
5	population and missing		adherence (eg, as randomised analysis), and any statistical	
6	data		methods to handle missing data (eg, multiple imputation)	
7				
8				
9				
10	Methods: Monitoring			
11				
12	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary of	19
13	formal committee		its role and reporting structure; statement of whether it is	
14			independent from the sponsor and competing interests; and	
15			reference to where further details about its charter can be found,	
16			if not in the protocol. Alternatively, an explanation of why a	
17			DMC is not needed	
18				
19				
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21				
22	Data monitoring:	#21b	Description of any interim analyses and stopping guidelines,	n/a
23	interim analysis		including who will have access to these interim results and make	
24			the final decision to terminate the trial	
25				
26				
27	Harms	#22	Plans for collecting, assessing, reporting, and managing solicited	n/a
28			and spontaneously reported adverse events and other unintended	
29			effects of trial interventions or trial conduct	
30				
31				
32				
33	Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and	n/a
34			whether the process will be independent from investigators and	
35			the sponsor	
36				
37				
38	Ethics and			
39	dissemination			
40				
41				
42	Research ethics	#24	Plans for seeking research ethics committee / institutional review	22
43	approval		board (REC / IRB) approval	
44				
45				
46	Protocol amendments	#25	Plans for communicating important protocol modifications (eg,	n/a
47			changes to eligibility criteria, outcomes, analyses) to relevant	
48			parties (eg, investigators, REC / IRBs, trial participants, trial	
49			registries, journals, regulators)	
50				
51				
52				
53	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial	9
54			participants or authorised surrogates, and how (see Item 32)	
55				
56				
57	Consent or assent:	#26b	Additional consent provisions for collection and use of	n/a
58	ancillary studies		participant data and biological specimens in ancillary studies, if	
59				
60				

		applicable	
1			
2	Confidentiality	#27 How personal information about potential and enrolled	19
3		participants will be collected, shared, and maintained in order to	
4		protect confidentiality before, during, and after the trial	
5			
6			
7	Declaration of interests	#28 Financial and other competing interests for principal	23
8		investigators for the overall trial and each study site	
9			
10			
11	Data access	#29 Statement of who will have access to the final trial dataset, and	19
12		disclosure of contractual agreements that limit such access for	
13		investigators	
14			
15			
16	Ancillary and post trial	#30 Provisions, if any, for ancillary and post-trial care, and for	n/a
17	care	compensation to those who suffer harm from trial participation	
18			
19			
20	Dissemination policy:	#31a Plans for investigators and sponsor to communicate trial results	23
21	trial results	to participants, healthcare professionals, the public, and other	
22		relevant groups (eg, via publication, reporting in results	
23		databases, or other data sharing arrangements), including any	
24		publication restrictions	
25			
26			
27			
28	Dissemination policy:	#31b Authorship eligibility guidelines and any intended use of	n/a
29	authorship	professional writers	
30			
31			
32	Dissemination policy:	#31c Plans, if any, for granting public access to the full protocol,	19
33	reproducible research	participant-level dataset, and statistical code	
34			
35			
36			
37	Appendices		
38			
39	Informed consent	#32 Model consent form and other related documentation given to	supplement
40	materials	participants and authorised surrogates	
41			
42			
43	Biological specimens	#33 Plans for collection, laboratory evaluation, and storage of	n/a
44		biological specimens for genetic or molecular analysis in the	
45		current trial and for future use in ancillary studies, if applicable	
46			
47			

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