BMJ Open

ACTonDiabetes: study protocol of a pragmatic randomised controlled trial for the evaluation of an acceptance and commitment-based internet-based and mobile-based intervention for adults living with type 1 or type 2 diabetes

Eileen Bendig [1], Andreas Schmitt [2,3], Amelie Wittenberg,[1] Bernhard Kulzer,[2,3] Norbert Hermanns [2,3], Morten Moshagen [4], Harald Baumeister[1]

For numbered affiliations see end of article.

Correspondence to
Eileen Bendig;
eileen.bendig@uni-ulm.de

ABSTRACT

Introduction Living with diabetes can be burdensome and lead to serious emotional distress and impaired mental health. Acceptance and commitment therapy (ACT) can support people facing the challenges of living with diabetes. This trial aims to evaluate the effectiveness and cost-effectiveness of the internet-based and mobile-based intervention (IMI) 'ACTonDiabetes' in reducing diabetes distress against enhanced treatment as usual (TAU+) following specialised diabetes care.

Methods and analysis A two-armed pragmatic randomised controlled trial will be conducted to evaluate the guided IMI ACTonDiabetes against TAU+. A total of 210 adults with type 1 or type 2 diabetes and elevated diabetes distress (Problem Areas in Diabetes ≥40) will be recruited at a specialised diabetes centre. The intervention begins 2–4 weeks after hospital discharge and takes about 7–10 weeks to complete. Assessments are performed at baseline and 5 and 10 weeks as well as 6 and 12 months after randomisation. The primary outcome is diabetes distress at a 10-week follow-up (T2). Secondary outcomes are depression (Patient Health Questionnaire-8), psychological well-being (WHO-5), quality of life (Assessment of Quality of Life-8 Dimension), Diabetes-related Self-Management Questionnaire, diabetes acceptance (Acceptance and Action Diabetes Questionnaire) and negative treatment effects (Inventory for the Assessment of Negative Effects of Psychotherapy). All statistical analyses will be performed based on the intention-to-treat principle with additional per-protocol analyses. Changes in outcomes will be evaluated using the general linear model. A health-economic evaluation will be conducted from a societal perspective. Reasons for dropout will be systematically investigated.

Ethics and dissemination This clinical trial has been approved by the State Medical Chamber of Baden-Württemberg (file no. B-F-2019-010). Trial results will be submitted for publication in a peer-reviewed journal and presented at conferences.

Trial registration number DRKS00016738.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first pragmatic randomised controlled trial investigating long-term effectiveness of a guided internet-based and mobile-based intervention for people with diabetes as aftercare intervention following inpatient diabetes care.
⇒ Cost-effectiveness analysis will inform healthcare policy about the economic value of the digital health intervention as part of diabetes inpatient aftercare.
⇒ Side effects and adverse events will be monitored.
⇒ ACTonDiabetes follows persuasive intervention design principles in order to keep intervention adherence on a high level.
⇒ Results of this monocentric trial might not be generalisable to diabetes inpatient aftercare, particularly internationally considering the varying healthcare systems.

INTRODUCTION

Living with diabetes mellitus type 1 or 2 comes along with a multitude of psychological challenges in addition to the requirements of persistent daily medical treatment and glucose management.[1–4] Psychological aspects of chronic somatic diseases can have important implications for promoting coping mechanisms, the general functioning level, quality of life as well as other health outcomes.[5–7] Psychological interventions can help people with diabetes to better cope with the diagnosis,[7] adhere to complex treatment plans and manage their chronic condition in daily life.[8–10] A growing body of evidence suggests the effectiveness of psychological interventions for diabetes distress and comorbid mental disorders such as depression and anxiety.[11 12]

Diabetes distress is an important psychological aspect of living with diabetes concerning mental health.[4] Diabetes distress is defined as negative emotion and burden triggered by the demanding and progressive conditions of living with diabetes.[13–15] It involves negative emotional reactions to specific aspects associated with diabetes.[4] About 36% of people with type 2 diabetes[15] and 41% of those with type 1[16] report elevated diabetes distress. Diabetes distress has been associated with an increased risk of developing depression.[17 18] Furthermore, elevated diabetes distress is often accompanied by limited quality of life[19 20] and has been associated with less optimal diabetes self-management.[20 21] Clinical guidelines recommend screening and treatment of diabetes distress as integral part of routine diabetes care.[22 23]

Apart from the consequences of living with diabetes on the individual level, the economic consequences for society, such as in terms of lost work time and healthcare costs, are also significant.[24–27] Kalsekar *et al*[28] estimate a society-wide cost increase of 50%–90% in people with type 2 diabetes with mental comorbidities versus without. There are multiple barriers regarding access to mental healthcare such as limited mobility, time, resources as well as access to and availability of healthcare offers in the target population.[29–32]

People with diabetes may attend specialised diabetes education and treatment programmes offered as part of secondary or tertiary care (eg, diabetes self-management education) to update diabetes knowledge, improve their healthcare and diabetes management skills, check diabetes outcomes or to treat acute or long-term complications of diabetes.[33] There is evidence that diabetes distress may improve after an inpatient hospital stay, but effects may diminish on medium term and long term.[33] Psychological interventions can help to sustain treatment effects and help patients to transfer new insights, skills and routines into daily life.[34–36] Such interventions can be based on different psychotherapeutic approaches like acceptance and commitment therapy (ACT).[37] In comparison to the traditional cognitive–behavioural therapy (CBT) approach, ACT adds a focus on mindfulness.[37] Instead of focussing strategies to reduce unfavourable thoughts and feelings (=CBT), ACT-strategies focus on experiential acceptance of unchangeable aspects of negative feelings and promotes a value-oriented search movement, which can help to accept unchangeable aspects of life.[37] Thus, experiential acceptance might be particularly helpful for people with a chronic somatic disease like diabetes as it may help people cope with the ongoing treatment requirements and diabetes-associated burdens. This could reduce diabetes distress. Recent meta-analyses on ACT-based interventions report promising results. One meta-analysis reveals reductions of diabetes distress (SMD=−0.37, 95% CI −0.63 to −0.12),[38] two meta-analyses report reductions in glycated haemoglobin (HbA_{1C}) (MD=−0.35 and −0.62% points)[38 39] in favour of intervention groups (IGs) when compared with treatment as usual (TAU) or enhanced TAU+. However,

both meta-analyses call for further high-quality studies in the field.[38 39]

Internet-based and mobile-based interventions (IMIs) could be a flexible and cost-effective medium to provide aftercare following a diabetes education and treatment programme in people with diabetes. IMI can help to overcome healthcare barriers by delivering low-threshold healthcare interventions on a large scale.[40] Recent meta-analyses show that IMIs may be as effective as face-to-face psychotherapy in treating comorbid mental disorders in people with chronic somatic diseases.[41] IMIs have been effectively used for the supportive treatment of diabetes (eg, for improving nutrition habits[42] and physical activity[42] as well as fostering more consistent diabetes self-management[43] and smoking cessation[44]) as well as for the treatment of psychosocial distress and common comorbid mental disorders of diabetes (eg, reducing anxiety,[45] depression,[45 46] diabetes distress[45 47]). However, these findings originate from studies carried out in more standardised research contexts rather than the 'real world'. IMIs as aftercare have proven their potential in a variety of mental disorders and somatic conditions,[48–50] while evidence on diabetes aftercare is missing.

Objectives

The aim of this trial is to evaluate the effectiveness and cost-effectiveness of ACTonDiabetes, an IMI based on ACT specifically developed for patients with diabetes. Primary aim is to investigate the research question:

1. Does ACTonDiabetes result in improved diabetes distress compared with TAU+ a psychoeducative booklet (=TAU+)?

The following secondary research questions will be investigated:

2. Does ACTonDiabetes result in improved secondary medical and psychosocial outcomes compared with TAU+?
3. Is ACTonDiabetes cost-effective compared with TAU+?
4. Are there side effects and adverse events associated with ACTonDiabetes?
5. Which variables moderate and mediate the effects of ACTonDiabetes?

METHODS AND ANALYSIS
Study design

A two-armed pragmatic randomised controlled trial (RCT) will be conducted comparing the effects of a guided version of ACTonDiabetes (IG) compared with a control group (CG) receiving enhanced standard care (TAU+). Primary and secondary outcomes will be assessed over a period of 12 months. Assessments will take place at baseline (T0), intermediately (4 weeks, T1), as well as 10-week and 6-month and 12-month (T2–T4) follow-up (figure 1). Data collection started in June 2019 and will end approximately in December 2022.
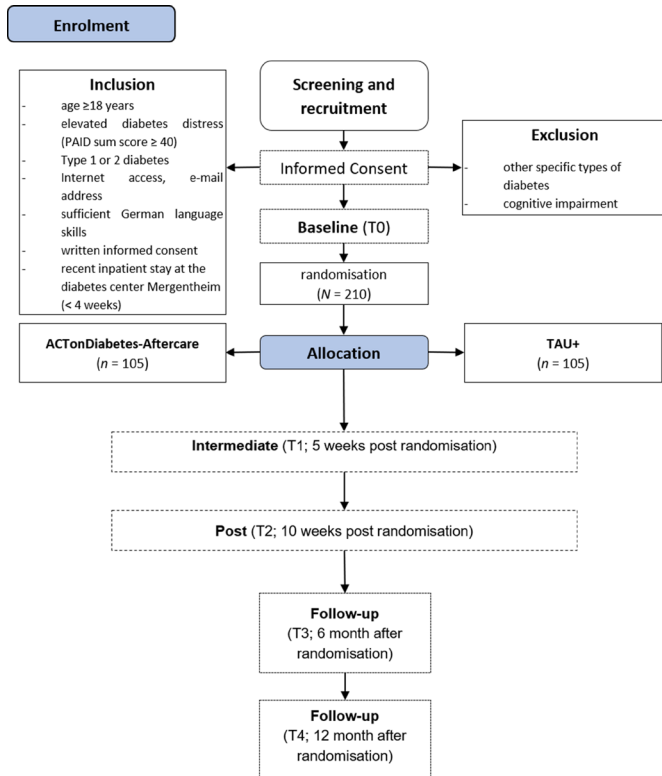
Figure 1 Flow chart of the planned study procedure. PAID, Problem Areas in Diabetes; TAU, treatment as usual.

Eligibility criteria

Patients are eligible for inclusion if they: have type 1 or type 2 diabetes mellitus, indicate elevated diabetes distress (Problem Areas in Diabetes, PAID sum score ≥40), age 18 years or older, were recently treated as an inpatient in the diabetes centre (<4 weeks), have internet access and an email address; have sufficient German language skills and provide written informed consent. Exclusion criteria are: other specific types of diabetes and cognitive impairment (eg, dementia, diagnoses according to patient records).

Recruitment

This clinical trial is carried out in collaboration with a specialised inpatient diabetes centre in Germany (Diabetes Center Mergentheim). On admission at the clinic, patients with diabetes are asked whether they would be willing to be informed about current research projects. People providing consent will be screened for inclusion and exclusion criteria within the first days of their stay by research staff. Screening will include a self-report measure of diabetes distress. Eligible patients for the present trial will be contacted by research staff and informed about the study and ACTonDiabetes. People providing written informed consent will be referred to the study centre (Ulm University) for baseline assessment and randomisation. Participating patients are asked to complete the baseline assessment (T0) within 4 weeks after discharge from the diabetes clinic.

Randomisation and blinding

The group allocation is performed by persons who are blinded towards the endpoints and study procedures and not otherwise involved in the study. After completion of the baseline assessment, participants are randomised to either the IG or the control condition (TAU+). A permuted block randomisation with 6, 9 and 12 block-size and an allocation ratio of 1:1 will be used. Group membership is only known by the persons administering allocated treatments to participants (MM and AW). Data collectors are blinded with regard to group membership. The randomisation list is created by an automated web-based programme named 'sealed envelope' (https://sealedenvelope.com). Participants are informed about their group allocation via email.

Intervention

ACTonDiabetes was developed on the basis of an already evaluated IMI 'ACTonPain'.[51 52] ACTonPain was found to be effective in reducing pain interference in people with chronic pain.[52] The content of the ACTonPain intervention was adapted to the population of people with diabetes and subsequently tested in a pilot trial.[53] Based on the findings of the pilot trial, ACTonDiabetes was further developed. Changes concern a strengthened ACT focus, shortened text passages supplemented with more persuasive design components[54] such as interactive materials and visualisations. The feasibility trial also showed that participants wanted to bring in more of their personal lives and work on their own stories. To address this finding, a therapeutic writing was incorporated. One reason for adding a writing intervention was to foster the feeling that the intervention is personalised for the individual, with space for reflections about life and living. Another reason was to support contact with positive aspects in life and inducing positive emotions following positive psychological writing approaches.[55–58] Writing tasks include writings on the personal life story and benefit finding writing.

The intervention consists of seven core elements: psychoeducation, exemplary people with diabetes, ACT-based exercises, for example, mindfulness exercises, diaries to document their progress, a therapeutic writing intervention, feedback from e-coaches (trained psychologist) and optional SMS coaching. Illustrations of contents comprise video sequences and ACT-metaphors in the form of text or audio.

Participants are recommended and encouraged by e-coaches to complete one module per week (ie, process through the intervention within 7 weeks) and to complete the refresher module 4 weeks after the seventh module is finished. Similar to a face-to-face psychotherapy session, processing through one module is conceptualised to take approximately 45–60 min. However, there is no time limit and participants can take breaks whenever they want to and are actively encouraged to do so every 15–20 min. After completing a module, participants are encouraged to set a concrete date for the next module and to practice

Table 1 Content and techniques of the ACTonDiabetes intervention based on Hayes *et al*[101]

Title of module	Content	ACT technique
Module 1: Introduction	Introduction to the training, information about diabetes and diabetes distress, reflection of participants' personal coping strategies (short term and long term), introduction to mindfulness, therapeutic writing	Coping strategies, mindfulness
Module 2: Control and acceptance	Definition of diabetes distress, primary and secondary suffering, influenceable variables, acceptance as an alternative to control	Experiential acceptance, mindfulness
Module 3: Thought and feelings	Definition of negative thoughts and feelings and dealing with them, goal setting using the SMART method, relevance of 'and' instead of 'but', therapeutic writing	Contact with the present moment, cognitive defusion, mindfulness
Module 4: You and your self	Definition and dealing with self-perception, influence of contextual perspective on feelings and thoughts	Self as context, mindfulness
Module 5: What I appreciate in life	Information on personal values and their importance for one's behaviour, 'compass of values' for reflection on own values, therapeutic writing	Values, mindfulness
Module 6: Commitment	Introduction to ACT formula, definition of commitment and its influence on the implementation of values, meaningful actions/taking action	Committed action, values, mindfulness
Module 7: The way forward	Conclusion and future plans, reflection of own progress	Repetition of all techniques, mindfulness
Module 8: Refresh	Refreshment of core concepts and strategies	All techniques, mindfulness

SMART method=goal-setting strateg. ACT techniques mirror the six core processes of ACT which aim at increasing psychological flexibility. Psychological flexibility means to accept negative thoughts and feelings and committing to and acting in line with personal values.[101]
ACT, acceptance and commitment therapy; SMART, Specific, Measurable, Achievable, Reasonable, Time-bound.

the newly learnt strategies in between. Participants of the IG are guided by e-coaches who are psychologists supervised by a senior e-coach (EB) and a senior psychotherapist (HB). Tasks of the e-coaches comprise a welcoming message, answering questions, giving feedback on each module as well as reminding participants to do the training if they pause without prior notice. If participants do not complete the weekly module, they are reminded by their e-coach twice to complete it. If the participants have not completed the module by then, the module is deactivated and the participants need to reactivate it by contacting the e-coach to gain access. Within 2 weekdays after finishing a module, participants receive a feedback email from their e-coach and the following module is being activated. Emails are standardised, existing templates are chosen and partly adapted to participants input. Participants can reaccess the intervention and download key content (table 1) until 1 year after randomisation. At the end of every module, a conclusion and a brief preview of the next module is presented. The intervention structure and procedures are shown in figure 2.

Participants are advised to document their mindfulness practice and write an 'acceptance diary' to reflect on their progress of using acceptance in stressful situations. Detailed information on intervention contents can be retrieved from online supplemental material S1.
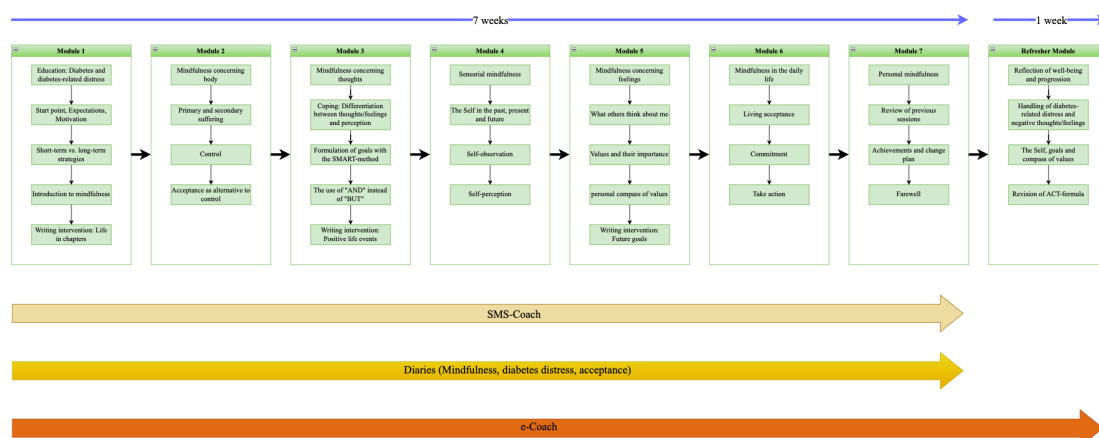
Figure 2 Intervention structure and procedure. ACT, acceptance and commitment therapy.

ACTonDiabetes is offered on the minddistrict platform (https://www.minddistrict.com). Access to the platform is via a unique username-password combination and is available 24/7 from all devices with internet access. However, ACTonDiabetes is optimised for PCs, notebooks and (large-screen) tablets. All transferred data are secured via www.minddistrict.com based on ISO27001:2013, ISAE 3402 type II and guidelines NEN7510, ISO14001.

Mechanisms to foster adherence
Guidance
If participants do not complete the next module 2 weekdays after their scheduled time point, participants receive three standardised reminders by their e-coach before an email about the upcoming deactivation of the account is sent. Participants receive a call before deactivation and can reactive their account anytime during the trial. Guidance aims at encouraging and motivating the participants. Total amount of time invested by an e-coach across the whole programme for one participant should be on average not exceed 60 min. Actual guidance time spent by e-coaches will be documented.

SMS coach
In module 1, participants can choose if they want to be supported by text messages for the next 7 weeks during the training. Participants selecting the SMS coach receive one SMS per week. SMS will be sent at different times (morning, noon and afternoon). These text messages are standardised and have motivating and supportive content (eg, tiny tasks and reminders to practice mindfulness).

Administrative and technical support
In case participants forget their password or have other technical issues, they can contact the study team for technical support at every point during the training.

Enhanced TAU control condition
Participants of the IG and CG both have unrestricted access to TAU. Participants of the CG receive a booklet with psychoeducation (=enhanced TAU, TAU+) on basic principles of ACT and diabetes distress. Additionally, the booklet contains information on further treatment options in primary and secondary (mental) healthcare. This means that the intervention will be tested against a control condition including a minimal intervention, resulting in a stricter, more conservative test of its effectiveness.

ASSESSMENTS
Data will be collected on-site (screening) and online at baseline (T0), intermediately (5 weeks postrandomisation=T1) and 10 weeks (proxy for post-treatment=T2), 6 months (T3) and 12 months (T4) after randomisation. A flow chart of the study can be seen in figure 1. The outcomes, their measurement instrument and points of assessment are shown in table 2.

Screening
The German version of the PAID questionnaire[59] is administered to assess diabetes distress when admitted to the diabetes clinic. Additionally, the screening includes age, sex, diabetes type and duration, long-term complications of diabetes and concomitant diseases and glycated haemoglobin (HbA_{1c}; according to medical records/current diagnostics) as well as the assessment of sufficient knowledge of German language, internet access and preliminary release date (leaving the diabetes clinic).

Sociodemographic and medical data
Sociodemographic data (collected at T0 survey) includes information on sex, age, citizenship, federal state, marital status and education. Diabetes-related medical data (collected as part of the screening) includes diabetes type and duration in years, long-term complications of diabetes and concomitant diseases, HbA_{1c} as well as information on illness and treatment like physical and psychological treatment, physical activity, alcohol and tobacco use and somatic risk factors (body mass index, arterial hypertension, comorbid chronic diseases).

Outcome measurements
Primary outcome
The primary outcome is the reduction of diabetes distress at T2 assessed with the German version of the 'PAID' scale.[59] Twenty items evaluate common diabetes-related emotional burdens (eg, 'Feeling alone with your diabetes?'). Participants can answer on a 5-point Likert scale (0 = 'no problem' to 4 = 'serious problem'). The sum of raw scores is multiplied with 1.25 and produces a total score (range: 0–100). Higher scores indicate more severe diabetes distress: Values of 40 or higher indicate serious diabetes distress.[60] The German version shows internal consistencies between α=0.92 and 0.95.[61 62] The reduction of diabetes distress will also be evaluated at 6-month follow-up and 12-month follow-up as secondary outcome.

Secondary outcomes and covariates
Psychological well-being
Psychological well-being is measured by the 'WHO-Five Well-being Index (WHO-5)'.[63] Psychological well-being for the past 2 weeks is rated with five items (eg, 'I have felt cheerful and in good spirits') on a 6-point Likert scale (0 = 'at no time' to 5 = 'all the time'). The raw sum score is transformed to a total score ranging from 0 to 100 (by multiplication by 4). Higher scores indicate higher well-being. Cronbach's α in a large representative German sample is high (α=0.92).[64]

Depressive symptoms
Depressive symptoms are assessed by the 'Patient Health Questionnaire-8'.[65] Eight items request the defining symptoms of depression according to the DSM (eg, 'feeling down, depressed or hopeless'). Symptom frequency is rated on a 4-point Likert scale (0 = 'not at all' to 3 = 'almost every day'). There is an additional item which requests to

Table 2 Measurement instruments, constructs and points of assessment

Construct	Measurement instrument	Time of measurement					
		Screening	T_0	T_1	T_2	T_3	T_4
Sociodemographic data	Patient file (screening) Self-report (T0)	X	X	–	–	–	–
Medical data	Patient file (screening) Self-report (T0–T4)	X	X	X	X	X	X
Primary outcome							
Diabetes distress	Problem Areas in Diabetes Scale	X	X	X	X*	X	X
Secondary outcomes							
Psychological well-being	WHO-Five Well-being Index	–	X	X	X	X	X
Depressive symptoms	Patient Health Questionnaire-8	–	X	X	X	X	X
Quality of life	Assessment of Quality of Life-8 Dimension	–	X	–	X	X	X
Diabetes acceptance	Acceptance and Action Diabetes Questionnaire	–	X	X	X	X	X
Psychological flexibility	Acceptance and Action Questionnaire-II	–	X	X	X	X	X
Diabetes self-management	Diabetes Self-Management Questionnaire	–	X	–	X	X	X
Fear of progression	Fear of Progression Questionnaire, Short Form	–	X	–	X	X	X
Emotion regulation	Emotion Regulation Questionnaire	–	X	X	X	–	–
Metacognition	Metacognitions About Symptom Control Scale	–	X	X	X	–	–
Glycaemic outcome	Glycated haemoglobin	X	–	–	–	X	–
Measurement instruments to evaluate treatment expectations and acceptance							
Treatment expectations	Credibility/Expectancy Questionnaire	–	X	–	–	–	–
Satisfaction	Client Satisfaction Questionnaire	–	–	–	X†	–	–
Side effects	Inventory for the Assessment of Negative Effects of Psychotherapy	–	–	–	X†	–	–
Alliance participants	Working Alliance Inventory, short revised (WAI-SR)	–	–	–	X‡	–	–
Alliance e-coach	WAI, SR therapist version (WAI-SRT)	–	–	–	X§	–	–
Measurement instruments for cost-effectiveness							
Utilisation of healthcare services	Trimbos Institute and Institute of Medical Technology Questionnaire for Costs Associated with Psychiatric Illness	–	X	–	–	X	X
Measurement for participants leaving within the course of the trial							
Reasons for drop-out	Drop-out questionnaire	Study process drop-out					
Evaluation of the writing sessions							
Manipulation-check writing	Postwriting Questionnaire	After each writing session‡					
Centrality of events	Centrality of Events Scale						
Gratitude	Gratitude Questionnaire						

Table 2 Continued

Construct	Measurement instrument	Time of measurement					
		Screening	T_0	T_1	T_2	T_3	T_4

Screening during inpatient stay.
*Primary endpoint.
†Different versions for IG and CG.
‡Questionnaire only used by IG.
§Questionnaire only used by e-coach.
CG, control group; IG, intervention group; T0, baseline; T1, intermediate (5 weeks postrandomisation); T2, post (10 weeks postrandomisation); T3, 6-month follow-up; T4, 12-month follow-up.

which degree functioning in daily life is limited and/or to which degree the person suffers from the reported symptoms. A total score of 10 or more indicates likely depression.[65] Cronbach's α is high (α=0.82).[65]

Diabetes acceptance

Psychological flexibility towards diabetes will be measured using the 'Acceptance and Action Diabetes Questionnaire',[66] an 11-item questionnaire with a five-point Likert response scale (1 = 'never' to 5 = 'nearly always'). Items concern the acceptance of diabetes-related negative feelings and thoughts and its impact on valued action (eg, 'I do not take care of my diabetes because it reminds me that I have diabetes'). The German version has shown an internal consistency of α=0.85.[66]

Psychological flexibility

The German version of the 'Acceptance and Action Questionnaire-II'[67] is a measure of psychological inflexibility consisting of 7 items. On a 7-point Likert scale, ranging from 0 = 'never true' to 6 = 'always true', a person's willingness to experience unwanted thoughts and feelings and their ability to act despite the presence of undesirable thoughts and feelings is assessed. In this study, items were reverse coded to reflect psychological flexibility rather than inflexibility. Sum scores (range: 0–42) are computed with higher values indicating higher psychological flexibility. The questionnaire has shown good psychometric properties in a German sample.[67]

Diabetes-related self-management

The participants' self-management is measured by the 'Diabetes Self-Management Questionnaire (DSMQ)'.[68] It consists of 16 items formulated as behaviour descriptions from the participant's perspective (eg, 'I take my diabetes medication (eg, insulin, tablets) as prescribed'). Answers are given on a 4-point Likert scale (0 = 'does not apply to me' to 3 = 'applies to me very much'). The DSMQ covers five different aspects of self-management: dietary control, medication adherence, blood glucose monitoring, physically activity and physician contact. The items refer to the previous 8 weeks.[69] The DSMQ shows an internal consistency of α=0.88.[70]

Fear of progression

The short form of the 'Fear of Progression Questionnaire' worries and fear of disease progression can be captured

within people with chronic diseases.[71] The response to twelve Items is documented on a 5-point Likert scale (1 = 'never' to 5 = 'very often'). Internal consistency is good (Cronbach's α=0.87).[71]

Emotion regulation

The 'Emotion Regulation Questionnaire'[72] is a 10-item questionnaire measuring positive and negative feelings as well as their regulation. Items refer to two different emotion regulation strategies: Reappraisal and suppression. Participants rate the items on a scale from 1 ('strongly disagree') to 7 ('strongly agree'). Means show the preference for each strategy indicating higher preference at higher mean scores. Internal consistencies (α) are acceptable to good and differ from 0.75 to 0.82.[72]

Metacognition

The revised 'Metacognitions about Symptoms Control Scale'[73] assesses negative and positive metacognitions by focusing on and thinking about symptoms. A 4-point Likert scale (1 = 'do not agree' to 4 = 'agree strongly') is used to rate the eight items in the revised version. Internal consistencies for the German version for both of the factors (positive/negative) are between acceptable and good, differing from α=0.70 to α=0.80.[73]

Treatment expectancy

Treatment expectancy is measured with the 'Credibility/Expectancy Questionnaire'[74] with six items at T0. Four items are rated on a 9-point and two items on a 10-point Likert scale with varying descriptions. The scale can be separated in the two factors credibility and expectancy. Cronbach's α for credibility varies from 0.79 to 0.90, for expectancy from 0.81 to 0.86 and for the total scale from 0.84 to 0.85 indicating acceptable to high internal consistency.[74]

Intervention satisfaction

To assess satisfaction with intervention, the 'Client Satisfaction Questionnaire (CSQ)'[75] is used at T2. In the CSQ, participants rate their satisfaction with the intervention on a 4-point Likert scale for each of the eight items. Higher scores indicate higher satisfaction. Cronbach's α is very good (α=0.9).[76] For psychosomatic populations, a mean of M=23.5 (SD=5.0) and Cronbach's α=0.93 is reported.[75] Values greater than M=23 are classified as good treatment satisfaction.[75] Treatment satisfaction should at least be

deemed as 'good' for indicating that the intervention is acceptable with regard to treatment satisfaction.

Negative side effects

Experienced negative side effects of the intervention and enhanced TAU are recorded with the Inventory for the 'Assessment of Negative Effects of Psychotherapy'[77] at T2. It consists of 22 (IG) or 18 (CG) Items. Items are partly rated on a 4-point Likert scale (0 = 'no agreement' to 3 = 'total agreement') partly on a bipolar 7-point scale. Adverse effects in social life, intrapersonal factors or work-related situations are taken into consideration. The original inventory with 32 items has an internal consistency of α=0.95.[78] Additionally, as an indicator of (serious) adverse events, reliable symptom deterioration rates will be reported.

Working alliance

The short, revised version of the 'Working Alliance Inventory (WAI-SR)'[79] will be applied to measure the therapeutic alliance between client and e-coach at T2. The 12-item self-report questionnaire covers the three subscales, namely: (A) agreement on tasks, (B) agreement on goals and (3) development of an affective bond. For the German version, internal consistencies (α) between 0.81 and 0.91 were reported for the subscales and between 0.90 and 0.93 for the total score.[80] Participants in IG will complete the WAI-SR at T2. Additionally, e-coaches will be requested to complete the 10-item therapist version (WAI-SRT)[81] at T2. This will allow us to compare how the therapeutic relationship is experienced by client and by e-coach, to gain a comprehensive picture of the experienced working alliance. The WAI-SR and the WAI-SRT were adapted in wording for the current study investigating therapeutic alliance in guided IMI. The items were changed to refer to e-coaches instead of therapists and to online trainings instead of therapy.

Healthcare utilisation

Healthcare utilisation will be measured with the TiC-P[82] to achieve a detailed description of TAU+. Cost evaluation will be based on the German version of the Dutch cost questionnaire 'Trimbos Institute and Institute of Medical Technology Questionnaire for Costs Associated with Psychiatric Illness' (TiC-P).[82] This self-report questionnaire assesses the usage of healthcare services (eg, general practice services, intake of medications, sessions with psychotherapists or psychiatrists) and productivity loss (eg, hospital days, absenteeism and presentism). The questionnaire was specifically adapted to people with type 1 or type 2 diabetes.

Quality of life

Quality of life will be assessed using the 'Assessment of Quality of Life Inventory-8 Dimension (AQoL-8D)'.[83] Each of 35 items loads on 1 of 8 dimensions of life of quality and is rated on 4–6 point scales. For analysis, there is an algorithm which can be used for quality of life in general as well as for subdimensions (independent living, pain, senses, mental health, happiness, coping, relationships and self-worth). The total scores can range between 0 and 1. Norm values are available. Reliability of AQoL-8D is very good with a Cronbach's α of 0.96.[83]

Drop-out

Reasons for participants dropping out are assessed systematically using a drop-out questionnaire with various items and open questions at the time of drop-out.[84] The following are recorded in the IG: prerandomisation (potentially eligible persons who expressed an initial interest in participating but then do not participate), pretreatment (persons who were randomised but then do not start the intervention) and treatment drop-out (persons who began the treatment but do not complete it). Additionally, participants in the CG receive a questionnaire on drop-out reasons if they decide to end their participation.

Centrality of events

The 'Centrality of Event Scale (CES)'[85] is used to evaluate the paradigm of therapeutic writing. The CES measures the centrality of an event to a person, differentiating three independent characteristics. Whether the event is seen as (1) a reference point for everyday inferences, (2) a turning point in the life story and (3) as an element of the personal identity. Participants rate the 7 items of the short-term version on a 5-point Likert scale from 1 = 'totally disagree' to 5 = 'totally agree'. With a Cronbach's α of 0.88 the scale shows good internal consistency.[85]

Gratitude

The 'Gratitude Questionnaire (GQ-6)'[86] is used to evaluate the gratitude task within the expressive writing paradigm. GQ-6 measures the level of dispositional gratitude in participants. The GQ-6 is a 6-item self-report scale (eg, 'I have so much in live to be thankful for') using a 7-point Likert scale from 1 ('strongly disagree') to 7 ('strongly agree'). Two items are negatively keyed to inhibit response bias. Total scores can range from 6 to 42 with higher scores indicating greater levels of dispositional gratitude. Internal consistency is high (Cronbach's α=0.87).[86]

Postwriting questionnaire

To assess the paradigm of expressive writing after every writing session the participants answer four questions about their feelings and thoughts during and after the writing experience. Answers are rated on a 5-point Likert scale (1 = 'not at all', 3 = 'few', 5 = 'very much/extremely'). The questionnaire was adapted from the English version of Pennebaker et al[87] by the authors.

Intervention use

The minddistrict platform collects data on user activity. Data include the time of the start and end of a module as well as the previously described postwriting questionnaire and participants narratives.

Sample size

Primary endpoint of this study is the standardised mean difference between the IG and TAU +in diabetes distress at T2. A meta-analysis on ACT in comparison to (active) controls found an effect of g=0.42 favouring the ACT condition.[88] Spijkerman *et al* found an effect for guided mindfulness-based IMIs of g=0.43.[89] For an IMI comparable to ours targeting diabetes distress and depressive symptoms, Nobis *et al*[90] found an effect size of *d*=0.58 (intention-to-treat, ITT) for the reduction of diabetes distress at post-treatment. A meta-analysis on ACT interventions for the reduction of diabetes distress revealed a reduction of Standardized Mean Difference (SMD) =0.37 in favour of IGs in comparison to TAU or TAU +controls.[38] As a consequence the pooled effect size of *d*=0.45 is being expected. Power analysis with G*Power[91] recommend a sample size of 105 participants per group on the assumption of two-tailed testing, an alpha error probability of α=0.05 and power of 1−β=0.90. Thus, we aim at recruiting n=105 per group, that is 210 randomised persons per total sample. As data analysis will be based on ITT principles, increasing sample size in order to compensate for drop-outs is not necessary.

Statistical analyses

Patterns of missing data will be examined and analyses will be adjusted accordingly (ie, multiple imputation), provided that no patterns of systematically missing data can be found.[92] If the missing data mechanism will not be at least missing at random, sensitivity analysis will be employed. Analyses will be conducted on a two-sided level of significance (α=0.05). Participant characteristics will be described using descriptive statistics. No interim analyses will be performed to the primary outcome.

All statistical analyses will be performed based on (ITT principle. Additionally, per-protocol analyses will be conducted based on the subsample who substantially completed the intervention (at least 80% of the modules) until 10 weeks (T2), 6 months (T3) and 12 months (T4) after randomisation.

Linear regression analysis with robust SEs will be used to evaluate group differences between IG and CG on the primary outcome (reduction of diabetes distress) at T2 (10 weeks after randomisation), adjusting for baseline scores and also evaluating the baseline × group interaction. Standardised mean differences and 95% CIs at all measurement points will be calculated. Long-term effects will be evaluated using linear mixed-effect modelling.

Secondary outcomes will be analysed accordingly. Exploratory mediation and moderation analyses involving the primary and secondary outcomes as well as demographic data will be performed. Sociodemographic (eg, age, sex) and health-related variables (eg, baseline diabetes distress) will be analysed. Regression analyses will be applied with group as an effect-coded predictor along with the main effects of moderator variables and their interaction effects with group. Effect coding will be applied to categorical and z-standardisation to continuous variables. Each moderator will be tested in a separate regression model. Mediation analyses will be conducted to examine potential processes that explain effects on health outcomes (eg, psychological flexibility, emotion regulation, metacognition, working alliance). Analyses on cost-effectiveness will be performed from a societal (eg, all relevant costs) and public healthcare perspective (eg, direct medical costs) within a time frame of 12 months. Missing cost and effect data will be imputed (eg, multiple imputation by chained equations), given there are no patterns of systematically missing data.

Patient and public involvement

Patient and public involvement (PPI) representatives provide input to this study in several stages. Results of the feasibility trial on ACTonDiabetes were used to further develop and optimise study design and procedures. PPI representatives were included in the intervention development to improve content and usability of ACTonDiabetes.

DISCUSSION

ACTonDiabetes has the potential to decrease diabetes distress following diabetes inpatient care. Considering the high prevalence rate of diabetes worldwide, amounting to 451 million and estimated to increase to 693 million adults until 2045 as well as the prevalence of 36%–41% of people with diabetes affected by diabetes distress[15 16] the possible population targeted with ACTonDiabetes is substantial.[93] Adults experiencing elevated diabetes distress hold a threefold risk of developing depressive symptoms,[17] which illustrates the psychological burden that often comes along with living with diabetes as well as increased macrosocial cost that arise for comorbid psychosocial issues in people with diabetes.[28] These findings support a high need and potential for improvement of an easily accessible and potentially cost-effective treatment for the large and growing diabetes population.

The planned study is characterised by a number of strengths: First, ACTonDiabetes has been successfully tested within a randomised controlled pilot trial and has shown its feasibility in people with diabetes.[53] ACTonDiabetes could provide a suitable intervention for patients with diabetes and diabetes distress. It may help people maintaining psychosocial health and further decrease diabetes distress. Second, we will systematically collect data on potential adverse events/negative effects and investigate if they could be related to the intervention. Third, long-term effectiveness of ACTonDiabetes will be investigated. To our knowledge, there are no data from previous studies regarding long-term effectiveness of an ACT-based intervention for people with diabetes. This trial will gather information on cost-effectiveness of an IMI programme over a follow-up period of 12 months.

Potential obstacles need to be taken into account. One problem could arise from suboptimal treatment acceptance. Baumeister *et al*[94] found that 91.5% of people with diabetes displayed a moderate or even low level of

acceptance towards an IMI aiming at reducing depressive symptoms. However, the feasibility trial on ACTonDiabetes revealed neutral or positive average acceptance levels as reported by the participants.[53] Implementing the ACTonDiabetes intervention immediately after an inpatient stay might even be more favourable for acceptance as patients might be more open to receiving an intervention and aiming for personal change.

Furthermore, moderate to high discontinuation rates are a general problem within online and offline psychological interventions, which has to be considered.[34] In the feasibility trial on ACTonDiabetes, 42% of the participants dropped out at some point during the study which could be (partly) explained by unfulfilled expectations concerning the intervention contents.[53] Another explanation for high drop-out rates might be the high temporal effort and textual content of the modules.[53] To improve study adherence, the online training was therefore edited to shorten contents and text passages. More interactive and illustrative elements were included in the intervention. Besides this, guidance by trained e-coaches as well as an SMS coach were added to the intervention. Both components have shown to improve intervention adherence.[95 96] In addition, standardised reminding procedures are applied. Reasons for intervention drop-out will be assessed via questionnaire to help improve future IMI for decreasing drop-out rates.

This trial enrols people with both type 1 and type 2 diabetes. This is because diabetes distress is a common concern in both types and we expect that the tested intervention may be effective for both of them. Furthermore, people with type 2 diabetes referred to the centre usually have long-standing diabetes treated with insulin, so they are likely to experience similar conditions as those with type 1 diabetes and the potential sources of diabetes distress may be similar. Nevertheless, specific requirements and burdens may vary with treatment regimens, thus there is a risk of heterogeneity due to the inclusion of more than one diabetes type, which will need to be considered.

ETHICS AND DISSEMINATION
This clinical trial has been approved by the State Medical Chamber of Baden-Württemberg (file no. B-F-2019-010). Written informed consent for participation in the study will be obtained from all participants prior to their involvement. Participants will receive written information on study conditions, data security, publication of anonymised results, voluntariness of participation and the right to leave the study at all times. This clinical trial will be reported in accordance with the Consolidated Standards of Reporting Trials Statement 2010, the extension for reporting pragmatic trials[97 98] and the Standard Protocol Items: Recommendations for Interventional Trials guidelines for reporting protocols of RCTs[99] as well as the guidelines for executing and reporting IMI research.[100] Trial results will be submitted for publication in a peer-reviewed

journal and presented at conferences. Central results will be communicated to the DDS. External researchers may get access to the final trial dataset (from HB) on request depending on to be specified data security and data exchange regulation agreements. According to German law, data will only be shared with parties outside the project team in de facto anonymised form.

Author affiliations
¹Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, University of Ulm, Ulm, Germany
²Research Institute of the Diabetes Academy Mergentheim, Diabetes Center Mergentheim, Bad Mergentheim, Germany
³German Center for Diabetes Research (DZD), Muenchen-Neuherberg, Germany
⁴Department of Research Methods, Institute of Psychology and Education, University of Ulm, Ulm, Germany

Twitter Eileen Bendig @EileenBendig

ORCID iDs
Eileen Bendig http://orcid.org/0000-0001-6727-1751

Andreas Schmitt http://orcid.org/0000-0002-5913-1457
Norbert Hermanns http://orcid.org/0000-0002-2903-2677
Morten Moshagen http://orcid.org/0000-0002-2929-7288

REFERENCES

1 Fisher L, Polonsky WH, Hessler DM, *et al*. Understanding the sources of diabetes distress in adults with type 1 diabetes. *J Diabetes Complications* 2015;29:572–7.
2 Skinner TC, Joensen L, Parkin T. Twenty-Five years of diabetes distress research. *Diabet Med* 2020;37:393–400.
3 Dennick K, Sturt J, Speight J. What is diabetes distress and how can we measure it? A narrative review and conceptual model. *J Diabetes Complications* 2017;31:898–911.
4 Snoek FJ, Bremmer MA, Hermanns N. Constructs of depression and distress in diabetes: time for an appraisal. *Lancet Diabetes Endocrinol* 2015;3:450–60.
5 Cochran J, Conn VS. Meta-Analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educ* 2008;34:815–23.
6 Harkness E, Macdonald W, Valderas J, *et al*. Identifying psychosocial interventions that improve both physical and mental health in patients with diabetes: a systematic review and meta-analysis. *Diabetes Care* 2010;33:926–30.
7 Fisher EB, Thorpe CT, Devellis BM, *et al*. Healthy coping, negative emotions, and diabetes management: a systematic review and appraisal. *Diabetes Educ* 2007;33:1080–103.
8 Winkley K, Landau S, Eisler I, *et al*. Psychological interventions to improve glycaemic control in patients with type 1 diabetes: systematic review and meta-analysis of randomised controlled trials. *BMJ* 2006;333:65.
9 Ismail K, Winkley K, Rabe-Hesketh S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *Lancet* 2004;363:1589–97.
10 Padgett D, Mumford E, Hynes M, *et al*. Meta-Analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *J Clin Epidemiol* 1988;41:1007–30.
11 Mathiesen AS, Egerod I, Jensen T, *et al*. Psychosocial interventions for reducing diabetes distress in vulnerable people with type 2 diabetes mellitus: a systematic review and meta-analysis. *Diabetes Metab Syndr Obes* 2019;12:19–33.
12 Schmidt CB, van Loon BJP, Vergouwen ACM, *et al*. Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress. *Diabet. Med.* 2018;35:1157–72.
13 Fisher L, Hessler D, Glasgow RE, *et al*. REDEEM: a pragmatic trial to reduce diabetes distress. *Diabetes Care* 2013;36:2551–8.
14 Lipscombe LL, Fischer HD, Austin PC, *et al*. The association between diabetes and breast cancer stage at diagnosis: a population-based study. *Breast Cancer Res Treat* 2015;150:613–20.
15 Perrin NE, Davies MJ, Robertson N, *et al*. The prevalence of diabetes-specific emotional distress in people with type 2 diabetes: a systematic review and meta-analysis. *Diabet Med* 2017;34:1508–20.
16 Fisher L, Hessler D, Polonsky W, *et al*. Diabetes distress in adults with type 1 diabetes: prevalence, incidence and change over time. *J Diabetes Complications* 2016;30:1123–8.
17 Ehrmann D, Kulzer B, Haak T, *et al*. Longitudinal relationship of diabetes-related distress and depressive symptoms: analysing incidence and persistence. *Diabet. Med.* 2015;32:1264–71.
18 Reimer A, Schmitt A, Ehrmann D, *et al*. Reduction of diabetes-related distress predicts improved depressive symptoms: a secondary analysis of the DIAMOS study. *PLoS One* 2017;12:e0181218.
19 Carper MM, Traeger L, Gonzalez JS, *et al*. The differential associations of depression and diabetes distress with quality of life domains in type 2 diabetes. *J Behav Med* 2014;37:501–10.
20 Jannoo Z, Wah YB, Lazim AM, *et al*. Examining diabetes distress, medication adherence, diabetes self-care activities, diabetes-specific quality of life and health-related quality of life among type 2 diabetes mellitus patients. *J Clin Transl Endocrinol* 2017;9:48–54.
21 Gonzalez JS, Shreck E, Psaros C, *et al*. Distress and type 2 diabetes-treatment adherence: a mediating role for perceived control. *Health Psychol* 2015;34:505–13.
22 Kulzer B, Albus C, Herpertz S. Psychosoziales und diabetes (Teil 1). *Diabetol Stoffwechsel* 2013;8:198–242.
23 Kulzer B, Albus C, Herpertz S. Psychosoziales und diabetes (Teil 2). *Diabetol Stoffwechsel* 2013;8:292–324.
24 Robert-Koch-Institut R. Gesundheit in Deutschland – die wichtigsten Entwicklungen 2015.
25 Molosankwe I, Patel A, José Gagliardino J, *et al*. Economic aspects of the association between diabetes and depression: a systematic review. *J Affect Disord* 2012;142:S42–55.
26 Lehnert T, Konnopka A, Riedel-Heller S, *et al*. Diabetes und komorbide depression: Systematische Literaturübersicht gesundheitsökonomischer Studien. *Psychiatr Prax* 2011;38:369–75.
27 Hutter N, Schnurr A, Baumeister H. Healthcare costs in patients with diabetes mellitus and comorbid mental disorders—a systematic review. *Diabetologia* 2010;53:2470–9.
28 Kalsekar ID, Madhavan SM, Amonkar MM, *et al*. The effect of depression on health care utilization and costs in patients with type 2 diabetes. *Manag Care Interface* 2006;19:39–46.
29 Andrade LH, Alonso J, Mneimneh Z, *et al*. Barriers to mental health treatment: results from the who world mental health surveys. *Psychol Med* 2014;44:1303–17.
30 Nübling R, Bär T, Jeschke K. Versorgung psychisch kranker Erwachsener in Deutschland. *Psychotherapeutenjournal* 2014:389–97.
31 Groschwitz RC, Fegert JM, Plener PL. Psychiatrische und psychotherapeutische Versorgung in Deutschland: Ergebnisse einer repräsentativen Umfrage. *Psychotherapeut* 2017;62:12–17.
32 Petrak F, Baumeister H, Skinner TC, *et al*. Depression and diabetes: treatment and health-care delivery. *Lancet Diabetes Endocrinol* 2015;3:472–85.
33 Ernst G, Hübner P. Intervallrehabilitation bei diabetes mellitus: Ergebnisse einer randomisierten kontrollierten studie Zur Nachsorge in Der medizinischen rehabilitation. *Rehabilitation* 2012;51:308–15.
34 van Bastelaar KMP, Pouwer F, Cuijpers P, *et al*. Web-Based depression treatment for type 1 and type 2 diabetic patients: a randomized, controlled trial. *Diabetes Care* 2011;34:320–5.
35 Tovote KA, Schroevers MJ, Snippe E, *et al*. Long-Term effects of individual mindfulness-based cognitive therapy and cognitive behavior therapy for depressive symptoms in patients with diabetes: a randomized trial. *Psychother Psychosom* 2015;84:186–7.
36 Keers JC, Groen H, Sluiter WJ, *et al*. Cost and benefits of a multidisciplinary intensive diabetes education programme. *J Eval Clin Pract* 2005;11:293–303.
37 Hayes SC. Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behav Ther* 2004;35:639–65.
38 Ngan HY, Chong YY, Chien WT. Effects of mindfulness- and acceptance-based interventions on diabetes distress and glycaemic level in people with type 2 diabetes: systematic review and meta-analysis. *Diabet Med* 2021;38:e14525.
39 Sakamoto R, Ohtake Y, Kataoka Y, *et al*. Efficacy of acceptance and commitment therapy for people with type 2 diabetes: Systematic review and meta-analysis. *J Diabetes Investig* 2022;13:262–70.
40 Bendig E, Bauereiß N, Ebert DD, *et al*. Internet-Based interventions in chronic somatic disease. *Dtsch Arztebl Online* 2018:659–66.
41 Carlbring P, Andersson G, Cuijpers P, *et al*. Internet-Based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis. *Cogn Behav Ther* 2018;47:1–18.
42 Bian RR, Piatt GA, Sen A, *et al*. The effect of technology-mediated diabetes prevention interventions on weight: a meta-analysis. *J Med Internet Res* 2017;19:e76–12.
43 Hou C, Carter B, Hewitt J, *et al*. Do mobile phone applications improve glycemic control (HbA1c) in the self-management of diabetes? A systematic review, meta-analysis, and grade of 14 randomized trials. *Diabetes Care* 2016;39:2089–95.
44 Palmer M, Sutherland J, Barnard S, *et al*. The effectiveness of smoking cessation, physical activity/diet and alcohol reduction interventions delivered by mobile phones for the prevention of non-communicable diseases: a systematic review of randomised controlled trials. *PLoS One* 2018;13:e0189801.
45 Steed L, Cooke D, Newman S. A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. *Patient Educ Couns* 2003;51:5–15.
46 van der Feltz-Cornelis CM, Nuyen J, Stoop C, *et al*. Effect of interventions for major depressive disorder and significant depressive symptoms in patients with diabetes mellitus: a systematic review and meta-analysis. *Gen Hosp Psychiatry* 2010;32:380–95.
47 Sturt J, Dennick K, Hessler D, *et al*. Effective interventions for reducing diabetes distress: systematic review and meta-analysis. *International Diabetes Nursing* 2015;12:40–55.

48 Sander LB, Paganini S, Terhorst Y, *et al*. Effectiveness of a guided web-based self-help intervention to prevent depression in patients with persistent back pain: the PROD-BP randomized clinical trial. *JAMA Psychiatry* 2020;77:1001–11.

49 Baumeister H, Paganini S, Sander LB, *et al*. Effectiveness of a guided internet- and mobile-based intervention for patients with chronic back pain and depression (WARD-BP): a multicenter, pragmatic randomized controlled trial. *Psychother Psychosom* 2021;90:255–68.

50 Hennemann S, Farnsteiner S, Sander L. Internet- and mobile-based aftercare and relapse prevention in mental disorders: a systematic review and recommendations for future research. *Internet Interv* 2018;14:1–17.

51 Lin J, Lüking M, Ebert DD, *et al*. Effectiveness and cost-effectiveness of a guided and unguided Internet-based acceptance and commitment therapy for chronic pain: study protocol for a three-armed randomised controlled trial. *Internet Interventions* 2015;2:7–16.

52 Lin J, Paganini S, Sander L. An Internet-based intervention for chronic pain: a three-arm randomized controlled study of the effectiveness of guided and unguided acceptance and. *Dtsch Arztebl Int* 2017;114:681–8.

53 Bendig E, Bauereiss N, Schmitt A, *et al*. ACTonDiabetes-a guided psychological Internet intervention based on acceptance and commitment therapy (act) for adults living with type 1 or 2 diabetes: results of a randomised controlled feasibility trial. *BMJ Open* 2021;11:e049238.

54 Baumeister H, Kraft R, Baumel A. Persuasive e-health design for behavior change. In: Baumeister H, Montag C, eds. *Digital phenotyping and mobile sensing*. Cham: Springer Nature, 2019: 261–76.

55 Bolier L, Haverman M, Westerhof GJ, *et al*. Positive psychology interventions: a meta-analysis of randomized controlled studies. *BMC Public Health* 2013;13:119.

56 Crawford J, Wilhelm K, Proudfoot J. Web-Based Benefit-Finding writing for adults with type 1 or type 2 diabetes: preliminary randomized controlled trial. *JMIR Diabetes* 2019;4:e13857.

57 Burton CM, King LA. The health benefits of writing about intensely positive experiences. *J Res Pers* 2004;38:150–63.

58 Baikie KA, Geerligs L, Wilhelm K. Expressive writing and positive writing for participants with mood disorders: an online randomized controlled trial. *J Affect Disord* 2012;136:310–9.

59 Polonsky WH, Anderson BJ, Lohrer PA, *et al*. Assessment of diabetes-related distress. *Diabetes Care* 1995;18:754–60.

60 de Wit M, Pouwer F, Snoek FJ. How to identify clinically significant diabetes distress using the problem areas in diabetes (paid) scale in adults with diabetes treated in primary or secondary care? Evidence for new cut points based on latent class analyses. *BMJ Open* 2022;12:e056304.

61 Hermanns N, Kulzer B, Krichbaum M, *et al*. How to screen for depression and emotional problems in patients with diabetes: comparison of screening characteristics of depression questionnaires, measurement of diabetes-specific emotional problems and standard clinical assessment. *Diabetologia* 2006;49:469–77.

62 Schmitt A, Reimer A, Kulzer B, *et al*. How to assess diabetes distress: comparison of the problem areas in diabetes scale (paid) and the diabetes distress scale (DDS). *Diabet. Med.* 2016;33:835–43.

63 Topp CW, Østergaard SD, Søndergaard S, *et al*. The WHO-5 well-being index: a systematic review of the literature. *Psychother Psychosom* 2015;84:167–76.

64 Brähler E, Mühlan H, Albani C, *et al*. Teststatistische Prüfung und Normierung Der deutschen Versionen des EUROHIS-QOL Lebensqualität-Index und des WHO-5 Wohlbefindens-Index. *Diagnostica* 2007;53:83–96.

65 Pressler SJ, Subramanian U, Perkins SM, *et al*. Measuring depressive symptoms in heart failure: validity and reliability of the patient health questionnaire-8. *Am J Crit Care* 2011;20:146–52.

66 Schmitt A, Gahr A, Hermanns N. Evaluation Der deutschen Fassung des Fragebogens AADQ Zur Diabetesakzeptanz. *Diabet Stoffw Herz* 2013;22:9–15.

67 Hoyer J, Gloster AT. Psychologische Flexibilität messen: Der Fragebogen zu Akzeptanz und Handeln II. *Verhaltenstherapie* 2013;23:42–4.

68 Schmitt A, Gahr A, Hermanns N, *et al*. The diabetes self-management questionnaire (DSMQ): development and evaluation of an instrument to assess diabetes self-care activities associated with glycaemic control. *Health Qual Life Outcomes* 2013;11:138.

69 Schmitt A, Reimer A, Hermanns N, *et al*. Assessing diabetes self-management with the diabetes self-management questionnaire

70 Schmitt A, Reimer A, Hermanns N, *et al*. Der diabetes self-management questionnaire (DSMQ) identifiziert Diabetespatienten MIT hohem Risiko einer negativen Prognose. *Diabetologie und Stoffwechsel* 2014;9:P301.

(DSMQ) can help analyse behavioural problems related to reduced glycaemic control. *PLoS One* 2016;11:e0150774.

71 Mehnert A, Herschbach P, Berg P. Progredienzangst bei Brustkrebspatientinnen - Validierung der Kurzform des Progredienzangstfragebogens PA-F-KF. *Z Psychosom Med Psychother* 2006;52:274–88.

72 Gross JJ, John OP. Individual differences in two emotion regulation processes: implications for affect, relationships, and well-being. *J Pers Soc Psychol* 2003;85:348–62.

73 Fernie BA, Aoun A, Kollmann J, *et al*. Transcultural, transdiagnostic, and concurrent validity of a revised metacognitions about symptoms control scale. *Clin Psychol Psychother* 2019;26:471–82.

74 Devilly GJ, Borkovec TD. Psychometric properties of the credibility / expectancy questionnaire. *J Behav Ther Exp Psychiatry* 2000;31:73–86.

75 Schmidt J, Nübling R. ZUF-8. Fragebogen zur Patientenzufriedenheit. In: Brähler E, Schumacher J, Strauß B, eds. *Diagnostische Verfahren in Der Psychotherapie*. Göttingen: Hogrefe, 2002: 392–6.

76 Kriz D, Nübling R, Steffanowski A. Patients' satisfaction in inpatient rehabilitation. Psychometrical evaluation of the ZUF-8 based on a multicenter sample of different indications. *Z Med Psychol* 2008;17:67–79.

77 Ladwig I, Rief W, Nestoriuc Y. Welche Risiken und Nebenwirkungen hat Psychotherapie? - Entwicklung des Inventars zur Erfassung Negativer Effekte von Psychotherapie (INEP). *Verhaltenstherapie* 2014;24:252–63.

78 Rozental A, Kottorp A, Boettcher J, *et al*. Negative effects of psychological treatments: an exploratory factor analysis of the negative effects questionnaire for monitoring and reporting adverse and unwanted events. *PLoS One* 2016;11:e0157503.

79 Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the working alliance inventory. *Psychother Res* 2006;16:12–25.

80 Munder T, Wilmers F, Leonhart R, *et al*. Working alliance Inventory-Short revised (WAI-SR): psychometric properties in outpatients and inpatients. *Clin Psychol Psychother* 2010;17:231–9.

81 Horvath AO. WAI - Working Alliance Inventory. Available: http://wai.profhorvath.com

82 Bouwmans C, De Jong K, Timman R, *et al*. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a psychiatric disorder (TiC-P). *BMC Health Serv Res* 2013;13:217.

83 Richardson J, Iezzi A, Khan MA, *et al*. Validity and reliability of the Assessment of Quality of Life (AQoL)-8D multi-attribute utility instrument. *Patient* 2014;7:85–96.

84 Bendig E, Braun L, Simon L, *et al*. *Dropout reasons questionnaire for internet interventions (DRQi) - Questionnaire for the systematic recording of dropout reasons at different stages in the implementation of an online intervention [Unpublished manuscript*. Department of Clinical Psychology and Psychotherapy, University of Ulm, 2020.

85 Berntsen D, Rubin DC. The centrality of event scale: a measure of integrating a trauma into one's identity and its relation to post-traumatic stress disorder symptoms. *Behav Res Ther* 2006;44:219–31.

86 McCullough ME, Emmons RA, Tsang J-A. The grateful disposition: a conceptual and empirical topography. *J Pers Soc Psychol* 2002;82:112–27.

87 Pennebaker JW, Beall SK. Confronting a traumatic event: toward an understanding of inhibition and disease. *J Abnorm Psychol* 1986;95:274–81.

88 Powers MB, Zum Vorde Sive Vording MB, Emmelkamp PMG. Acceptance and commitment therapy: a meta-analytic review. *Psychother Psychosom* 2009;78:73–80.

89 Spijkerman MPJ, Pots WTM, Bohlmeijer ET. Effectiveness of online mindfulness-based interventions in improving mental health: a review and meta-analysis of randomised controlled trials. *Clin Psychol Rev* 2016;45:102–14.

90 Nobis S, Lehr D, Ebert DD, *et al*. Efficacy of a web-based intervention with mobile phone support in treating depressive symptoms in adults with type 1 and type 2 diabetes: a randomized controlled trial. *Diabetes Care* 2015;38:776–83.

91 Faul F, Erdfelder E, Buchner A, *et al*. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behav Res Methods* 2009;41:1149–60.

92 Van Buuren S, Groothuis-Oudshoom K. Mice: multivariate imputation by Chained equations. R package version 2.9. *J Stat Softw* 2011;45:1–67.

93 Cho NH, Shaw JE, Karuranga S, *et al*. IDF diabetes atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. *Diabetes Res Clin Pract* 2018;138:271–81.

94 Baumeister H, Nowoczin L, Lin J, *et al*. Impact of an acceptance facilitating intervention on diabetes patients' acceptance of Internet-based interventions for depression: A randomized controlled trial. *Diabetes Res Clin Pract* 2014;105:30–9.

95 Baumeister H, Reichler L, Munzinger M, *et al*. The impact of guidance on Internet-based mental health interventions — a systematic review. *Internet Interv* 2014;1:205–15.

96 Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. *J Med Internet Res* 2009;11:e16.

97 Schulz KF, Altman DG, CONSORT MD. Statement: updated guidelines for reporting parallel group randomised trials. *BMC Medicine* 2010;2010:8.

98 Zwarenstein M, Treweek S, Gagnier JJ, *et al*. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008;337:a2390–6.

99 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.

100 Proudfoot J, Klein B, Barak A, *et al*. Establishing guidelines for executing and reporting Internet intervention research. *Cogn Behav Ther* 2011;40:82–97.

101 Hayes SC, Luoma JB, Bond FW, *et al*. Acceptance and commitment therapy: model, processes and outcomes. *Behav Res Ther* 2006;44:1–25.