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Effectiveness of a web-based behavioural activation intervention for individuals with depression based on the Health Action Process Approach: protocol for a randomised controlled trial with a 6-month follow-up

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ABSTRACT

Introduction Behavioural activation is a highly effective treatment for depression. However, there is considerable heterogeneity of interventions grouped under the term 'behavioural activation'. A main reason for the heterogeneity is the lack of a unified theory in the intervention development: few of the established intervention manuals give a theoretical rationale for their intervention techniques. For the first time, this study will examine the effectiveness of a theory-based behavioural activation intervention (*InterAKTIV*) based on the Health Action Process Approach. The intervention is implemented online to ensure broad dissemination and standardisation.

Methods and analysis In a two-arm randomised controlled trial, the effectiveness of a guided web-based behavioural activation intervention for people with depression will be evaluated. Participants are recruited via the print and online media of a large German healthcare insurance company. Individuals (age 18–65), who meet criteria for major depressive episode in a clinical interview and no exclusion criteria are eligible for inclusion. A target sample of 128 participants is randomly allocated to either the intervention group (immediate access to *InterAKTIV*) or treatment as usual (access after follow-up assessment). The primary outcome of depressive symptom severity (Quick Inventory of Depressive Symptomatology Clinician Rating) and secondary outcomes, including behavioural activation, physical activity and motivational and volitional outcomes are assessed at baseline, post treatment and 6-month follow-up. Data will be analysed on an intention-to-treat basis with additional per-protocol analyses.

Ethics and dissemination This trial is approved by the ethics committee of the Albert-Ludwigs-University of Freiburg (no.: 20-1045). All participants are required to submit their informed consent online before study inclusion. The results will be submitted for publication in a peer-reviewed journal and presented at conferences.

Trial registration number This trial was registered in the German Clinical Trials Register (DRKS): DRKS00024349 (date of registration: 29 January 2021).

Strengths and limitations of this study

- The proposed study will be the first randomised controlled trial to investigate the effectiveness of a web-based behavioural activation intervention based on the Health Action Process Approach for individuals with depression.
- We use validated self-report scales, standardised interviews and clinical rating scales for the diagnosis of a major depressive episode and the assessment of depressive symptomatology.
- In addition to changes in depressive symptomatology, the study also examines changes in behavioural activation, as well as motivational, volitional and cognitive outcomes.
- Participant recruitment via a large health insurance company facilitates the generalisability of results.
- Since sample size calculations are based on the primary outcome, moderator analyses might be underpowered.

INTRODUCTION

More than 264 million people worldwide are affected by depressive disorders, making it one of the most prevalent mental illnesses.[1] With a 1-year prevalence of about 7% in Germany, the direct medical costs amount to around €5.2 billion annually, while the indirect costs are far higher.[2 3] Given the high burden of depressive disorders, the need for effective and easily accessible treatments is high.

A highly effective form of therapy for the treatment of depressive disorders is behavioural activation (BA). The rationale of BA was described in the early 1970s by Lewinsohn.[4] He proposed a behavioural model according to which depressive symptoms

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result from a loss of positive reinforcing activities. Thus, a reuptake of reinforcing activities should result in symptom reduction.[4 5] The efficacy of BA has been proven in numerous randomised controlled trials and meta-analyses.[6–10] A recent systematic review and meta-analysis examining 53 studies found BA to be more effective than treatment as usual (TAU) and showed no difference in short-term treatment efficacy between BA and cognitive behavioural therapy.[9] Aside from reducing depression severity, there is preliminary evidence supporting BA's ability to reduce anxiety symptoms and increase activation.[11] BA has several strengths. It is very cost-effective and easy to administer,[12] and its parsimonious rationale leads to a high degree of transparency and comprehension in patients.[13 14] Moreover, BA can be used flexibly in various contexts.[15–18]

Several different BA therapy manuals have been developed over the past decades.[19–21] Two commonly used intervention components are the initial observation of behaviour (behaviour monitoring) and subsequent planning of behaviour (behaviour scheduling), aimed at supporting depressive patients in the reuptake of reinforcing activities. However, the techniques and principles to achieve this goal are diverse, as there are significant differences regarding the addressed target behaviours and the methods used to achieve behavioural change.[5] One main reason for the heterogeneity might be a lack of a unified theory in intervention development. The established intervention manuals (cf. [9 22]) often emphasise rationales *why* an increase of activity levels improves depressive symptoms. Also, they provide descriptions of *how* certain intervention components can effectively induce behaviour change. Yet, theoretical assumptions remain limited to individual intervention components; no comprehensive theoretical model that determines the selection and sequencing of intervention components has been developed.[4 13 19 21 23] Research in other fields suggests that theory-based interventions are, on average, more effective than purely evidence-based or pragmatic approaches.[24 25] Providing a structured, coherent theoretical framework to the selection and sequencing of intervention components might increase the intervention's effectiveness, improve replicability of results and facilitate the systematic evaluation of intervention components.

We developed a theory-based BA intervention called *InterAKTIV*. The intervention is based on the Health Action Process Approach (HAPA,[26 27] figure 1), a model originally developed to explain and predict health behaviour (eg, exercising, healthy eating). Previous research has shown that the motivational and volitional processes can also explain activity limitations in depressed patients.[28 29]

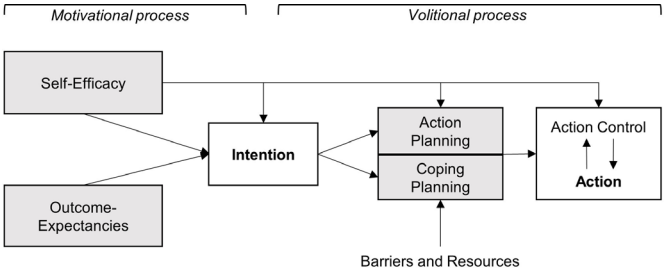

Figure 1 Health Action Process Approach of depression[62 96].

The HAPA proposes that the process of behaviour change consists of a preintentional (motivational) and a postintentional (volitional) phase. In the motivational phase, *risk perceptions* (eg, 'I am at risk of feeling depressed'), *outcome expectancies* (eg, 'If I am regularly active in my everyday life, I will simply feel better afterwards') and *action self-efficacy* (eg, 'I am confident to be active regularly in my everyday life') contribute to the formation of a behavioural intention (eg, 'I intend to be active regularly').[26] Second, in the volitional phase, planning and volitional self-efficacy processes facilitate the adoption and maintenance of behaviour in everyday life. Here, the HAPA distinguishes action planning, coping planning and volitional self-efficacy (maintenance self-efficacy and recovery self-efficacy). While *action plans* define when, where and how the behaviour will be performed, *coping plans* describe how to act on intentions even if barriers or obstacles arise.[30] *Maintenance self-efficacy* describes the confidence in one's ability to deal with barriers that arise during the maintenance period, whereas *recovery self-efficacy* defines one's ability to recover from setbacks.[31] According to HAPA, behaviour implementation should continuously be accompanied by the self-regulatory process of *action control*.[32] The HAPA model has previously successfully been used to explain health behaviours[33 34] and guide behavioural health interventions.[35–38] However, the effectiveness of a HAPA based intervention has not yet been tested as a treatment for depression.

The intervention *InterAKTIV* consists of seven self-help modules targeting motivational and volitional competencies (cf. the Methods section). It will be administered via the Internet to ensure standardised implementation and wide dissemination. Several meta-analyses show that web-based interventions are effective in the treatment of depression.[39–43] Web-based interventions are a cost-effective[44 45] and an accessible[46] alternative to face-to-face psychotherapy. Previous randomised controlled trials (RCTs) have also supported the efficacy of web-based BA[47–50] In a recent meta-analysis, Huguet *et al* found effects of web-based BA on depression, anxiety and quality of life.[22] Yet, due to the low quality of many of the included trials, the results' validity is limited, and high-quality RCTs are needed.

The proposed study will contribute to the literature on the effectiveness of web-based BA by investigating the effects of the intervention on depressive symptomatology with a high-quality RCT and by investigating the effects on social cognitive and behavioural outcomes. For the first time, the effectiveness of a web-based BA intervention based on the HAPA model will be examined in people with depressive disorders. The following research questions will be investigated:

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1. Does the web-based intervention have an effect on depressive symptomatology?
2. Does the web-based intervention have an effect on activity levels, motivational and volitional variables, and other secondary outcomes?
3. What participant characteristics moderate the effectiveness of the web-based intervention?

METHODS AND ANALYSIS

Study design

This is a two-arm RCT with a parallel design to compare an online BA intervention with a TAU control group (CG). Participants are recruited via the print and online media of a German healthcare insurance company (AOK, Allgemeine Ortskrankenkasse). After an online screening (t0) and a baseline survey (t1), participants are randomised either to the intervention group (IG) or the CG. Further assessments take place 8 weeks (t2) and 6 months after randomisation (t3). Participants of the IG immediately receive access to the online intervention after randomisation. Participants of the CG receive access to the online intervention after completing the 6-month follow-up assessments. Participants of both the IG and CG have full access to TAU, meaning that all healthcare services can be used without restriction (eg, visits to the general practitioner, psychiatrist, psychotherapist; inpatient care). Generally, healthcare costs in Germany are covered by the health insurance companies without extra costs for the individual. See figure 2 for a detailed study flow.

The trial is conducted and reported following the Consolidated Standards of Reporting Trials 2010 Statement (CONSORT[51]), the Extension of the CONSORT Statement for Pragmatic Effectiveness Studies[52] and the guidelines for executing and reporting internet intervention research.[53] This study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials 2013 Checklist for clinical trial protocols[54](online supplemental file 1). This trial is supervised by a Data Monitoring Committee (DMC) consisting of three independent researchers. The DMC advises the project team in case of serious adverse events.

Recruitment

Participants are recruited via the print and online media of the AOK Baden-Württemberg, a large German statutory healthcare insurance company. In the German healthcare system, healthcare insurance is mandatory for all citizens and permanent residents. The majority of the population are covered by statutory health insurance (around 85%)[55]; all others are covered by private healthcare schemes. Statutory healthcare insurances provide coverage for a wide range of healthcare services (eg, medical checkups, inpatient and outpatient treatment, psychotherapy). The AOK Baden-Württemberg promotes participation through its' various media channels (eg, members' magazines, webpage and Facebook). There, information about depression and treatment

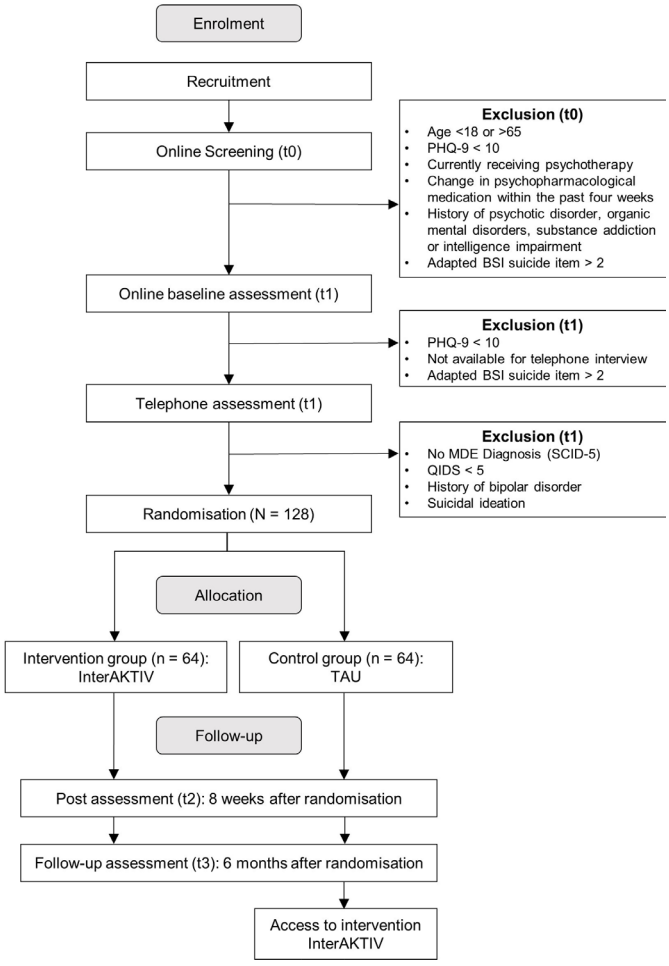

Figure 2 Study flow. BSI, Brief Symptom Inventory; MDE, major depressive episode; PHQ-9, Patient Health Questionnaire; QIDS, Quick Inventory of Depressive Symptomatology; SCID-5, Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; TAU, treatment as usual.

options, including this study, are given. An informational website on the AOK webpage with more details about study participation remains online throughout the entire recruitment phase. On this website, the screening survey (t0) is linked. Recruitment started in February 2021 and will be completed once the target sample of 128 participants is reached. Participants are financially compensated with 10€ per completed measurement point (max. 30€).

Study procedures

Individuals interested in the study can access the online screening questionnaire via a link provided on the AOK Baden-Württemberg webpage. Positively screened individuals receive detailed information about the study and data privacy via email (online supplemental file 2), as well as a direct link to the consent form. After signing informed consent online, participants take part in the online baseline assessment (t1). Once the baseline assessment is completed, and no exclusion criteria are met, participants are scheduled for a semistructured interview conducted via telephone. The interviews are conducted

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by trained psychologists (MSc in psychology, currently in training to become a licensed psychotherapist). The interviews encompass the major depressive episode (MDE) questions A1–A14 and A54–A55 of the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (SCID-5-Clinical Version (CV)[56]), a clinician rating of depression severity (Quick Inventory of Depressive Symptomatology Clinicial Rating; QIDS-C[57]), and a thorough investigation of suicidal ideation. Participants are contacted systematically via email and telephone to remind them about completing the assessments.

Eligibility criteria

We include subjects (1) aged 18–65, (2) with self-reported depressive symptoms in the Patient Health Questionnaire (PHQ-9≥10 at t0 and t1[58]), (3) and clinician-rated depressive symptoms above cut-off (QIDS-C≥6[57]) and (4) meeting the DSM-5 criteria for an MDE (SCID-5-CV[58]). Subjects are excluded from the study if they (1) are currently receiving psychotherapy, (2) had a change in their psychopharmacological medication within the last 4 weeks before screening, (3) have a history of bipolar disorder, psychotic disorder, substance use disorder, organic mental disorders or intellectual disability, (4) state suicidal ideation in the screening or telephone interview (cf. procedures on suicidal ideation). Participants without MDE are not randomised and excluded from further analyses but are granted access to the online intervention.

Procedures on suicidal ideation

Suicidal ideation is assessed thoroughly at all measuring points of the study (t0–t3). In the questionnaires, an adapted item of the Brief Symptom Inventory (BSI item 9,[59]) is used ('Over the last 2 weeks, how often have you been bothered by any of the following problems? (…) Thoughts of ending your life'). The response scale was matched to the PHQ items (0='not at all' to 3='nearly every day'). If participants demonstrate high suicidal ideation in the screening or baseline questionnaires, they are excluded from the study and provided with an informational email. Additionally, suicidal ideation is identified by exploration during telephone interviews (SCID-5-CV, QIDS-C[57 58]). We use a suicide protocol adapted from previous trials[60 61] and distinguish between (1) no suicidal ideation, (2) thoughts of death, (3) suicidal thoughts without intent, (4) suicidal thoughts with unclear intent. In case of low suicidal ideation (BSI item score=1 or interviewer's assessment), participants receive in-depth information on available health services via email. If participants report 'suicidal thoughts without intent' in the interview, they must return a signed non-suicide contract within 2 days to remain in the study. If they do not send back the nonsuicide contract, they are contacted via phone by a licensed psychotherapist. Participants are strongly advised and assisted in seeking further help and support if they report any suicidal thoughts during the telephone interviews. If participants report 'suicidal thoughts with unclear intent', they are excluded from the study. Further steps (eg, seeking inpatient care; visits to the psychiatrist) are planned immediately via the phone. Participants' communication with the study team and all text entries in the online intervention are also monitored for suicidal ideation. A licensed psychotherapist supervises all steps of the suicide protocol and will directly contact participants via telephone if necessary.

Randomisation and blinding

Following the baseline assessments, participants are randomised to either the IG or the CG by an independent researcher at the Institute of Medical Biometry and Statistics (University Medical Centre Freiburg) not otherwise involved in the study. Before the first randomisation, the independent researcher creates a randomisation list using an automated online-based programme (www.sealedenvelope.com), performing permuted block randomisation with variable block sizes of 2, 4 and 6 (randomly arranged; with a ratio of 1:1). The randomisation list is only available to the independent researcher. Allocation concealment is ensured, as participants are not randomised until they have been included in the trial, which is after all baseline measurements have been completed. For each participant to be randomised, the independent researcher receives the participant identification (ID) from the study supervisor by email. Based on the pre-existing list, the participant is then randomised and information about group assignment is sent back to the study supervisor. After randomisation, we inform participants about their assigned group via email. Telephone interviewers (outcome assessors) and data analysts are blinded to participants' allocation. E-Coaches cannot be blinded.

Intervention condition

The intervention (*'InterAKTIV*: Internettraining zum Aktivitätenaufbau'; eng.: *'InterACTIVE*: Internet training for increasing activity') is based on the HAPA[62]. It consists of one short introductory and seven guided content modules, each about 45 min in length, that can be accessed online via a website. An overview of the topics covered in each module is presented in table 1. Sample screenshots to illustrate the intervention can be found in the online supplemental file 3.

The sequencing of the modules is based on the HAPA, with modules 1–3 focusing on motivation and modules 4–7 focusing on volition. Module 1 provides general information about depressive disorders and introduces the intervention rationale. Module 2 takes a closer look at the target variable 'behaviour'. Following the example of Lejuez *et al*,[19] a value-oriented approach is used. The selection of personally important activities has a unique potential for positive reinforcement.[63] Further motivational reinforcement takes place in module 3, where participants contrast their positive and negative *outcome expectancies* and form an intention

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Table 1 Modules of the web-based intervention *InterAKTIV*

Module	Topic	Content
Intro	Introduction	► A brief explanation of the intervention and module structure ► Technical instructions
1	Psychoeducation and rationale	► Information about depressive symptoms ► Relationship between activity and mood and intervention rationale ► Homework assignment: activity and mood diary (1)
2	Identification of relevant activities	► Exploration of important areas of life and values ► Identifying concrete activities based on values ► Homework assignment: activity and mood diary (2)
3	Outcome expectancies	► Exploring negative and positive outcome expectancies ► Explicitly stating the intention to perform chosen activities ► Homework: developing a motivational phrase
4	Action planning	► Psychoeducation: intention–behaviour gap ► Concrete action planning: What? Where? When? With whom? What else? ► Homework assignment: activity scheduling
5	Coping planning	► Coping planning: preventative and acute strategies ► Creating if–then plans ► Homework assignment: activity scheduling and coping planning (1)
6	Action control	► How to maintain activities long-term and deal with setbacks ► Exercises to improve action control concerning self-monitoring, awareness of standards and self-regulatory efforts ► Homework assignment: activity scheduling and coping planning (2)
7	Consolidation and outlook	► Review of past modules ► Downloadable workbook including key intervention components and previous homework assignments ► Outlook: planning an activity for the upcoming week

to implement the behaviour. In module 4, participants are guided to develop a concrete *action plan* for their activity. They learn how to manage possible obstacles that may arise and hinder activity completion (*coping planning*; module 5). Module 6 focuses on long-term *action control*, and lastly, module 7 recapitulates the previous modules to consolidate the intervention content. According to HAPA *self-efficacy* is important at all stages of behaviour change and is therefore incorporated into all modules (eg, via observational learning[64]). As the construct of health-related risk perceptions did not prove to be a significant predictor of everyday activity in depression,[29] it is therefore not targeted in the intervention.

All modules contain interactive elements such as texts, videos, audios, testimonials, illustrated examples and exercises (eg, writing tasks, quizzes). *InterAKTIV* focuses on the practical implementation of intervention principles in everyday life. Therefore, participants are to complete homework assignments between each module. After each module, participants receive semi-standardised, written feedback from an e-coach via a messaging tool on the intervention website. E-coaches are psychologists in training for psychotherapy under the supervision of a licensed psychotherapist. E-coach feedbacks are designed to support treatment adherence and motivate participants to complete intervention modules, for example, through positive reinforcement and homework reminders. Optionally, participants can activate motivating daily text messages on their mobile phone. Once activated, participants will receive 50 text messages containing motivational phrases, homework reminders and module-specific suggestions, in accordance with HAPA. Participants are instructed to complete one module per week. They can access *InterAKTIV* at any time and on any device with internet access. Modules can be completed for up to 12 weeks and viewed in a read-only mode until 6 months after randomisation. Participants in the IG have unlimited access to TAU.

Control condition

The CG can access *InterAKTIV* after follow-up assessments (6 months after randomisation). In the CG, access to TAU is not restricted. Since TAU may vary across participants, a detailed TAU description is obtained via the Questionnaire for Health-Related Resource Use in an Elderly Population at post-treatment (FIMA,[65] see moderators).

Outcome measures

The questionnaires are surveyed online at all measurement points. Additionally, structured telephone interviews are conducted with all participants at all measurement points. A second rater evaluates 10% of the interviews to determine interrater reliability. For an overview of

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Table 2 Overview of variables, outcome assessments and assessment time points

Variables	Measurement	Scr.	t1	t2	t3
Inclusion and exclusion criteria					
Age (18–65 years old)	Self-report	x			
Depressive episode	PHQ-9[69]	x	x		
	SCID-5-CV, Sect. A[58]		x		
Non-suicidality	BSI (adapted suicidality item[59])	x	x	x	x
	SCID-5-CV (suicidality item[58])		x	x	x
Not currently receiving psychotherapy; no current change in medication	Self-report	x			
No psychotic disorder, organic mental disorder, substance addiction or intelligence impairment	Self-report	x			
No bipolar disorder	SCID-5-CV, Sect. A[58]	x			
Primary outcome					
Severity of depressive symptoms	QIDS-C[57]		x	x	x
Secondary outcomes					
Severity of depressive symptoms (self-report)	PHQ-9[69]		x	x	x
Depression remission	SCID-5-CV, Sect. A[58]			x	x
Depression response	QIDS-C[57]			x	x
Behavioural activation	BADS[72]		x	x	x
Physical activity	IPAQ-SF[76]		x	x	x
Motivational and volitional outcomes	OE, mSE, INT, AP, CP, vSE, AC[30 35 78–80]		x	x	x
Rumination	RSQ-D[81]		x	x	x
Intervention side effects	INEP[83]			x	x
Moderators					
Sociodemographic variables	Self-report (adapted from[86])		x		
Severity of depressive symptoms	QIDS-C[57]		x		
Initial motivational level	Stage of change[28]		x		
Healthcare utilisation	FIMA (mod.[65])			x	
Intervention satisfaction	CSQ-8[97]			(x)	
COVID-19-related restrictions	Self-report		x	x	x

AC, action control; AP, action planning; BADS, Behavioral Activation for Depression Scale; BSI, Brief Symptom Inventory; CP, coping planning; CSQ-8, Client Satisfaction Questionnaire; FIMA, Questionnaire for Health-Related Resource Use in an Elderly Population; INEP, Inventory for the Assessment of Negative Effects of Psychotherapy; INT, intention strength; IPAQ-SF, International Physical Activity Questionnaire—Short Form; mSE, motivational self-efficacy; OE, outcome expectancies; PHQ-9, Patient Health Questionnaire-9; QIDS-C, Quick Inventory of Depressive Symptomatology Clinician Rating; RSQ-D, Response Style Questionnaire—German Version; SCID-5-CV, Structured Clinical Interview for DSM-5 Clinical Version; Scr., Screening; t1, baseline assessment; t2, post assessment; t3, follow-up assessment; vSE, volitional self-efficacy; (x), only intervention group; x, intervention and control group.

instruments at screening, baseline (t1), post treatment (t2) and follow-up (t3), see table 2.

Primary outcome

The primary outcome is depressive symptom severity assessed with the 16-item QIDS-C.[57 66] The QIDS-C measures the nine depression criterion symptom domains from the DSM during the past 7 days[67]: sad mood, concentration/decision-making, self-outlook, suicidal ideation, involvement, energy/fatigability, weight/appetite change and psychomotor changes. Items are scored on a scale from 0 to 3 (total score=0–27). The QIDS-C has displayed good psychometric properties, such as a good internal consistency (α=0.85), an acceptable concurrent validity and sensitivity to symptom change in patients with major depressive disorder (MDD[66 68]).

Secondary outcomes

Depression outcomes

Severity of depressive symptoms is assessed in a self-report format using the German version of the PHQ-9.[69] The PHQ-9 consists of nine items rated on a 4-point scale ranging from 0 to 3 (0=not at all to 3=nearly every day) and assesses depressive symptoms during the past 2 weeks.

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The computerised version of the PHQ-9 has shown high internal consistency (α=0.88[70]).

Depression remission is assessed using the SCID-5-CV (section A[58]) at post measurement (t2) and follow-up (t3). Participants that no longer fulfil diagnostic criteria for a MDE classify as remitted.

Depression response is assessed according to Jacobson and Truax[71] using the QIDS-C scores. Participants are classified as responders if they received a symptom reduction according to the reliable change index (Reliable Change Index (RCI)>1.96).

BA and physical activity

BA is assessed with the Behavioral Activation for Depression Scale (BADS; German version[72]). The BADS is a 25-item self-report scale assessing individuals' activity levels and avoidance behaviour during the past 7 days.[73] Items are scored on a 7-point scale from 0 (not at all) to 6 (completely). The BADS comprises four subscales: Activation, Avoidance/Rumination, Work/School Impairment and Social Impairment. Its total scores indicate whether the intervention increases the participants' activity levels in their everyday life. The German version of the BADS has shown good psychometric properties, with good internal consistency (α=0.85), construct validity and change sensitivity.[72]

Physical activity is assessed using the International Physical Activity Questionnaire—Short Form (IPAQ-SF, German version[74]). This 7-item self-report scale assesses the frequency and duration with which vigorous, moderate and walking activity was performed during the past 7 days. The IPAQ protocol is used to generate the total physical activity score (MET-minutes/week).[75] The IPAQ-SF has shown good validity and test-retest reliability.[76]

Motivational and volitional outcomes

Following the HAPA-model, the subsequent motivational and volitional outcomes are assessed at baseline, post measurement and follow-up: outcome expectancies, self-efficacy, intention strength, action planning, coping planning and action control. For this study, existing scales assessing HAPA-related motivational and volitional variables were adapted to the target behaviour 'behavioural activation' and the target population of participants with MDE, according to semantic rules (cf.[77]). Except for strength of intention (0='do not intend at all' to 5='strongly intend'), all motivational and volitional outcomes are rated on a 4-point scale ranging from 1 ('not correct') to 4 ('correct'). In the IG, changes in the motivational and volitional variables and depressive symptomatology are also assessed after each intervention module via a single item.

The following motivational outcomes are assessed: *Positive and negative outcome expectancies* regarding the ability to be active in everyday life are assessed with a 6-item scale adapted from Fuchs.[78] The scale comprises three positive expectancies (eg, 'If I am active regularly in my everyday life, this has positive consequences for me.') and three negative expectancies (eg, 'If I am active regularly in my everyday life, I feel worse afterwards.'). The three positive items and the three negative items are each cumulated into one score. *Motivational self-efficacy* is assessed using three items (eg, I am confident to be active regularly in my everyday life.) based on Schwarzer.[79] The three items are cumulated into one score. *Strength of intention* is assessed using the item 'How strong is your intention to be active regularly in your everyday life?' adapted from.[80] The item is rated on a 6-point scale ranging from 0 (not at all) to 5 ('very strong').

The following volitional outcomes are assessed and cumulated into one score per outcome: *Action planning* is assessed by asking the participants if they already have a detailed plan on when, where, how, with whom and how often they will be active in their everyday lives. The five items are adapted from Sniehotta *et al*.[30] *Coping planning* is assessed with three items also adapted from Sniehotta *et al*[30] (eg, 'I have already made detailed plans, what to do in difficult situations in order to act according to my intentions') and cumulated into one score. *Volitional self-efficacy* consists of (1) maintenance self-efficacy and (2) recovery self-efficacy, adapted from.[79] Both facets are assessed with three items each (eg, 'I am confident in myself to be active in my everyday life, even if obstacles arise.'; 'I have confidence in myself to become active again in my everyday life, even if I have postponed my plans several times.'). *Action control* covers three facets (1) self-monitoring, (2) awareness of standards and (3) self-regulatory effort, assessed with two items each. The items are adapted from Sniehotta *et al*[32] (eg, (1) 'In the past seven days, I regularly checked whether I was active enough in my everyday life.', (2) 'In the past seven days, I often kept an eye on my planned activities.', (3) 'In the past seven days, I really tried to be active regularly.').

Other outcomes

Rumination is assessed using the Response Styles Questionnaire (RSQ-D, German Version[81]). The RSQ-D was developed to measure coping styles according to the response styles theory.[82] It is a 23-item scale containing the three subscales: symptom-focused rumination, self-focused rumination and distraction. Items are rated on a 4-point scale ranging from 1 ('almost never') to 4 ('almost always'). The three subscales display good psychometric properties, including internal consistency and validity.[81]

Intervention side effects are assessed with the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP[83]). In accordance with previous studies,[84 85] the version used in this trial consists of 15 items assessing a range of common changes in participants experienced in line with the online intervention. Changes in the following domains are assessed: (1) intrapersonal, (2) intimate relationship, (3) family/friends, (4) dependence on the psychotherapeutic intervention and (5) stigmatisation. Items are rated on a 4-point scale from 0 ('no agreement at all') to 3 ('total agreement'). The INEP has a good internal consistency (α=0.86).[83]

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Moderators

Sociodemographic variables are assessed at baseline and adapted from Deck and Röckelein.[86] They include, among others, age, gender, education, employment, sick days and income.

The stage of change is calculated based on a single item ('In the last four weeks, have you engaged in activities that bring you joy?'). The item is rated on a 5-point scale ranging from 0 ('No, and I do not intend to') to 4 ('Yes, and I find it easy'). Participants are classified into three groups: non-intenders (item=0), intenders (1–2) and actors.[3 4 87]

Healthcare utilisation is assessed at post treatment using an adapted version of the FIMA.[65] The FIMA is specifically tailored to the German healthcare system and is therefore well suited to assess its different services. Items concerning seniority-specific aspects, such as the usage of nursing services or domestic help, were removed to better match this sample of non-elderly participants, leaving 10 items assessing the number of utilised healthcare services and medication intake in the past 8 weeks. An additional item measures other psychotherapeutic services, such as attending self-help groups or participating in other online trainings.

Intervention satisfaction of the IG is assessed at post treatment with a version of the Client Satisfaction Questionnaire (CSQ-8[88 89]), specifically adapted to evaluate the satisfaction with web-based interventions. The scale contains eight items, rated on a 4-point scale ranging from 0 to 4. The CSQ-8 has shown high psychometric properties.[89] One additional item assesses technical difficulties regarding the intervention.

COVID-19 related restrictions are assessed in a self-report format. The 9-item scale used in this study assesses the impact of the COVID-19 pandemic in different domains of life (eg, work, family, health). The items are rated on a 5-point scale ranging from −2 ('negative impact') to 2 ('positive impact'). Two additional items assess (1) whether participants were in domestic quarantine during the past 8 weeks and (2) to what extend BA within the intervention was limited due to the COVID-19 pandemic (IG only).

Proposed sample size

The sample size calculation is based on the difference in depressive symptom severity between IG and CG at post treatment (intention-to-treat (ITT) analysis). It is conducted using G*Power and the method of difference between two independent means. This procedure was used as an approximation to the needed sample size, as the data basis was too poor to perform a sample size calculation based on linear mixed models (s. statistical analyses). A recent Cochrane review found a standardised mean difference (SMD) of 0.78 favouring BA at post-treatment comprared to TAU, with a CI ranging from 0.51 to 1.05.[9] In a meta-analysis on web-based BA, an overall standardised mean difference of SMD=0.68 (0.53, 0.83) was found favouring BA over TAU.[22] To detect at least a medium effect size of 0.50—marking the lower bound of the confidence intervals—with a two-sided significance level of 0.05 and a power of 80%, a sample size of 64 participants per intervention arm (total N=128) will be needed. Around 325 individuals will need to complete the online screening to achieve the required sample size (based on the target N and an expected recruitment dropout of 60%).

Statistical analyses

Outcome analyses will follow an ITT design by including all randomised participants in the analyses. We will use linear mixed-model (LMM) analyses to analyse the primary outcome, assuming data are missing at random. The mixed models include group (IG, CG), time (t1, t2, t3) and the interaction of group and time as fixed effects as well as participants as random effects. Variation among participants will be modelled using a random intercept. For main and interaction effects, F-statistics and p values will be reported and interpreted. Analyses will use restricted maximum likelihood estimation (REML). An autoregressive covariance structure with heterogeneous variances is assumed. The primary hypothesis that the development of depression severity over time differs between groups will be tested with an F-test of the group*time interaction term. If the F-test is found statistically significant at $p<0.05$ with participants in the IG showing a greater decrease in depressive symptoms over time, this result will be interpreted as participants of the IG improving more due to the intervention compared with the CG. If the F-test of the group*time interaction term is not statistically significant, it will be interpreted that no supporting evidence for a difference in the development of the primary outcome was found. Continuous secondary outcomes will be analysed accordingly. Potential moderators influencing treatment effects will be analysed exploratorily in the mixed model analyses for the primary outcome. Additionally, between-group effect sizes (Cohen's d) will be calculated for the primary outcome using the postintervention estimated means from the REML model and their pooled observed SD.[90]

Furthermore, per protocol analyses will be conducted for treatment completers and study completers. Study completers who have completed all three assessments (IG and CG) and treatment completers who completed at least 5 of 7 modules (IG only) will be investigated. The clinical relevance of symptom change will be assessed for study completers by estimating numbers of treatment response and deterioration based on the SCID diagnosis and the RCI,[71] and by calculating the number needed to treat for one more remitted participant. Participants will be classified as remitted if they no longer fulfil the criteria for MDE in the SCID. Analyses will be performed with an alpha level of 5% and using IBM SPSS.

Patient and public involvement

Patients were not involved in the initiation of the project or the development of the study design. In a qualitative

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usability investigation of the intervention, however, four patients gave feedback on the first five intervention modules. Based on their suggestions, the intervention was improved. Additionally, patients' satisfaction with and side effects of the intervention is assessed at post treatment to capture the burden of the intervention. Study results will be disseminated via publications in international peer-reviewed journals and presentations at conferences. Furthermore, results will be made available for participants on the research group's website in plain language.

Ethics and dissemination

This study is approved by the ethics committee of the Albert-Ludwigs-University of Freiburg (no.: 20-1045). All participants submit their informed consent online before study inclusion. Participants can withdraw participation and request the deletion of their data at any time if the data has not yet been anonymised. Data collection is pseudonymised via ID numbers in a reference list. On the completion of data collection, the reference list will be deleted. Then study data will be anonymised. The results will be submitted for publication in a peer-reviewed journal and presented at conferences.

DISCUSSION

This study is the first to evaluate a theory-based BA intervention based on the HAPA model in people with depressive disorders. The HAPA model has established itself as an effective theory and intervention model for health behaviour change.[26] This study is the first to use the HAPA as an intervention model aimed at changing activity levels and depressive symptomatology in depressed individuals.

We conduct an RCT comparing an IG receiving immediate access to *InterAKTIV* to a TAU CG. It is expected that *InterAKTIV* will reduce depressive symptom severity between IG and CG over the course of 6 months (t1, t2, t3). We also expect changes in motivational, volitional and other secondary outcomes due to participation in the intervention.

The study has several strengths: (1) the BA intervention *InterAKTIV* is modelled on a theory-based intervention rationale. The theoretical basis within the HAPA model explicitly defines the selection and sequence of intervention components applied in the intervention. To our knowledge, this study is the first to investigate the effectiveness of BA based on the HAPA. Using a theory-based intervention development approach, we follow the UK Medical Research Counsel's guidelines on intervention research.[91] Analogous to research in other fields, we expect this theory-based intervention to be more effective than pragmatic or evidence-based approaches.[24 25] (2) This high-quality RCT with three assessment points, including a 6-month follow-up, is in line with current standards in efficacy trials.[51] Roles and responsibilities within the study team are predefined and strictly separated (eg, strict separation of e-coaches, interviewers, study coordination). An independent DMC is installed to advise study organisers in case of adverse events. The recruitment strategy via a health insurance company is close to the healthcare system and shows a possible means of implementation in the future. (3) In addition to self-report questionnaires, this study also includes clinician-rated outcomes (QIDS-C, SCID). An MDE diagnosis based on the DSM-5 is obtained via telephone interviews. Interviewers are trained and blinded to participants' treatment allocation to reduce detection bias. (4) Using the HAPA model in the intervention rationale and including motivational and volitional secondary outcomes enables us to investigate the potential change in motivational and volitional indicators suggested by the HAPA model. Although this study is not specifically designed to inform about mechanisms of change in BA interventions, it still offers the potential to give a deeper understanding of how motivational and volitional variables might change due to BA and contribute to BA's efficacy. Recent studies suggest that the change in activity levels and depressive symptomatology might co-occur bi-directionally.[11 92] Exploratory analyses of the weekly assessments in the IG might inform about this issue.

Some limitations should also be considered: (1) study recruitment and participation coincides with the COVID-19 pandemic, leading to changes in the environment that could possibly limit the generalisability of results[93] (eg, public lockdown, quarantine). (2) The recruitment strategy via a large health insurance company was chosen to reach a broad part of the population and to favour the generalisability of results. Nonetheless, the external validity might be slightly limited by the fact that only about 85% of the general population is insured by statutory health insurance providers.[55] The remaining 15% are privately insured and include mainly civil servants, the self-employed and high-income earners. (3) For sample size calculation, t-statistics with post-treatment effect sizes from previous studies were used to approximate the necessary sample size. As a result of this approach, models for the sample size calculation and the outcome analysis (LMM) are not the same and the power analysis does not account for the full complexity of the outcome analysis. Yet, we have opted for this proximate approach as the data basis on LMMs in this field of research is too poor to gain valid assumptions for LMM-specific sample size simulations (eg, effect sizes, estimates for the random intercept across participants, residual error variation; cf.[94 95]). Furthermore, the power to detect moderating effects is limited, as sample size calculations are based on the primary outcome. Moderator analyses will be exploratory.

(4) For ethical reasons, only individuals without substantial suicidality (ie, suicidal intent or plans) are included in the study. However, a considerable proportion of people with depression are affected by suicidal intent or plans. The external validity of the study is therefore limited (to people without suicidal intent or plan), resulting potentially in a diminished proportion of severely depressed

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individuals in our sample. (5) Participant recruitment has started before the submission of the study protocol. However, the trial was registered before recruitment started, and no changes were made to the registry.

The study investigates the effectiveness of an online BA intervention by comparing the IG to a passive comparison group. In future research, comparisons should also be made with active CGs. For example, comparing *InterAKTIV* with a BA treatment not based on intervention theory could offer insights into the impact of theory-based approaches on the effectiveness of BA interventions.

Overall, by combining perspectives from health psychology and clinical psychology, this study will provide valuable information on the effectiveness of a web-based BA intervention based on the HAPA. By strengthening research on web-based BA, the study will increase our knowledge about economical treatment options for MDD. The first results are expected in 2022.

Trial status

Participant recruitment started in February 2021. The trial is currently ongoing.

Protocol version no.: 1 (date of submission: 23 June 2021).

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Competing interests HB received consultancy fees, reimbursement of congress attendance and travel costs as well as payments for lectures from Psychotherapy and Psychiatry Associations as well as Psychotherapy Training Institutes in the context of E-Mental-Health topics. DE reports to have received consultancy fees/served in the scientific advisory board from several companies such as Minddistrict, Lantern, Sanofi, Novartis, Schoen Kliniken and German health insurance companies. He is a stakeholder of the Institute for Health Training online (GET.ON/HelloBetter), which aims to implement scientific findings related to digital health interventions into routine care. He has been the beneficiary of study support (third-party funding) from several public funding organisations.

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description/Page
Administrative information		
Title	1	Page 1
Trial registration	2a	Page 2
	2b	See table below
Protocol version	3	Page 22
Funding	4	Page 23
Roles and responsibilities	5a	Page 1 & Page 23
	5b	University of Freiburg Department of Rehabilitation Psychology and Psychotherapy Institute of Psychology Engelbergerstr. 41, 79085 Freiburg, Germany
	5c	This trial is investigator-initiated. The sponsor (University of Freiburg) and funding source (German Research Foundation) had no role in the design of this study. Sponsor and funding source will have no role during trial execution, analyses, interpretation of the data, or decision to submit results.
	5d	LK is the principal investigator. CMW is responsible for recruitment and data acquisition. JB and TZ supervise the recruitment of participants. JB is responsible for all aspects of local organisation including identifying potential recruits and taking consent. CMW, JB and TZ meet weekly throughout the trial to oversee trial conduct and recruitment. JB supervises the trial.
Introduction		
Background and rationale	6a	Pages 4-7
	6b	Pages 4-7
Objectives	7	Page 6-7

Trial design	8	Page 7

Methods: Participants, interventions, and outcomes

Study setting	9	Page 8
Eligibility criteria	10	Page 9
Interventions	11a	Pages 10-12
	11b	Page 10
	11c	Pages 10-12
	11d	Pages 10-12
Outcomes	12	Pages 12-18
Participant timeline	13	Page 7
Sample size	14	Page 18
Recruitment	15	Page 8

Methods: Assignment of interventions (for controlled trials)

Allocation:		
Sequence generation	16a	Page 10
Allocation concealment mechanism	16b	Allocation concealment is ensured as participants are not randomised until they have been included in the trial, which is after all baseline measurements have been completed.
Implementation	16c	Page 10
Blinding (masking)	17a	Page 10
	17b	In case of adverse events (e.g. acute suicidal ideation), unblinding of the telephoneinterviewer is permissible if necessary. All cases of unblinding will be documented.

Methods: Data collection, management, and analysis

Data collection methods	18a	Pages 12-18
	18b	Page 8

Data management	19	All data will be handled and stored as described in our data protection plan and ethical approval. Within the data protection plan, records of processing activities are specified.
Statistical methods	20a	Page 19
	20b	Page 19
	20c	Page 19
Methods: Monitoring		
Data monitoring	21a	A Data Monitoring Committee (DMC) has been established. The DMC is independent of the study organisers and consists of Prof. Dr Brunna Tuschen-Caffier, Prof. Dr Erik Farin-Glattacker and Prof. Dr Dr Martin Härter. The DMC will advise the project team in case of adverse events and recommend if the trial should be modified or discontinued.
	21b	Data collection will continue until the targeted sample of 128 participants is reached.
Harms	22	Pages 9-10
Auditing	23	The recruitment management group (CMW, TZ, JB) meets weekly throughout the trial to oversee trial conduct and recruitment.
Ethics and dissemination		
Research ethics approval	24	Page 2 & Page 22
Protocol amendments	25	Deviations from the study protocol will be fully documented and disclosed in further publications. In case of deviations, the protocol in the clinical trial registry will be updated.
Consent or assent	26a	Positively screened individuals receive in-depth study and data privacy information via email. All participants submit their informed consent online before study inclusion. Participants can withdraw their participation in the study at any time and request the deletion of their data as long as the data is not yet anonymised.
	26b	Participant data will not be used in ancillary studies. This trial does not involve the collection of biological specimens.
Confidentiality	27	All data will be handled and stored as described in our data protection plan and ethical approval. Rules of data security were developed with the approval of the data security officer of the University of Freiburg.
Declaration of interests	28	Page 23

Access to data	29	Only the project team in Freiburg has access to personal data. Anonymised data can be made available to other scientists based on cooperation agreements.
Ancillary and post-trial care	30	The trial centre provides no post-trial care. Generally, health care costs in Germany are covered by the health insurance companies without extra costs for the individual.
Dissemination policy	31a	Pages 19-20 & Page 22
	31b	No professional writers will be hired.
	31c	The study protocol is published in an open-access format.
Appendices		
Informed consent materials	32	All participant materials have been approved by the ethics committee and can be obtained in German from the corresponding author.
Biological specimens	33	No biological specimens are collected.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

WHO Trial Registration Data Set (Version 1.3.1)		
1	Primary Registry and Trial Identifying Number	German Clinical Trials Register; Main ID: DRKS00024349
2	Date of Registration in Primary Registry	29/01/2021
3	Secondary Identifying Numbers	N/A
4	Source(s) of Monetary or Material Support	German Research Foundation
5	Primary Sponsor	University of Freiburg Department of Rehabilitation Psychology and Psychotherapy Institute of Psychology Engelbergerstr. 41, 79085 Freiburg, Germany
6	Secondary Sponsor(s)	N/A
7	Contact for Public Queries	Name: Claudia Mueller-Weinitschke Address: Engelbergerstr. 41 79085 Freiburg Germany Telephone: 07612039439 Email: interaktiv@psychologie.uni-freiburg.de Affiliation: University of Freiburg, Department of Rehabilitation Psychology and Psychotherapy , Institute of Psychology
8	Contact for Scientific Queries	Name: Lena Krämer Address: Engelbergerstr. 41 79085 Freiburg Germany Telephone: 07612039315 Email: kraemer@psychologie.uni-freiburg.de Affiliation: University of Freiburg, Department of Rehabilitation Psychology and Psychotherapy , Institute of Psychology
9	Public Title	Behavioral activation based on the Health Action Process Approach – Efficacy of a theory-based online intervention in depression
10	Scientific Title	Behavioral activation based on the Health Action Process Approach – Efficacy of a theory-based online intervention in depression - InterAKTIV
11	Countries of Recruitment	Germany
12	Health Condition(s) or Problem(s) Studied	F32 - Depressive episode
13	Intervention(s)	Intervention 1: Intervention group: Participants receive access to the web-based intervention, comprising 7 modules (45 minutes each, plus an introductory module), daily motivating SMS, weekly homework assignments, and weekly feedback from a psychologist.

		Participants of the intervention group have unrestricted access to other health care services. Intervention 2: Control group: Participants of the control group receive access to the web-based intervention after follow-up assessments. Participants of the control group have unrestricted access to other health care services.
14	Key Inclusion and Exclusion Criteria	Inclusion criteria: Depression diagnosis in clinical interview Exclusion criteria: current psychotherapy, current change of psychopharmaceuticals, exclusion diagnosis Age minimum: 18 Years Age maximum: 65 Years Gender: Both, male and female
15	Study Type	interventional
16	Date of First Enrollment	08/02/2021
17	Sample Size	128
18	Recruitment Status	Pending
19	Primary Outcome(s)	Primary outcome is the change of depression severity, measured by the QIDS (Quick Inventory of Depressive Symptomatology, externally assessed during the telephone interview), between baseline (t1) and post-intervention (t2, eight weeks after randomization). In addition, depression severity will be assessed at follow-up (t3, six months after randomization).
20	Key Secondary Outcomes	1. Remission of depression (SCID-1, Structured clinical interview for DSM-V) 2. Depression response (PHQ-9; Patient Health Questionnaire-9) 3. Actitity behavior: Everyday activity (BADS; Behavioral Activation for Depression Scale) 4. Activity behavior: Physical activity (IPAQ-SF; International Physical Activity Questionnaire - Short Form) 5. Motivational and volitional indicators (outcome expectancies, motivational self-efficacy, intention, volitional self-efficacy, action planning, coping planning, action control) 6. Perseverative cognitive processes (RSQ-D; Response Style Questionnaire – German Version) 7. Side effects of the intervention (INEP; Inventar zu Erfassung negativer Effekte von Psychotherapie) All assessments take place at baseline (t1), eight weeks (t2) and six months after randomization (t3).

		Covid-19-related limitations are recorded at all three time points (self-report). Additionally, sociodemographic information and the initial motivational level will be assessed at baseline (t1; self-report). At t2, received health care services (FIMA) as well as satisfaction with the intervention will be assessed.
21	Ethics Review	Status: approved Approval date: 19/11/2020 Contact: (leading) Ethics Committee-No. 20-1045 (Ethik-Kommission der Albert-Ludwigs-Universität Freiburg)
22	Completion date	N/A
23	Summary Results	N/A
24	IPD sharing statement	It is planned to make the anonymised evaluation data set available to external scientists for research purposes on the basis of cooperation agreements.

Albert-Ludwigs-Universität Freiburg. 79085 Freiburg

Studieninformation

InterAKTIV: Internetbasiertes Training zum Aktivitätenaufbau

Sehr geehrte Damen und Herren,

wir freuen uns sehr, dass Sie Interesse an unserer Studie haben, um in Ihrem Alltag aktiver zu werden und Ihre Stimmung zu verbessern. Hier erhalten Sie einige Informationen zu Inhalt und Ablauf der Studie sowie zu den Rahmenbedingungen.

Albert-Ludwigs-Universität Freiburg

Institut für Psychologie

Abteilung für Rehabilitationspsychologie und Psychotherapie

Projekt:
„InterAKTIV: Internetbasiertes Training zum Aktivitätenaufbau bei Depressionen“

Abteilungsleitung:
Prof. Dr. Dr. Jürgen Bengel
Projektleitung:
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Was sind die Hintergründe der Studie?

Depressionen zählen zu den am weitesten verbreiteten psychischen Erkrankungen in Deutschland und werden oft als sehr einschneidend und belastend erlebt. Betroffene leiden unter Niedergeschlagenheit, Interessenlosigkeit, Sorgen und Selbstzweifeln und ziehen sich häufig aus ihren früheren Aktivitäten zurück.

In wissenschaftlichen Studien hat sich gezeigt, dass Online-Trainings, d.h. internetbasierte Selbsthilfe-Trainings, wirksam sind, um Depressionen zu bewältigen und die Lebensqualität zu steigern. Sie werden daher zunehmend eingesetzt, um die Versorgung von Menschen mit depressiven Erkrankungen zu verbessern.

Vor diesem Hintergrund führt das Institut für Psychologie der Universität Freiburg eine wissenschaftliche Studie durch, um die Wirksamkeit des Online-Trainings InterAKTIV bei Depressionen zu untersuchen.

Die Bewerbung der Studie wird in Kooperation mit der AOK Baden-Württemberg über verschiedene Online- und Print-Medien der AOK Baden-Württemberg durchgeführt.

Worum geht es in dem Online-Training?

Unser Online-Training wurde von PsychologInnen entwickelt und verwendet Methoden, die sich in der psychologischen Forschung als wirksam erwiesen haben. Es handelt sich um ein kostenloses begleitetes Selbsthilfe-Training, das auf einer verschlüsselten Internetseite bereitgestellt wird. Es umfasst sieben Sitzungen, deren Bearbeitung jeweils circa 45 Minuten Zeit beansprucht. Es ist vorgesehen, dass Sie jeweils eine Sitzung pro Woche bearbeiten. Das Training soll Menschen mit depressiven Erkrankungen dabei unterstützen, im Alltag (wieder) aktiver zu werden und Ihre Stimmung zu verbessern.

Konkret können Sie sich im Training mit Ihren persönlichen Werten und Zielen auseinandersetzen und Ihre Motivation steigern. Das Training kann Ihnen außerdem dabei helfen Aktivitäten konkret zu planen und Hindernisse zu bewältigen. Wochenübungen zwischen den Sitzungen helfen Ihnen das Gelernte zu vertiefen und im Alltag zu erproben. Zu jeder Sitzung, die Sie bearbeiten, erhalten Sie schriftliche Rückmeldungen von einem E-Coach. Der E-Coach ist ein/e PsychologIn aus dem Projektteam dieser Studie, der Ihnen während der gesamten Zeit des Trainings mit Rückmeldungen zur Seite steht. Zusätzlich haben Sie die Möglichkeit, sich zusätzlich kostenlos durch tägliche motivierende SMS unterstützen zu lassen.

Hilft Ihnen das Online-Training?

Wir sind zuversichtlich, dass Ihnen das Training helfen kann, Ihre Stimmung und Lebensqualität zu verbessern. Zahlreiche internationale, nationale und auch eigene Studien haben gezeigt, dass internetbasierte Depressionstrainings wirksam sind. Natürlich hängt der Trainingserfolg aber von vielen Einflüssen ab, sodass ein Erfolg wahrscheinlich ist, aber nicht garantiert werden kann.

Was sind die Ziele der Studie?

Ziel dieser Studie ist es, zu prüfen, in welchem Ausmaß das Online-Training Betroffenen mit einer depressiven Erkrankung dabei hilft, ihre Stimmung und ihr Aktivitätslevel zu verbessern. Außerdem wird untersucht, wie sich ihre Motivation, ihre Aktivitäten, und ihr Verhalten im Alltag verändern.

Wie läuft die Studie ab?

Als Studienteilnehmende/r füllen Sie zu Beginn der Untersuchung zunächst einen Online-Fragebogen aus. Die Befragungen beziehen sich im Wesentlichen auf Ihre aktuelle Befindlichkeit, Ihr Aktivitätslevel und Ihre Aktivitätsplanungen. Anschließend werden wir Sie telefonisch kontaktieren, um mit Ihnen einen Telefontermin zu vereinbaren. Der Telefontermin wird von einer Psychologin geführt und dauert circa 60 Minuten. In dem Telefonat werden Sie genauer zu Symptomen psychischer Erkrankungen befragt und inwiefern diese auf Sie zutreffen. Die Psychologin prüft abschließend, ob das Online-Training eine geeignete Maßnahme für Sie darstellt. Wenn Sie in die Studie eingeschlossen werden, werden Sie nach dem Zufallsprinzip einer von zwei Untersuchungsgruppen zugewiesen. Die eine Gruppe erhält innerhalb weniger Tage Zugang zum Online-Training (Gruppe A). Die andere Gruppe erhält verzögert Zugang zum Online-Training (Gruppe B). Nach zwei sowie nach insgesamt sechs Monaten füllen alle Studienteilnehmenden weitere Online-Fragebögen aus und werden erneut für eine kurze Telefonbefragung kontaktiert (ca. 30 Minuten). Diese Befragungen beziehen sich erneut im Wesentlichen auf Ihre Befindlichkeit, Ihr Aktivitätslevel und Ihre Aktivitätsplanung. Im Anschluss an die Befragungen erhalten auch die Teilnehmenden der Gruppe B Zugang zum Online-Training. Dieses Vorgehen ist nötig, um eine Vergleichsgruppe zu schaffen, welche die Zwischenzeit so verbringt, wie sie es sonst – ohne das Online-Training –, auch getan hätte. Wenn Sie sich für eine Teilnahme entscheiden, ist es sehr wichtig, dass Sie an allen Befragungen teilnehmen, unabhängig davon, welcher Gruppe Sie zugeteilt wurden.

Welcher Aufwand ist mit der Studienteilnahme verbunden?

Für die Studienteilnahme benötigen Sie einen Internetzugang, eine E-Mail-Adresse, einen Festnetz- oder Handyanschluss und einen Computer. Als Teilnehmende/r können Sie das Online-Training in Anspruch nehmen und werden zusätzlich gebeten, an den drei Telefon- und Online-Befragungen teilzunehmen.

Welchen Nutzen haben Sie durch die Studienteilnahme?

Als Studienteilnehmende/r erhalten Sie kostenlosen Zugang zu InterAKTIV, einem psychologischen Online-Training, das auf modernsten psychologischen Verfahren aufbaut. Sie lernen Techniken kennen, die Sie auch im Alltag anwenden und in der Zeit nach dem Training vertiefen können,

UNI FREIBURG

um Ihre Stimmung nachhaltig zu verbessern und (wieder) aktiver zu werden.

Für den erhöhten Zeitaufwand bei der Teilnahme an den Fragebögen und Telefoninterviews erhalten Sie insgesamt eine Aufwandsentschädigung in Höhe von 30,- € (je 10€ pro Befragungszeitpunkt). Für die Aufwandsentschädigung per Banküberweisung werden Sie im Rahmen der Studieneinwilligung gebeten Ihre IBAN und BIC, sowie Ihren Namen und Ihre Anschrift anzugeben. Darüber hinaus können Sie das Online-Training kostenfrei nutzen.

Welche Nebenwirkungen kann die Teilnahme am Training haben?

Im Rahmen der Studienteilnahme füllen Sie Fragebögen aus und nehmen an Interviews teil. Die Auseinandersetzung mit den Themen kann belastend für Sie sein. Insbesondere im Rahmen des Online-Trainings befassen Sie sich mit psychologischen Themen. Wie bei jeder psychologischen Intervention kann es dadurch in Einzelfällen zu einer Verschlechterung der Symptomatik oder auch zu Verschlechterungen in verschiedenen Lebensbereichen (z.B. Beruf, Partnerschaft) kommen.

Ist die Teilnahme freiwillig?

Die Teilnahme an der Studie ist freiwillig. Wenn Sie an der Studie nicht teilnehmen möchten, entstehen Ihnen hieraus keine Nachteile. Sie können jederzeit – auch bei schon gegebener Einwilligung – ohne Angabe von Gründen aus der Studie ausscheiden und die sofortige Löschung Ihrer Daten veranlassen. Auch hierdurch entstehen Ihnen keinerlei Nachteile. Es wird ausdrücklich versichert, dass die Studie nicht von Kostenträgern (z.B. Krankenkassen) oder sonstigen Dritten (z.B. Arbeitgebern) veranlasst wurde. Es werden keine Angaben über die Studienteilnahme an die AOK Baden-Württemberg weitergegeben, das heißt die AOK erfährt nicht ob Sie an der Studie teilnehmen oder nicht.

Wie schützen wir Ihre Daten?

Der Schutz persönlicher Daten hat Priorität für uns! Ihre Daten werden vertraulich behandelt. Ausführliche Informationen zur Erhebung, Nutzung, Speicherung und Weitergabe Ihrer Daten gemäß Artikel 13 DSGVO entnehmen Sie bitte den Datenschutzinformationen (ebenfalls im Anhang Ihrer E-Mail).

Die Studie wurde vom Datenschutzbeauftragten des Universitätsklinikums Freiburg sowie der Ethikkommission der Universität Freiburg geprüft: Gegen die Studie bestehen keine datenschutzrechtlichen oder ethischen Bedenken. Die Studie wurde im Deutschen Register Klinischer Studien (DRKS) registriert; Zielsetzung, Planung und vorgeschlagene praktische Durchführung entsprechen den Anforderungen, die an ein solches Projekt zu stellen sind.

Wenn Sie an der „InterAKTIV-Studie“ teilnehmen möchten, klicken Sie bitte auf den Link in der E-Mail, um zur Plattform des Trainings zu gelangen und sich dort zu registrieren. Nach Abschluss der Registrierung und Ihrer Einwilligungserklärung in die Studienteilnahme und den Datenschutz erhalten Sie Zugang zur ersten Online-Befragung.

Für die Teilnahme an dieser Studie danken wir Ihnen sehr herzlich!

M.Sc. Claudia Mueller-Weinitschke Dr. Lena Krämer Prof. Dr. Dr. Jürgen Bengel

[This study information sheet is distributed to all participants via e-mail before study inclusion. Informed consent is given via an online form by agreeing with the study information and the additional information on data protection as per Art. 13 GDPR.]

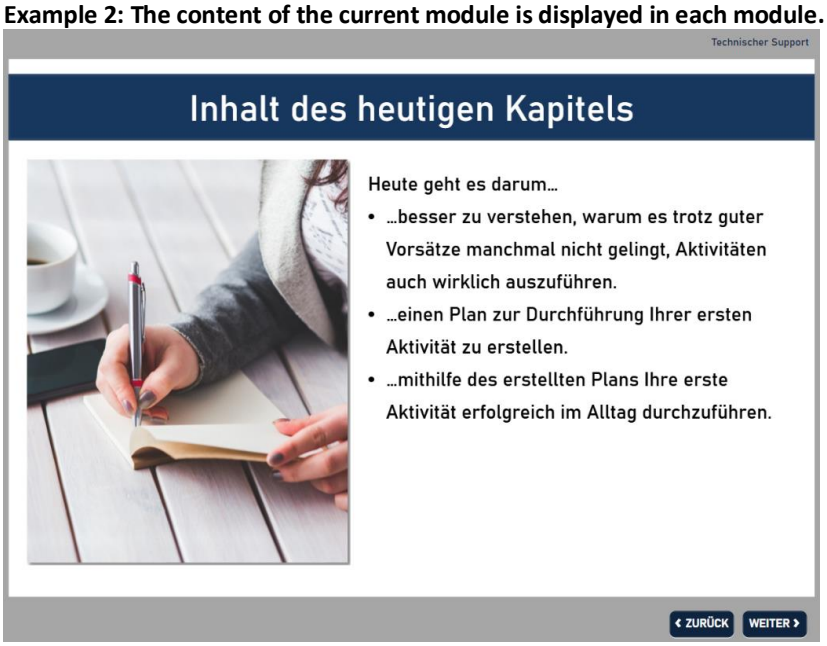
InterAKTIV: Examples of intervention components

1. Examples of recurring elements

Example 1: At the beginning of each module participants see an overview of their progress.

(InterAKTIV, Module 1, "Where are you currently at?")

Example 2: The content of the current module is displayed in each module.



(InterAKTIV, Module 4, "Content of today's module")

Example 3: Towards the end of each module participants can download the homework assignments:

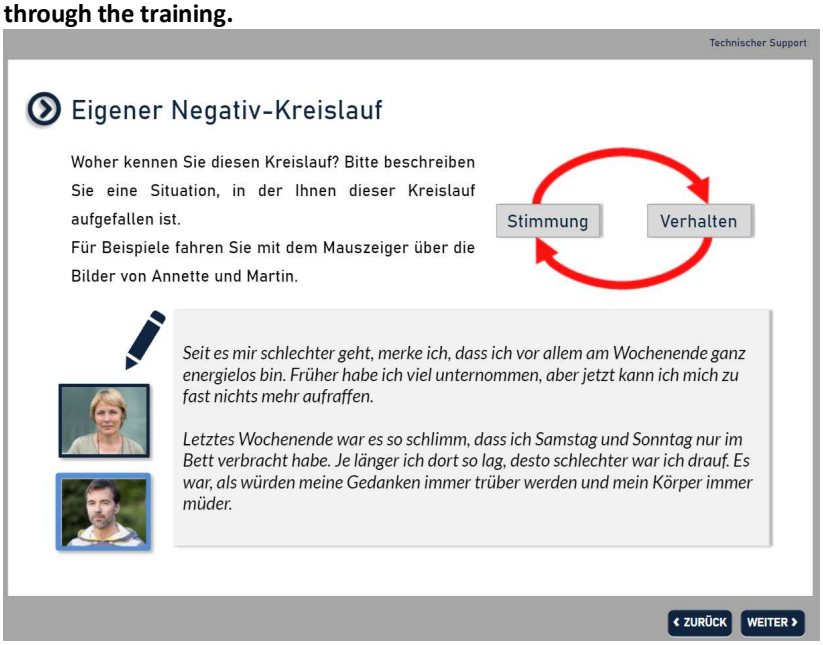
(InterAKTIV, Module 1, "Weekly homework: mood tracking")

2. Examples of module-specific components

Example 1: Module 1 → Psychoeducation on the relationship between activity and mood

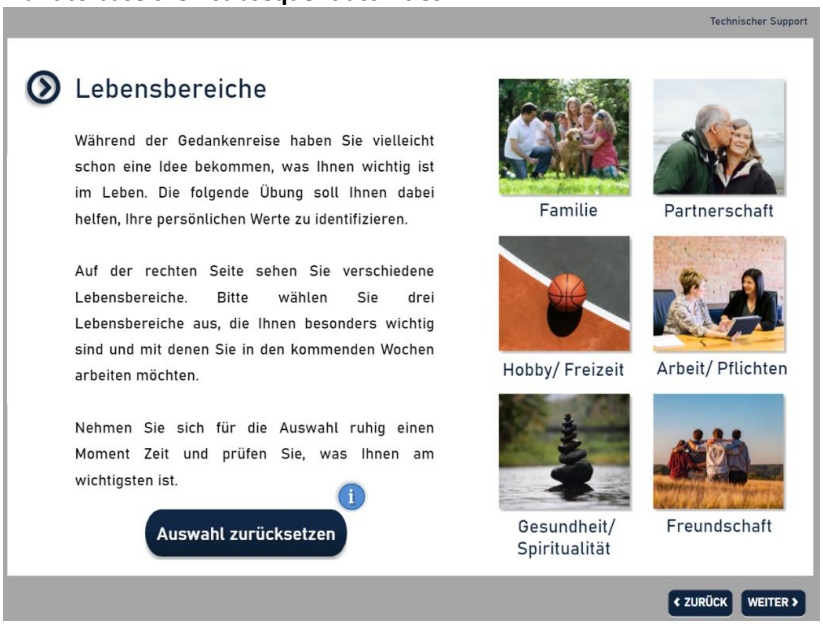
(InterAKTIV, Module 1, "My own negative cycle")

With the help of the two model subjects, study participants can see examples of how to work through the training.



(InterAKTIV, Module 1, "My own negative cycle", Exemplary participant)

Example 2: Module 2 → Participants explore and choose relevant areas in their life on which they want to base their subsequent activities.



(InterAKTIV, Module 2, "Areas of life")

Example 3: Module 4 → Action planning of a specific activity

(InterAKTIV, Module 4, "When? Where? With whom? What else?")