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Digital Prevention of Mental Disorders: Evaluation of Cost-Effectiveness and Implementation Science as Bridges between Research and Practice

Johanna Freund, M.Sc.

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Prüferinnen der Dissertation:

1. Jun.-Prof. Dr. Claudia Buntrock
2. Priv.-Doz. Dr. Caroline Jung-Sievers

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"An ounce of prevention
is worth a pound of cure."

Benjamin Franklin[1]

[1]Franklin, Benjamin (1736, February 4), Protection of Towns from Fire, *The Pennsylvania Gazette*.

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List of Abbreviations

AI	Artificial intelligence
AQoL-8D	Assessment of Quality of Life
AFI	Acceptance facilitating intervention
CBA	Cost-benefit analysis
CBT	Cognitive Behavioral Therapy
CEA	Cost-effectiveness analysis
CFA	Confirmatory Factor Analysis
CFI	Comparative Fit Index
CFIR	Consolidated Framework for Implementation Research
CUA	Cost-utility analysis
DHI	Digital health intervention
EBP	Evidence-based practice
EBPAS	Evidence-based Practice Attitude Scale
GSE	General Self-Efficacy
G-NoMAD	German Normalization MeAsure Development
IBI	Internet-based intervention
iCBT	Internet-based Cognitive Behavioral Therapy
ICER	Incremental cost-effectiveness ratio
ImplementIT	Implementation of Internet- and Tele-based interventions
ILS	Implementation Leadership Scale
IPD-MA	Individual participant data meta-analysis
NB	Net-benefit
NMB	Net-monetary-benefit
NBRF	Net-benefit regression framework

NoMAD	Normalization MeAsure Development
NPT	Normalization Process Theory
ORIC	Organizational Readiness for Implementing Change Questionnaire
PSS-10	Perceived Stress Scale
QALYs	Quality-adjusted life-years
RCT	Randomized controlled trial
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance Framework
ROI	Return-on-investment
RMSEA	Root Mean Square Error of Approximation
SIRC	Society for Implementation Research Collaboration
SMD	Standardized mean differences
SRMR	Standardized Root Mean Square Residual
SUAs	Standard units of alcohol
SVLFG	Social Insurance for Agriculture, Forestry, and Horticulture
TiC-P	Treatment Inventory of Costs in Patients with psychiatric disorders
TLI	Tucker Lewis Index
TMFs	Theories, Models, and Frameworks
TC	Tele-based coaching
UTAUT	Unified Theory of Acceptance and Use of Technology
WLC	Waiting-list control
WTP	Willingness-to-pay

Abstract

A growing body of research has demonstrated that digital health interventions (DHIs) effectively prevent mental disorders. This dissertation focuses on relevant challenges to DHIs for preventing mental disorders including: limited evidence on the cost-effectiveness, a need for validated measures in implementation science, and limited evidence on DHI implementation in routine care. The economic evaluation in Study 1 demonstrated that a universal digital stress management intervention for employers had a 56% probability of being cost-effective at a societal willingness-to-pay (WTP) of €0 per symptom-free person gained and a 55% probability per quality-adjusted life years (QALYs) gained, compared to the control group. From an employer's perspective, the DHI had a high probability of a positive return on investment at 78%. In Study 2, the guided DHI to reduce harmful alcohol drinking among employees had a 55% (54%) probability of being the most efficient strategy at a societal willingness-to-pay of €0 per responder (QALY) gained, compared to the unguided DHI and the control condition. The guided DHI was also superior from an employer's point of view, with a higher probability of a positive return on investment (81%) than the unguided DHI (58%). The findings of Study 3 indicated an acceptable to good internal consistency ($0.79 \leq$ Cronbach's $\alpha \leq 0.85$) of the German version of the Normalization MeAsure Development (G-NoMAD), an instrument derived from Normalization Process Theory. In the confirmatory factor analysis, the best model fit was yielded in the four-factor and hierarchical models (each CFI = 0.97, TLI = 0.96, SRMR = 0.08, RMSEA = 0.10). In Study 4, the design of a national implementation study was developed to evaluate the implementation of two DHIs to prevent depression among farmers, foresters, and gardeners on various individual and organizational levels within a mixed-method approach. Study 5

evaluated participants' experiences regarding the acceptance of and satisfaction with guided DHIs in an agricultural setting. The results emphasized the importance of the eCoach guidance and the distinctive intervention characteristics, including anonymity, flexibility, and location independence. Participants also reported different needs concerning intervention content and use, indicating the potential benefit of personalization. In Study 6, determinants influencing the implementation of two DHIs to prevent depression among farmers and individuals in related occupations were investigated from the perspective of healthcare workers and intervention implementers. The DHIs seemed to be broadly accepted by employees. Identified barriers were related to the needs of the target group, available resources at the insurance company, employees' access to knowledge and information, and self-efficacy among healthcare workers, which should be addressed in future implementation strategies. This dissertation shows that DHIs for stress management and reducing alcohol consumption in employees appear to be cost-effective from a societal perspective while also being favorable to employers. For German implementation settings, the G-NoMAD provides a promising tool to assess implementation outcomes among the individuals involved. To improve the implementation of DHIs in preventing depression among high-risk occupational groups such as farmers, this research highlights the importance of personalizing interventions, increasing mental health awareness in the target population, and strengthening the exchange of knowledge and experiences among healthcare workers.

1. Introduction

1.1 Mental Disorders

Mental disorders are considered to be “the core health challenge of the 21st century” (1). In the European Union, 164.8 million people (38%) suffer from mental disorders each year, with anxiety disorders (14%), insomnia (7%), major depression (7%), somatoform disorders (6%), and alcohol and drug dependence (>4%) being the most prevalent (1). The quality of life of people suffering from mental disorders as well as their relatives is often considerably impaired (2–4). This also extends into other aspects of the affected individual’s life, impacting education, work activities, relationships, and physical illnesses (5). Beyond that, mental disorders contribute to substantial economic costs. The global cost of mental disorders was estimated at US$ 2.5 trillion in 2010, with costs estimated to rise to US$ 6.0 trillion by 2030 (6). Of the total costs, about two-thirds are indirect costs, such as productivity loss due to absenteeism and presenteeism (i.e., decreased efficiency while at work). The rest are direct costs resulting from the utilization of healthcare services. In Germany, mental disorders represent the second most common reason for days absent from work, accounting for 20% of the total days absent and causing 45 working days lost per year (7).

1.2 Treatment Gap

Due to major advances in the treatment of mental disorders over the past few decades, there are evidence-based interventions, including psychotherapy and pharmacologic therapy (8,9). Despite these promising developments, the majority of individuals that require mental health services remain untreated (10). In Germany, only 25 - 30% of those affected by mental disorders receive any kind of treatment, and only 10 - 15% obtain psychotherapeutic treatment (11). Even

when treatment is accessed, it is often severely delayed. Based on patients' self-reports, the time between symptom onset and disorder diagnosis takes an average of 6 years for anxiety disorders and 7 years for mood disorders (12). The reasons for this are manifold. In Germany, waiting times for psychotherapy, an established treatment for many mental disorders, are, on average, five months, and outside conurbations, five to six months (13). Since the beginning of the Covid-19 pandemic, waiting times for psychotherapy have increased further (14). In addition to structural difficulties, attitudinal barriers such as the stigmatization of mental disorders, the desire to solve the problem by oneself, and the low perceived need inhibit patients from seeking help for mental disorders (15,16). These challenges contribute to a large treatment gap for mental disorders (17).

1.3 Prevention of Mental Disorders

In addition to improved care and treatment, the prevention of mental disorders is becoming increasingly important to reduce the number of new cases of mental disorders (18). Prevention includes all measures that specifically prevent damage to mental health, make mental disorders less likely, or delay their occurrence (19). Prevention is to be distinguished from health promotion, which focuses on stabilization and improving well-being. There are different types of prevention depending on the timing of prevention. The first focuses on early prevention, which includes measures directed at healthy individuals who have not yet been diagnosed with any symptoms of the disorders; this approach thus aims to prevent new cases ("primary prevention"). The second type targets groups of individuals at increased risk or with subclinical symptoms intended, aiming to detect the progression of the disorder at an early stage and to prevent the progression and manifestation of the disorder through intervention ("secondary prevention"). The third type targets groups of individuals who are already ill to avoid relapses and

concomitant disorders, as well as to counteract exacerbation or chronicity, and to restore quality of life as much as possible (“tertiary prevention”). Regarding the target group, preventive interventions can focus on reaching the entire population regardless of the risk (“universal prevention”). Alternatively, they can target specific subgroups of people that show risk factors for developing a disease (“selective prevention”) or individuals with subclinical symptoms (“indicated prevention”). As previous meta-analytic findings have shown, universal, selective, and indicated preventive measures can effectively reduce symptoms of mental disorders with small to moderate effect sizes (20,21). In terms of approach, individually oriented prevention takes into consideration the individual, his or her characteristics, and behavior (19). Environmentally-oriented prevention also exists, which focuses on improving external conditions, including the physical, ecological, social, and cultural environment, to minimize the probability of objective stress occurring.

For the provision of prevention services in Germany, the “Leitfaden Prävention” (Prevention Guidelines) (22) defines fields of action and criteria for the services supported by the health insurance funds in prevention and health promotion. This guideline forms the basis for the promotion or subsidization of measures that support insured persons in counteracting disease risks as early as possible and includes health promotion and prevention services in diverse environments, including schools, universities, communities, and the workplace. Priority areas of action for individual prevention focus on risk factors for numerous mental and physical illnesses, including physical activity, nutrition, stress management, and substance abuse. In order to determine areas of action with a focus on individual behaviors in primary prevention, available data sources were evaluated to determine the frequency, medical relevance, and economic significance of certain

diseases with particular epidemiological significance. For example, stress is associated with a higher risk for depression (23), sleeping problems (24), and numerous physical illnesses such as cardiovascular diseases and stroke (25–27). Similarly, alcohol and drug abuse has a direct impact on mental disorders (28), cardiovascular diseases (28,29), stroke (30), and other physical diseases (28). Therefore, the priority areas of action for individual behavioral primary prevention also focus on these risk factors (22).

1.4 Digital Health Interventions (DHIs)

1.4.1 Advantages

Digital health interventions (DHIs) represent a promising opportunity to improve mental healthcare and prevent the onset of mental disorders by potentially helping to overcome barriers currently present in traditional services (i.e., face-to-face interventions). The advantages of DHIs include the ability to access them independently of time and location, which allows for flexible use of DHIs (31). Primary advantages of DHIs also include low costs (32) and high scalability (33), enabling these self-help interventions to be delivered to a large number of people in need. Low-threshold access to DHIs can help individuals who would not otherwise seek traditional services because of low perceived need, desire to manage the problem themselves, and fear of stigmatization (34). DHIs can be accessed anonymously when needed, which can be particularly relevant for those affected by mental health issues (35). DHIs likewise allow many people to be self-directed in dealing with mental health problems autonomously (36), which may enhance participants' self-efficacy (37).

1.4.2 Types

There is a wide range of psychological interventions for the prevention and treatment of mental disorders that use the internet or digital components. DHIs are defined as services delivered via digital technologies (e.g., smartphones, websites, text messaging) (33) and aim to modify behavioral, cognitive, and emotional processes associated with the development and maintenance of mental health problems (31). In chat, phone, or video therapy, technology is used to conduct a consultation between the clinician and participant synchronously (38). These interventions are delivered remotely but with another individual (e.g., a clinician) and can be personalized depending on the individual needs and preferences of the participant (39). Furthermore, a DHI can be delivered via an online platform typically comprising texts, interactive elements (e.g., audio and video clips), exercises, testimonials, and diaries (31). The plethora of formats, methods, and technological solutions to psychological distress has also produced a multiplicity of terms, such as online, internet-delivered, or web-based interventions, telepsychiatry, and teletherapy (40).

In instances wherein the DHI is delivered via an online platform, the degree of therapeutic support varies. In self-help interventions (also referred to as “stand-alone” or “unguided” interventions), the participant works independently through a standardized psychological treatment protocol (32). In guided interventions, a psychologist, psychotherapist, or other health worker provides feedback on the tasks on a regular basis in the context of synchronous (e.g., via chat or phone) or asynchronous communication (e.g., by e-mail) (31). The intensity of the guidance varies, from short, relatively standardized feedback focused on working with the self-help program and answering questions (adherence-focused guidance) to more intensive guidance regarding the time and content provided, with detailed and

individualized answers (39). In addition, there are blended concepts, which consist of both usual on-site and digital elements such as self-help interventions, apps, or contact via e-mail, phone, or video (41). In blended approaches, digital components are often used before (e.g., to bridge waiting times) or afterward (e.g., follow-up or relapse prevention) an on-site intervention (39). When used in parallel, the focus can be on both the face-to-face sessions and the digital components. The other complementary format is usually used to prepare, consolidate, or repeat the content. This dissertation focuses mainly on guided and unguided DHIs, which are provided via an online platform and have been most frequently investigated in previous research.

1.4.3 Efficacy and Effectiveness of Preventive DHIs

A large body of research indicates that DHIs are efficacious for the prevention of mental disorders. In an individual participant data meta-analysis (IPD-MA) consisting of 7 studies and 2,186 participants, DHIs were found to be effective in reducing subthreshold depression at 6-12 weeks post-treatment (Hedges' g = 0.39, 95% CI: 0.25-0.53), at 3 - 6 months follow-up (g = 0.30, 95% CI: 0.15 - 0.45) and at 12 months follow-up (g = 0.27, 95% CI: 0.07 - 0.47), compared to the control groups (42). In addition, the IPD-MA reported a significant 28% reduction in the risk of developing a depressive disorder within one year of the DHI compared to the control group (hazard ratio = 0.72, 95% CI: 0.58 - 0.89). No difference was found between guided and unguided interventions (p = 0.057). A meta-analysis by Deady et al. (43) also showed significant improvements in anxiety symptom severity at 3 - 13 weeks post-treatment of DHIs compared to the control groups (standardized mean differences [SMD] = 0.31, 95% CI: 0.10 - 0.52), which remained stable at long-term follow-up (SMD = 0.24, 95% CI: 0.09 - 0.32). Another systematic review and meta-analysis (N = 20 studies) examined the

efficacy of DHIs for eating disorder symptoms and risk factors (44). DHIs significantly reduced body dissatisfaction (d = 0.28, 95% CI: 0.15 - 0.41), concern about shape and weight (d = 0.42, 95% CI: 0.13 - 0.71), internalization of the thin ideal (d = 0.36, 95% CI: 0.07 - 0.65), dietary restriction (d = 0.36, 95% CI: 0.23 - 0.49), bulimic symptoms (d = 0.31, 95% CI: 0.20 - 0.41), striving for thinness (d = 0.47, 95% CI: 0.33 - 0.60), purging frequency (d = 0.30, 95% CI 0.02 - 0.57), and negative affect (d = 0.32, 95% CI: 0.12 - 0.52), compared to control conditions. Similarly, the effects of the DHIs on risk factors for mental disorders, including stress and harmful alcohol consumption, have been studied in systematic reviews and meta-analyses. Meta-analytic evidence (N = 23 studies and N = 4,226 participants) showed that DHIs can effectively reduce stress post-treatment (Cohen's d = 0.43, 95% CI: 0.31 - 0.51), with guided DHIs (d = 0.64, 95% CI: 0.50 - 0.79) being more effective than unguided interventions (d = 0.33, 95% CI: 0.20 - 0.46) (45). In another meta-analysis, the authors concluded that unguided DHIs may also have small effects on stress, depression, and anxiety in students (46). Furthermore, low-intensity DHIs have been proven to be effective in reducing alcohol abuse. A meta-analysis by Riper et al. (47) with 16 included studies (N = 5,612 participants) demonstrated that DHIs are effective in reducing weekly consumption of standard units of alcohol (SUAs) in adults with problematic alcohol use (-5.02 SUAs, 95% CI: -7.57 to -2.48), with guided DHIs appearing to achieve better results than unguided DHIs (-6.78 SUAs, 95% CI: -12.11 to -1.45). Despite a small effect size on the reduction of alcohol consumption in favor of the intervention groups (g = 0.20, 95% CI: 0.13 - 0.27), the authors concluded that from a public health perspective, this might justify the large-scale and cost-effective implementation of DHIs for alcohol abuse in adults.

In previous research, the effectiveness of DHIs for preventing mental disorders has also been studied under routine conditions. A systematic review and meta-analysis of randomized controlled trials (RCTs) (N = 21 studies and N = 10,134 participants) examining the effectiveness of DHIs for depression prevention revealed a small effect for the reduction of depressive symptoms (SMD = -0.26, 95% CI: -0.36 to -0.16) (48). Additional RCTs on DHIs for anxiety symptoms and stress confirmed the effects found in efficacy research (49–51). However, a common problem with the use of DHIs is low intervention adherence (52). *Adherence* is defined as the extent to which a person's behavior meets the recommendations and guidelines of a healthcare provider (53); low adherence has the potential to reduce the effectiveness of DHIs in routine care (54).

1.4.4 Cost-Effectiveness of Preventive DHIs

Health-economic analyses help to assess interventions' profitability and serve as a decision-making aid upon which resources can be allocated according to their scarce availability in the healthcare system (55). The cost-effectiveness of DHIs is often emphasized. Despite high initial costs for their development, the low costs of deploying DHIs to additional users can lead to lower overall spending due to economies of scale (56). In addition, the demonstrated effectiveness and the low time investment by the involved health professionals suggest that DHIs are highly cost-effective compared with no treatment or with conventional face-to-face interventions for well-established health concerns. However, this has received little research attention thus far, especially in relation to the prevention of mental disorders (57). To date, evidence of the economic benefits of DHIs has been examined for the prevention of depression (58) and anxiety (57), suggesting that DHIs are both cost-saving (i.e., the financial benefits exceed the intervention costs and thus, the return on investment is positive) and cost-effective (i.e., the health

effects gained present satisfactory value for the money invested). The following section presents the current state of cost-effectiveness research related to DHIs in stress management as well as alcohol use reduction, both of which are risk factors for the development of mental disorders.

As stress is often associated with work-related factors, such as high work demands, little control, and lack of support from colleagues and superiors (59), stress management interventions in the work context may be pivotal for mental health support. The first studies evaluated the cost-effectiveness of DHIs for stress management within an indicated prevention approach, yielding good value for money from both an employer's and a societal perspective (60,61). A universal prevention approach is particularly desirable in the workplace because a DHI can be provided to more individuals without costly screening (62,63). To the best of the author's knowledge, the cost-effectiveness of a universal DHI in the working population has not yet been examined.

In addition to stress, alcohol consumption is a major public health concern. A recent systematic review of DHIs in substance use disorders revealed promising results indicating that DHIs offer a high likelihood of cost-effectiveness from both a public health and societal perspective (64). Another study compared unguided and guided DHIs for problematic alcohol drinking in a substance abuse center and found a higher likelihood of guided DHIs being more cost-effective than unguided DHIs (65). Costs attributable to alcohol consumption include public health costs but also costs due to reduced job performance, early retirement, sick leave, and involuntary unemployment (66). Therefore, alcohol interventions directed at employees might benefit the employee, the employer, and society. However, little

is known about comparing guided and unguided DHIs for problematic alcohol drinking from a health-economic perspective in an occupational setting.

1.5 Beyond (Cost-)Effectiveness: Implementation Science

As with many other innovations, evidence of effectiveness for DHIs does not guarantee their uptake into routine care. Previous studies showed that clinical research evidence takes between 17 to 20 years to be translated into practice (67,68). Moreover, less than 50% of clinical innovations make it into general use (67), reducing society's return on investment in health research (69). In addition to the evaluation of efficacy and effectiveness, implementation science has gained importance in recent decades. Efficacy research focuses on internal validity by reducing external influences to investigate the effect of interest. Effectiveness research prioritizes research conditions similar to those in which the innovation is typically used. The hypothesis of implementation trial designs fundamentally differs from those in efficacy or effectiveness studies, wherein the focus is on investigating intervention effects. Implementation science aims to identify barriers and facilitators to innovation uptake across multiple contexts and to develop appropriate implementation strategies that can be used to improve uptake (69,70). In addition to the user or patient level, other levels are often included in implementation science, such as the provider, organization, institution, clinic, community, and policy context (71). The so-called "biomedical research pipeline" according to Bauer & Kirchner (69) describes these research steps and is illustrated in Figure 1.

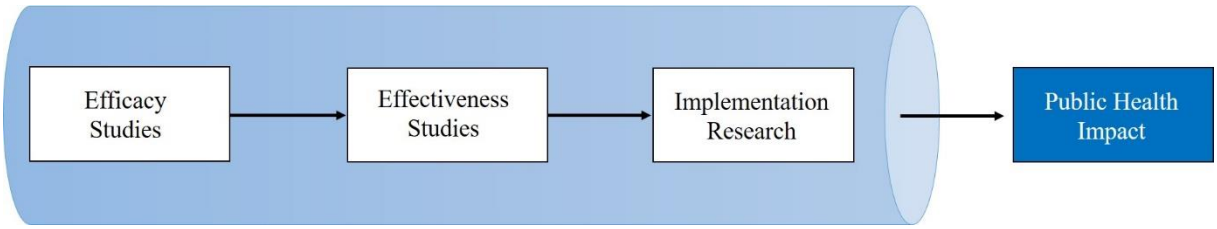

Figure 1. The biomedical research pipeline according to Bauer & Kirchner (69).

1.5.1 Implementation Theories, Models, and Frameworks

A coherent theoretical underpinning helps to understand and explain the success or failure of implementing evidence-based practice (EBP). Furthermore, it helps to identify factors that influence implementation and develop better strategies for more successful implementation (72). Nilsen (72) differentiates five categories of theories, models, and frameworks (TMFs) in implementation science. Process models, such as the Knowledge-to-Action Model (73), specify stages in the process of translating research into practice to describe and guide the translation process. Determinant frameworks specify types of determinants influencing implementation outcomes and help to understand and explain the implementation. An example of this is the Consolidated Framework for Implementation Research (CFIR) (71), which assesses implementation across five major domains and various constructs (i.e., determinants), including intervention characteristics (e.g., "evidence strength and quality", "relative advantage"), outer setting (e.g., "patient needs and resources", "external policy and incentives"), inner setting (e.g., "leadership engagement", "available resources", "compatibility"), characteristics of the individual (e.g., "knowledge and beliefs about the intervention", "self-efficacy"), and implementation process (e.g., "planning", "engaging"). Similarly, classic (change) theories that originate from fields outside of implementation science can be used to understand and explain aspects of implementation (72). An example of this is the Theory of Diffusion (74), which emphasizes the relevance

of intermediary actors (e.g., change agents, gatekeepers) for successful implementation and is one of the most influential theories in the field of knowledge utilization. Developed by implementation researchers, implementation theories help to understand and explain important aspects of implementation (72). This includes the Normalization Process Theory (NPT) (75–77), which posits that practices are "normalized" into social contexts because people work on an individual and collective level to realize them (78). NPT identifies four mechanisms of integration (i.e., normalization) of complex interventions into practice and explains the relationships among them. The mechanisms include: "coherence" as making sense of the innovation to its users, "cognitive participation" as involving or engaging of participants, "collective action" as the enactment of the intervention by its users, and "reflective monitoring" as the process of users understanding the implications of an intervention (79). In addition, evaluation frameworks define aspects of implementation that can be assessed to determine the success of implementation (72). In the RE-AIM framework (80), for example, the implementation success is evaluated along five dimensions: "reach" (i.e., the proportion of participants in comparison to the target population), "effectiveness" (i.e., success rate when the intervention is delivered according to the guideline), "adoption" (i.e., the proportion of facilities or organizations that plan to adopt the intervention), "implementation" (i.e., the degree to which the intervention is implemented as intended), and "maintenance" (i.e., the extent to which an intervention is maintained over time).

In subdividing TMFs, Nilsen (72) emphasizes noting the overlap between some categories. Determinant frameworks, classical theories, and implementation theories, for example, serve as guides for implementing practices because they

identify potential barriers to implementation and can equally be used to evaluate the implementation. According to Nilsen, different theoretical approaches can also be combined to obtain not only a partial but a more comprehensive understanding of the implementation.

1.5.2 Validated Instruments and the NoMAD

Pragmatic tools help to facilitate the implementation of evidence-based interventions and increase the understanding of the underlying mechanisms (81). However, existing measures of implementation outcomes have often not been systematically developed and validated. A systematic review by the Society for Implementation Research Collaboration (SIRC) has shown that most existing instruments lack information on psychometric properties and evidence on psychometric quality (82). Psychometric strength is critical to identifying which implementation strategies work best for which organizations and under what conditions. Widely used and well-validated questionnaires in implementation science include, among others, the Evidence-Based Practice Attitude Scale (EBPAS-36) (83), which measures positive and ambivalent attitudes towards evidence-based practices (EBPs), as well as the Implementation Leadership Scale (ILS), which assesses leadership behaviors that affect the implementation of EBP (84). A systematic review (85) also identified the German language questionnaires measuring implementation constructs. The findings revealed missing information on the validity and only adequate reliability of existing questionnaires. The authors concluded that most instruments need further refinement, item development, and retesting.

The Normalization MeAsure Development (NoMAD) questionnaire (79) is an instrument based on the NPT (75–77), a vigorously developed and thoroughly

tested theory, which helps to understand the implementation process of innovations in routine care. The original NoMAD questionnaire in English was developed through an iterative process consisting of item generation, consensus methods, interviews, and item scoring, piloted at multiple sites, and then psychometrically tested (77,86). The finalized NoMAD instrument consists of 23 items. The questionnaire demonstrated good validity and internal consistency ($0.65 \leq$ Cronbach's alpha ≥ 0.81) for assessing the degree of normalization of innovation among healthcare professionals or other involved individuals (79). The confirmatory factor analysis showed an acceptable model fit (CFI = 0.95, TLI = 0.93, RMSEA = 0.08, SRMR= 0.03). The NoMAD questionnaire has also been translated and validated in other languages, including Chinese, Dutch, Swedish, and Brazilian Portuguese while maintaining psychometric properties (87–90). A validated German version of the NoMAD (G-NoMAD) questionnaire has not yet been available.

1.6 Implementation of DHIs to Prevent Mental Disorders

To realize the full potential of DHIs for preventing mental disorders in routine care, it is critical to examine the implementation of DHIs in this setting. Evidence on implementing DHIs is needed to learn how these interventions can successfully be integrated into a healthcare system. In order for new technologies to be used on a broader scale, it is essential to understand the procedures surrounding healthcare professionals and related policies. To date, research on the implementation of digital mental health interventions is limited (91,92). The results of a recent scoping review by Ellis et al. (91) on the implementation of DHIs for depression and anxiety revealed insufficient methodological standards in many of the included studies. Less than half of the included studies used TMFs to evaluate and guide implementation. The authors concluded that further

implementation research with a solid theoretical foundation is needed to better understand the implementation of DHIs for mental disorders in everyday practices. To date, few studies have examined the implementation of DHIs to prevent mental disorders (93–96).

Among users, adherence and engagement have emerged as growing concerns in the implementation of digital mental health interventions in clinical settings. The advantage of quick and easy access to DHIs is countered by concerns surrounding the ease of dropping out, especially in the case of unguided interventions (97). Based on a scoping review of user engagement in DHIs treating depression, intervention completion varied between 14.4% and 93.0% (52). In Gilbody et al. (98), the authors concluded that the low effectiveness of DHIs was not caused by low efficacy but by low adherence. Baumel et al. (99) investigated user engagement of DHIs and found that the usage rate in trial settings was four times higher compared to real-world settings of the same intervention. This indicates an enormous impact of the research settings on user engagement in unguided DHIs and, consequently, affects the generalizability of the results.

Reasons for low adherence are diverse. Previous research in the digital treatment of mental disorders indicates that adherence can be affected by intervention characteristics (100), disorder severity (101), high workload (100), personal circumstances, and time constraints (101,102). Less is known about participants' experiences with DHIs for the prevention of mental disorders. Findings on digital prevention of depression in the workplace identified personal (e.g., lack of time, the belief that depression cannot be prevented) as well as program-level factors (e.g., large text amounts, functionality issues, insufficient help for severe symptoms) as barriers to intervention use (103).

In addition to intervention adherence, a scoping review by Drozd et al. (92) on implementing DHIs for depression treatment identified other key factors such as the recruitment of end users, qualification, training, and supervision of healthcare professionals. To date, aspects surrounding organizational and leadership factors have been neglected according to the authors. Factors associated with the success and failure of DHIs have been investigated in a systematic review by Granja et al. (104). While "quality of healthcare" was most frequently reported as contributing to the success of DHI implementation, "cost" was most frequently identified as contributing to DHI failure. Furthermore, workflow (e.g., the way people engage with their work and other people and their communication ways) appeared to be the most relevant factor for the outcome of DHIs across all settings. From the perspective of healthcare professionals, factors that hindered the success of DHIs include, among others, high workload, workflow disruption, a lack of alignment with clinical processes, and undefined and changing roles. The fit of DHIs within current organizational workflows was also identified as a critical factor for DHI success or failure in the systematic review by Ross et al. (105).

Project "With Us in Balance"

The potential of DHIs is examined in the German project "With Us in Balance", a nationwide depression prevention program of the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG). Farmers and individuals in related occupations are exposed to many risk factors for depression, including pesticide exposure (106–108), drought and bad weather conditions (108), stress (107), poor physical health (108), additional jobs off the farm (107), and financial concerns (109). While farming is associated with an increased risk of developing depression and other mental health issues (110–112), this occupational group

appears less likely to seek help and use mental healthcare services than non-farmers (113,114). In addition, farmers often live in rural areas where access to mental healthcare is limited (115) and associated with long waiting times for traditional face-to-face psychotherapy (116). To prevent depression in this occupational group, new avenues of delivering mental healthcare need to be explored that address these challenges. Thus, the SVLFG offers its insured members two digital health interventions, a tailored guided internet-based intervention (IBI) program and personalized tele-based coaching (TC) provided by external service companies. The newly implemented digital interventions are provided free of charge as an extension to existing group preventive services delivered on-site. The SVLFG, as the implementing organization, advertises preventive health services through public relation activities as well as through consultations conducted on-site and via phone by healthcare workers. Call center agents conduct the registration process for the DHIs.

The guided IBI program consisting of trainings addressing different risk factors for depression has been shown to be effective in numerous RCTs (61,117–130). For the project “With Us in Balance”, all IBIs were adapted to the agricultural target group with regard to content and graphics. Initial results from the project are promising, with small to moderate effect sizes on the reduction of depressive symptoms at 6-month follow-up in the guided IBI program ($d = -0.35$, 95% CI: −0.57 to −0.14) compared to treatment-as-usual (TAU) (131,132). However, no long-term effects for the IBIs were identified at the 12-month follow-up, possibly due to the reported low adherence (131). The effectiveness of the TC on the reduction of depressive symptoms was demonstrated at 6-month post-treatment with a small to medium effect ($d = -0.39$, 95% CI: −0.64 to −0.15) in comparison to the control group (132). However, little has been known about the routine care

use and implementation of digital interventions to prevent depression in high-risk occupational groups such as farmers, forest owners, and gardeners.

2. Aims of the Studies

The first aim of this dissertation was to contribute to the evidence for the cost-effectiveness of DHIs for the prevention of mental disorders. Therefore, the cost-effectiveness, cost-utility, and cost-benefit of an unguided DHI for stress management and (un-)guided DHIs to reduce problematic alcohol in employees were evaluated in Studies 1 and 2 compared with a waiting-list control (WLC) condition with a 6-month timeframe. The successful implementation of evidence-based interventions in routine care is critical to realize their full potential. The second goal of this dissertation was to fulfill the need for validated (German) measures in implementation science. Therefore, the NoMAD questionnaire, which helps to understand the implementation process of healthcare interventions in routine care, was translated into German, piloted, and validated in Study 3. The third aim of this dissertation focused on the limited evidence on implementing DHIs to prevent mental disorders in routine care. A study design was developed in Study 4 to evaluate the nationwide implementation of internet- and tele-based interventions (ImplementIT) to prevent depression among high-risk occupational groups such as farmers, forest owners, and gardeners on various individual and organizational levels. The focus of Study 5 was on the experiences of farmers and related professionals using a tailored, guided DHIs program for preventing depression by focusing on determinants for acceptance of and satisfaction with the intervention. Study 6 aimed to identify barriers and facilitating factors to implementing DHIs for depression prevention in an agricultural setting from the perspective of healthcare workers and implementers of DHIs.

3. Methods

In Studies 1 and 2, cost-utility and cost-benefit analyses were used for the economic evaluation of a universal digital stress management intervention and a DHI to reduce harmful alcohol drinking in employees. In Study 3, a measurement invariance analysis and a confirmatory factor analysis were conducted to validate the German version of the NoMAD questionnaire that assesses the degree of normalization as an implementation outcome. Studies 4 - 6 are part of the German depression prevention program "With Us in Balance" and, thus, are described jointly. In Study 4, the study protocol for the mixed methods implementation study, "ImplementIT", was developed. Studies 5 and 6 refer to several research questions from "ImplementIT". The qualitative analysis in Study 5 focused on the experiences of participating farmers, forest owners, and gardeners. The mixed-methods approach in Study 6 evaluated implementation determinants from the perspective of healthcare workers and intervention implementers.

3.1 Studies 1 - 2

Health economic evaluation methods are used to examine the cost-effectiveness of interventions and programs. These compare at least two alternative courses of action (e.g., prevention for mental disorders versus no prevention) and consider both the costs and health effects of the compared alternatives (55). An analysis in which costs are related to a single health effect (e.g., the reduction of symptoms or the number of symptom-free people) that might differ between the alternatives is typically referred to as "cost-effectiveness analysis" (CEA) (133). Many guidelines for economic evaluations, such as those described by the National Institute for Health and Care Excellence in the United Kingdom (134), recommend using quality-adjusted life-years (QALYs) as an outcome. QALYs

capture the effect of the intervention on survival, estimated in life years, as well as its effect on quality of life (135). QALYs are particularly useful because they provide a generic outcome measure for comparing costs and outcomes across interventions. The valuation of health conditions is in line with utility theories, and thus, the use of QALYs as an outcome is often referred to as "cost-utility analysis" (CUA). In contrast to CEA and CUA, "cost-benefit analysis" (CBA) aims to express the consequences and health effects of an intervention (e.g., disability days avoided or QALYs gained) in monetary terms, compared to intervention costs (133).

Different costs are included in the health economic evaluation depending on which perspective is considered. From a public health perspective, direct medical costs and costs of non-medical care services (e.g., transport costs, domestic care, informal care) are included (55). From the employer's point of view, both intervention costs and costs due to productivity loss, such as absenteeism and presenteeism, are relevant. The societal perspective takes into account all described costs incurred and is thus, the most comprehensive perspective.

In order to be able to compare different alternatives with each other, an incremental cost-effectiveness ratio (ICER) is calculated (55). This ratio compares the additional costs and effects of alternative A to alternative B. Thus, the ICER indicates how high the additional costs are for an additional effect unit gained by implementing alternative action A. It also represents the quotient of the difference between the average costs and the difference between the average effects of alternatives A and B. According to Hoch et al. (136), statistical problems with this ratio increasingly arise, among other instances, when interpreting the sample uncertainty in the ICER. Confusion arises with ICERs because the ratio is

not sufficient to provide distinct treatment recommendations (i.e., a negative ICER can represent either a more expensive, less effective intervention or a less expensive, more effective treatment). Visualizing the costs and effects using cost-effectiveness plans across four quadrants can help to graphically represent the uncertainty associated with the ICERs (e.g., the northeast quadrant indicates that an intervention is more effective and more costly; the southeast quadrant suggests that the intervention is more effective and less expensive; the southwest quadrant demonstrates that the intervention is less effective and less costly; the northwest quadrant indicates that an intervention is less effective and more costly). Constructing confidence intervals for cost-effectiveness ratios can also be problematic when the uncertainty involves more than one quadrant of the cost-effectiveness plane and ratios with the same sign, but different interpretations cannot be combined. A more recent framework for cost-effectiveness analysis is the net-benefit regression framework (NBRF) (137). It has been proposed to solve many statistical problems associated with the ICER. The NBRF allows for a cost-effectiveness analysis to be conducted in a simple regression framework and comprises a clear decision rule that the new intervention should be used in practice if the net-benefits are positive (136).

In the economic evaluation in Study 1, a DHI for stress management was compared with a waitlist control (WLC) condition. Guided and unguided DHIs to reduce problematic alcohol consumption were evaluated in comparison to a WLC condition in Study 2. Both studies aimed to perform a CEA and a CUA from a societal perspective and a cost-benefit analysis from the employer's perspective within a 6-month timeframe. The DHIs were targeted at the German working population and an open recruitment procedure was used (e.g., newspaper articles, open-access websites) supported by German health insurance companies. The

DHI for stress management (GET.ON Stress) was based on the transactional model of stress coping (138), consisted of seven weekly sessions plus one booster session, and was offered without guidance. Employees (N = 396) were randomly assigned to the DHI for stress management (n = 198) or the WLC group (n = 198) in Study 1. The DHI to reduce problematic alcohol consumption (GET.ON Clever weniger trinken) based on Cognitive Behavioral Therapy (CBT) included five weekly sessions and was provided with or without eCoach guidance. The final sample in Study 2 consisted of 432 participants, with 146 randomized to the unguided DHI, 142 to the guided DHI, and 144 to the WLC condition.

Both studies used online surveys to assess health outcomes, quality of life, and resource use. In Study 1, symptom-free status was assessed based on the Perceived Stress Scale (PSS-10) (139) for the CEA. Symptom-free status was defined as a PSS score at the 6-month follow-up that was two standard deviations below the baseline mean score of the study population (22.65; SD = 5.63). In Study 2, the outcome measure was responder status for the CEA, defined as the individual meeting the low-risk guideline for alcohol drinking (≤ 14 for women /≤ 21 for men weekly standard units of alcohol consumed) (140). In both studies, quality-adjusted life years (QALYs) were used for the CUA, which was measured with the Assessment of Quality of Life (AQoL-8D) instrument (141). The AQoL-8D generates utilities based on the participants' responses on a scale of 0 (death) to 1 (perfect health) using the time trade-off method (142). The Trimbos and Institute for Medical Technology Assessment "Treatment Inventory of Costs in Patients with psychiatric disorders" questionnaire (TiC-P) questionnaire was used in both studies to record data on healthcare utilization, patient and family costs, and productivity losses, retrospectively, over a 3-month period (143).

In Study 1, the ICER was calculated as the costs per additional symptom-free participant or QALY gained, respectively. Cost-effectiveness planes were used to represent the uncertainty related to the ICERs graphically. Additionally, the NBRF was applied to investigate subgroups in which the DHI is particularly cost-effective. In Study 2, the net-monetary-benefit (NMB) regression was applied to estimate the cost-effectiveness for each of the three study arms. The NMB is based on the NBRF and is calculated by subtracting the additional cost from the additional effect assessed in euros (136). Cost-effectiveness acceptability curves (CEACs) were used in both studies to assess the probability of being the most cost-effective alternative compared to the other alternative(s) with varying willingness-to-pay (WTP) thresholds, reflecting the amount the society would be willing to pay for a health benefit (144). In the cost-benefit analyses, the net-benefits (NB) (e.g., the amount of money gained after costs are considered) and the return-on-investment (ROI) (i.e., percentage of profit per Euros invested) were calculated. Costs in the CBA represent the intervention costs, and benefits are defined as the difference in productivity costs between the intervention groups and the control condition. The sampling error in both studies was handled using non-parametric bootstrapping (N = 2,500 simulations) and sensitivity analyses were conducted to account for uncertainty.

3.2 Study 3

In Study 3, a measurement invariance analysis and a confirmatory factor analysis (CFA) were used to investigate the G-NoMAD questionnaire. Data from four German research projects in primary care and digital mental healthcare settings were combined into a validation data set (N = 539). Two slightly different versions of the G-NoMAD existed, independently translated by two research groups. Therefore, a measurement invariance analysis, according to Bowen and

Masa (145), was conducted to compare the latent scale structures between the participant groups of both questionnaire versions. First, a CFA was conducted to estimate a baseline model for both groups. Second, the questionnaire was tested for various degrees of invariance (configural, metric, scalar, and uniqueness) across the two samples. Model parameters (i.e., factor loadings, thresholds, and residuals) were progressively constrained across groups to examine to what extent the instrument could be interpreted as invariant between groups (146).

To examine the factor structure of the G-NoMAD, a confirmatory factor analysis was conducted using three different models. According to the NPT (76), the NoMAD questionnaire consists of four factors (coherence, cognitive participation, collective action, and reflexive monitoring), and thus, the four-factor model was assessed in the CFA. Furthermore, a unidimensional and a hierarchical model was used. The latter model indicates that a global NoMAD score exists comprising four sub-scores. The Comparative Fit Index (CFI), Tucker Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR) were applied to evaluate the model fit. As recommended in the literature (147–149), conservative cut-off values were used for acceptable fit. Additionally, internal consistency and correlations between the four NoMAD factors were assessed. Cronbach's alpha was interpreted as acceptable when $0.7 \geq \alpha < 0.8$, good when $0.8 \geq \alpha < 0.9$, and excellent when $\alpha \geq 0.9$ (150). A consensus meeting was held to discuss the psychometric results and agree on the instructions, items, and scale format of a consensus version of the G-NoMAD.

3.3 Studies 4 - 6

The implementation study “ImplementIT” was based on a mixed methods design consisting of qualitative interviews, focus groups, reporting data, and quantitative surveys. A mixed methods approach is recommended in implementation science as it enables a deeper understanding of the implementation process (91). To evaluate the implementation of DHIs to prevent depression in farmers and individuals in related occupations, different TMFs were applied. The overall implementation success was assessed according to the RE-AIM framework (80), a frequently used evaluation framework in implementation science to assess the impact, quality, and speed of implementation on various individual and organizational levels. To understand what factors in the implementation could influence relevant outcomes from the perspective of healthcare professionals and intervention implementers, the CFIR (71) was used. This framework is helpful as it contributes to a deeper understanding of the RE-AIM “implementation” dimension. Furthermore, the degree of normalization and the organizational readiness for implementing change (151) were assessed. This evaluation design allowed for the consideration of several implementation theories, including the NPT (152) and the organizational readiness for change theory (153). To assess the experiences of participating farmers, forest owners, and gardeners with the DHIs, the Unified Theory of Acceptance and Use of Technology (UTAUT) model (154) and the evaluation model of patient satisfaction (155) were used for the development of the interview guide and the qualitative analysis.

The introduced IBI program was delivered by an external company, the GET.ON institute (www.geton-institut.de). Depending on the psychological-diagnostic assessment, one of seven IBIs was selected in an initial phone call with the eCoach. The IBIs (“GET.ON Stress”, “GET.ON Mood Enhancer”, “GET.ON

Mood Enhancer Diabetes", "GET.ON Recovery", "GET.ON Panic", "GET.ON Be smart - Drink less", "GET.ON Chronic Pain") addressed different risk factors for the incidence of depression and other mental disorders. The IBIs were based on the transactional model of stress and coping (138) ("GET.ON Stress"), Acceptance and Commitment Therapy (156) ("GET.ON Chronic Pain"), or CBT principles (all other IBIs). All IBIs were adapted to the agricultural target group with regard to content and graphics. In the active training phase, the participant completed the 6 - 8 online modules weekly, consisting of psycho-education, exercises, a diary, and interactive elements. The intervention was guided by an eCoach and the participant received feedback via e-mail or phone after each module. In the maintenance phase, there were monthly interactions with an eCoach via e-mail or the phone for up to 12 months.

Besides the IBI program, personalized tele-based coaching was offered to insured members, provided by the external company IVPNetworks (www.ivpnetworks.de). The TC entailed an "initial phase" for building a therapeutic relationship and defining the target problem, a "working phase" for problem solving, and a "stabilizing phase" for sustaining effects. As the name implies, the coaching was personalized in terms of the duration and frequency of the sessions, which depended on the personal participant's needs. A maximum of 850 coaching minutes or a period of 6 months could be carried out, and an optional extension of the coaching for another 150 minutes or 3 months was possible. The coaching methods used depended on the professional (psychologists and/or psychotherapists) and the therapeutic background of the coach (e.g., systemic therapy, psychodynamic psychology, hypnotherapy, CBT).

The design in Study 4 comprised two groups of participants, a) insured persons at the SVLFG with a need for prevention services, and 2) staff participants at the GET.ON institute, IVPNetworks, and SVLFG who were involved in the implementation process. However, in Study 5, the 22 interview participants were recruited from the intervention group (n = 171) of the parallel running effectiveness study (157). In this pragmatic RCT, the study team was responsible for the enrollment, while in routine care this is done through the SVLFG call center. In Study 6, healthcare workers (n = 86) and intervention implementers (n = 7) involved in counseling and referral to DHIs or conducting implementation activities were included. The employees from the SVLFG were recruited at the kick-off events in which the DHIs were introduced.

In Study 5, the semi-structured interviews were conducted by telephone, audiotaped, and transcribed verbatim using the software tool MAXQDA (158). The data analysis followed the deductive-inductive content analysis by Mayring (159). The main categories were developed deductively based on the UTAUT model (154) and the evaluation model of patient satisfaction (155). Codes were then developed inductively by paraphrasing, generalizing, and reducing the raw data. The preliminary code system was discussed in consensus meetings and further developed in feedback loops with clinical psychology and e-health experts. Finally, two independent raters coded all 22 interviews based on the code system and reached a substantial level of agreement (k = 0.73).

In Study 6, the CFIR was used to guide data collection, analysis, and interpretation. Thirty of 37 CFIR constructs (81.1%) were selected and assessed using online surveys, focus groups, and reporting data on dissemination activities. The survey comprised open and closed questions from questionnaires in

implementation science such as the Organizational Readiness for Implementing Change questionnaire (ORIC) (α = 0.88 - 0.92; 12 items) (151), the Implementation Leadership Scale (ILS; α = 0.93 - 0.97; 12 items) (84,160), adapted items from other CFIR studies (161–167), and the CFIR guide (168). Open questions regarding barriers and facilitating factors in the implementation were asked in the online surveys for healthcare workers and in the focus groups with the implementers whose answers could refer to all CFIR dimensions. The quantitative data was analyzed descriptively to assess outcomes across the CFIR dimensions. Reported dissemination activities were categorized by two coders according to the Cochrane Effective Practice and Organization of Care (EPOC) taxonomy (169). Similar to Study 5, the qualitative data were analyzed using a deductive-inductive approach. The CFIR was used to derive the main categories, and subthemes were identified based on the raw material.

4. Publications and Submissions

Article 1. Freund, J., Smit, F., Lehr, D., Zarski, A. C., Berking, M., Riper, H., Funk, B., Ebert, D. D., & Buntrock, C. (submitted). Health-economic Evaluation of a Universal Digital Stress Management Intervention for Employees Alongside a Randomized Controlled Trial. *JMIR Preprints*. 25/04/2023:48481

Article 2. Buntrock, C., Freund, J., Smit, F., Riper, H., Lehr, D., Boß, L., Berking, M., & Ebert, D. D. (2022). Reducing problematic alcohol use in employees: economic evaluation of guided and unguided web-based interventions alongside a three-arm randomized controlled trial. *Addiction*, 117(3), 611-622.

Article 3. Freund, J., Piotrowski, A., Buhrmann, L., Oehler, C., Titzler, I., Netter, A., Potthoff, S., Ebert, D. D., Finch, T., Köberlein-Neu, J., & Etzelmüller, A. (submitted). Validation of the German Normalization Process Theory Measure G-NoMAD: translation, adaptation, and pilot testing. *Research Square Preprint*. 22/06/2023:10.21203/rs.3.rs-3078205/v1.

Article 4. Freund, J., Titzler, I., Thielecke, J., Braun, L., Baumeister, H., Berking, M., & Ebert, D. D. (2020). Implementing internet-and tele-based interventions to prevent mental health disorders in farmers, foresters and gardeners (ImplementIT): study protocol for the multi-level evaluation of a nationwide project. *BMC psychiatry*, 20(1), 1-16.

Article 5. Freund, J., Buntrock, C., Braun, L., Thielecke, J., Baumeister, H., Berking, M., Ebert, D. D., & Titzler, I. (2022). Digital prevention of depression for farmers? A qualitative study on participants' experiences regarding determinants of acceptance and satisfaction with a tailored guided internet intervention program. *Internet Interventions*, 29, 100566.

Article 6. Freund, J., Ebert, D. D., Thielecke, J., Braun, L., Baumeister, H., Berking, M., & Titzler, I. (2022). Using the Consolidated Framework for Implementation Research to evaluate a nationwide depression prevention project (ImplementIT) from the perspective of health care workers and implementers: Results on the implementation of digital interventions for farmers. *Frontiers in Digital Health*, 4.

4.1 Article 1

Authors: Johanna Freund, Filip Smit, Dirk Lehr, Anna-Carlotta Zarski, Matthias Berking, Heleen Riper, Burkhardt Funk, David Daniel Ebert, & Claudia Buntrock

Title: Health-economic evaluation of a universal digital stress management intervention for employees alongside a randomized controlled trial

Journal: Manuscript submitted to Journal of Medical Internet Research (currently under review)

Doi: 10.2196/preprints.48481

Summary:

Occupational stress is highly prevalent and associated with a wide range of physical and mental disorders. Digital health interventions have been found to be effective in reducing stress; however, limited evidence of their economic merits is available. This study aimed to perform an economic evaluation of a universal digital stress management intervention for employees compared to a WLC group with a 6-month timeframe. A sample of 396 employees from the German working population was recruited and randomly assigned to the intervention group (n = 198) or the WLC (n = 198). The unguided digital intervention consisted of seven sessions plus one booster session. Self-reported health service use, patient and family costs, and productivity costs were used to assess costs from a societal and an employer's perspective. A cost-effectiveness analysis and a cost-utility analysis were performed, relating costs to symptom-free status (defined as a PSS-10 score 2 standard deviations below baseline mean) and QALYs gained, respectively. Nonparametric bootstrapping was used to handle sampling errors.

From a societal perspective, the digital stress management intervention had a 56% probability of being cost-effective per symptom-free person gained and a 55% probability per QALYs gained at a willingness-to-pay of €0, compared to the waiting list control group. When society is willing to pay €20,000 per QALY gained, this probability increased to 80%. From an employer's perspective, the digital intervention had a high probability for a positive return on investment at 78%. Thus, a universal digital stress management for employees appears to be cost-effective societally and provides a favorable return-on-investment for employers.

The manuscript was submitted in April 2023 and is currently under review by the *Journal of Medical Internet Research (JMIR). JMIR* is an international, open-access, peer-reviewed journal publishing digital medicine and healthcare research. The journal aims to advance digital health and innovations in healthcare technologies. The published preprint can be reproduced by the author under the terms of the Creative Commons Attribution 4.0 license.

Contribution:

Johanna Freund was the first author of this article. Burkhardt Funk and Matthias Berking obtained funding for the study. David Ebert and Dirk Lehr designed the RCT and developed the intervention content with Heleen Riper and Matthias Berking. Anna-Carlotta Zarski was responsible for the recruitment of participants, and data collection for the RCT. Claudia Buntrock and Johanna Freund accessed and verified the data. Claudia Buntrock conducted the analyses. Johanna Freund interpreted the data, together with Claudia Buntrock and Filip Smit, and drew conclusions from analyses. Johanna Freund drafted the manuscript, supervised by Claudia Buntrock, and received feedback from her co-authors.

Health-economic Evaluation of a Universal Digital Stress Management Intervention for Employees Alongside a Randomized Controlled Trial

Johanna Freund[1, 2] BSc, BA, MSc; Filip Smit[3, 4, 5] PhD; Dirk Lehr[6] PhD; Anna-Carlotta Zarski[1, 2, 7] PhD; Matthias Berking[1] PhD; Heleen Riper[5, 8, 9, 10] PhD; Burkhardt Funk[11] PhD; David Daniel Ebert[2] PhD; Claudia Buntrock[1, 12] PhD

[1]Department of Clinical Psychology and Psychotherapy Friedrich-Alexander-Universität Erlangen-Nürnberg Erlangen DE
[2]Professorship Psychology & Digital Mental Health Care Technical University of Munich Munich DE
[3]Trimbos Institute Utrecht NL
[4]Department of Epidemiology and Biostatistics Amsterdam University Medical Centers Amsterdam NL
[5]Department of Clinical, Neuro and Developmental Psychology VU University Amsterdam NL
[6]Department of Health Psychology and Applied Biological Psychology Leuphana University of Lueneburg Lueneburg DE
[7]eHealth in clinical psychology Philipps University Marburg Marburg DE
[8]Faculty of Behavioural and Movement Sciences VU University Amsterdam NL
[9]Amsterdam Public Health Research Institute VU University Amsterdam NL
[10]Medical Centre VUmc Amsterdam NL
[11]Institute of Information Systems Leuphana University of Lueneburg Lueneburg DE
[12]Institute of Social Medicine and Health Systems Research Otto von Guericke University Magdeburg Magdeburg DE

Corresponding Author:
Johanna Freund BSc, BA, MSc
Department of Clinical Psychology and Psychotherapy
Friedrich-Alexander-Universität Erlangen-Nürnberg
Nägelsbachstr. 25a
Erlangen
DE

Abstract

Background: Stress is highly prevalent and known to be a risk factor for a wide range of physical and mental disorders. The effectiveness of digital stress management interventions has been confirmed; however, research on its economic merits is still limited.

Objective: To assess the cost-effectiveness, cost–utility, and cost-benefit of a universal digital stress management intervention for employees compared to a waitlist control condition within a time horizon of 6 months.

Methods: Recruitment was directed at the German working population. A sample of 396 employees was randomly assigned to the intervention group (n = 198) or the waiting list control (WLC) group (n = 198). The digital stress management intervention included seven sessions plus one booster session and was offered without therapeutic guidance. Health service use, patient and family expenditures, and productivity losses were self-assessed and used for costing from a societal and an employer's perspective. Costs were related to symptom-free status (PSS-10 score 2 standard deviations below the study population baseline mean) and quality-adjusted life years (QALYs) gained. Sampling error was handled using nonparametric bootstrapping.

Results: From a societal perspective, the digital intervention had a 56% (55%) probability of being cost-effective at a willingness-to-pay of €0 per symptom-free person (QALY) gained, compared to WLC. This probability increased to 80% at a societal willingness-to-pay of €20,000 per QALY gained. Taking the employer's perspective, the digital intervention showed a probability for a positive return on investment of 78%.

Conclusions: Digital preventive stress management for employees appears to be cost-effective societally and provides a favorable return-on-investment for employers. Clinical Trial: German clinical trials register (DRKS00005699)

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Original Paper

Health-economic evaluation of a universal digital stress management intervention for employees alongside a randomized controlled trial

Abstract

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Conclusions: Digital preventive stress management for employees appears to be cost-effective societally and provides a favorable return-on-investment for employers.
Trial Registration: German clinical trials register (DRKS00005699)

Keywords: Economic evaluation; cost-utility; return-on-investment; employees; universal prevention; internet-based

Introduction

In Europe, up to 27% of the working population suffers from stress (1). Stress is often caused by work-related factors, including high perceived work demands, little work control, and little support from co-workers and supervisors (2). Stress is linked to numerous diseases including mental health problems and psychiatric diseases (3). Besides the great burden of disease for the individual, stress is linked to formidable costs for employers as well as the society as a whole. Due to stress and stress-related disorders individuals suffer from impairment at work and lower productivity, are more days

absent from work and utilize health services at a higher rate (4).

The efficacy of stress management interventions has been confirmed in numerous meta-analyses of randomized trials in the general population (5) and in occupational settings (6). However, high levels of psychological stress among employees are omnipresent and remain largely untreated (7). Easily accessible and highly scalable digital interventions independent of time and place represent a promising approach to lowering the threshold for use compared to face-to-face interventions (8). A recent meta-analysis provides cumulative evidence that digital or internet-based stress management interventions (iSMIs) are effective in terms of stress reduction in adults with small-to-moderate effects sizes (Cohen's *d*=0.43; 95% CI 0.31-0.51)(9). Evidence for efficacy in an occupational setting has also been reported in a randomised controlled trial (RCT) with a large effect size at 6-month follow-up (Cohen's *d*=1.02; 95% CI 0.76-1.27) (10). In the workplace in particular, a universal prevention approach is especially desirable because more employees can be reached without prior screening that might be costly (11). Compared to selective prevention with a focus on groups of people at increased risk or indicated prevention with a focus on individuals with elevated symptoms, universal prevention aims to reach the entire population regardless of any risk status (12). A scalable digital intervention for universal prevention of stress in the working population has potential for a substantial reach. Furthermore, with a focus on the entire working population, individuals can also be reached who do not want to disclose symptoms due to fear of stigmatization (13). Regarding the effectiveness of a universal iSMI for employees on stress symptoms, results of a pragmatic randomized controlled trial showed significantly lower perceived stress at post-treatment (*d*=0.71, 95% CI 0.51-0.91) and at 6-month follow-up (*d*=0.61, 95% CI 0.41-0.81) in the iSMI condition compared to a waitlist control (WLC) condition (14).

Yet, although the effectiveness of iSMI has been demonstrated, research on its economic merits is still limited. Evidence suggests that an indicated iSMI to proactively prevent onset of stress in employees represents good value for money from both a societal and an employer's perspective (15,16). However, no study has yet evaluated the cost-effectiveness of a universal iSMI in the working population. The present study might be the first to evaluate the cost-effectiveness and cost-utility of a universal iSMI for stress in employees compared to a WLC from a societal perspective and the cost-benefit from the employer's perspective over a time horizon of six months.

Methods

Study design

We carried out the health-economic evaluation alongside a two-arm RCT (German clinical trials register: DRKS00005699) comparing the effects of a self-guided iSMI for stress prevention with a WLC. Detailed information about the study design can be found elsewhere (14). We carried out and reported the health economic evaluation in accordance with the guidelines of the International Society for Pharmacoeconomics and Outcomes Research (17) and the Consolidated Health Economic Evaluation Reporting Standards statement (18). The study was approved by the ethics committee of the University of Marburg (Germany).

Recruitment

Recruitment was carried out as part of the occupational health program of a large German health insurance company (BARMER) in a way similar to the intended implementation of the intervention in routine practice in the future. The goal was to recruit from the general working population not limited to individuals insured by this health insurance company. This was done primarily through reports in the member magazine of the health insurance company and the insurance company's

occupational health and safety management staff who informed the human resources departments of collaborating companies about their employees' possibility to participate in the study. Interested individuals who completed an online screening questionnaire and met eligibility criteria were asked to fill out the informed consent form. To best reflect the routine conditions, the inclusion and exclusion criteria were reduced to a minimum. Individuals were included who (a) were 18 years and older, (b) were currently employed, and (c) had internet access and a valid email address. Exclusion criteria only included a) a risk of suicide as indicated by a score of greater than 1 on the Beck Depression Inventory suicide item (14) or b) any diagnosis with psychosis or dissociative symptoms (self-reported).

Overall, 396 participants were included for the study, with n = 198 randomized to either the iSMI or WLC condition. All participants completed the assessment at baseline, while 313 participants (79%) provided data at 6-month follow-up. The average participant was 41.76 years old (*SD*=10.09), female (302/396; 76%), highly educated (285/396; 72%), and employed full-time (296/396; 75%) with a working experience of 17.58 years (*SD*=10.36). Almost half of the participants worked in a management position (169/396; 43%).

Randomization and Masking

Study participants were randomly assigned to the invention or control group in a 1:1 ratio by an independent researcher not otherwise involved in the study. Randomization took place using a computer-based random numbers table (Randlist) to ensure equal sample sizes for both conditions. Detailed information about the randomization procedure can be found elsewhere (14). During the randomization process, the assignment was hidden from the participants as well as the researchers involved in the recruitment and in the study administration. After randomization, participants were not blind to the study conditions due to the nature of the intervention.

Control condition

In both study conditions, the participants had full access to treatment as usual (TAU). We did not interfere in TAU. Rather, we tried to maintain a naturalistic TAU state in order to represent routine care as much as possible.

Intervention

Participants in the intervention group (IG) received the iSMI GET.ON Stress. This iSMI entails seven regular modules and one additional booster session for reviewing the most relevant content. Each module consists of psychoeducation, strategies for problem-solving, emotion regulation techniques and plans for the future. It was recommended to complete 1-2 modules per week. The iSMI is based on the transactional model of stress (14). The training includes interactive education, exercises, testimonials, audio, and video files. The content of the intervention is tailored to the individual needs and interests of the participants, since several choices were made available through different answer options. In order to integrate the new knowledge sustainably into everyday life, homework, behavior planning, and an online diary are parts of the intervention. There was no therapeutic guidance provided. However, the participants had the opportunity to receive automatic text messages on their mobile phones. Participants could choose between light support with one text message every other day or intensive support with two or three text messages per day. Text messages contained very short exercises that should be carried out in everyday life to support the transfer from training to real life. More details about the intervention can be found elsewhere (14). In this study, IG participants completed on average 5.23 (*SD*=2.74) sessions. In total, 94 participants (48%) finished all seven modules, while 66 participants (33%) completed the additional booster session.

Outcome Measurements

Health-related outcome

The health outcome in the cost-effectiveness analysis (CEA) was symptom-free status based on the Perceived Stress Scale (PSS) and defined as a score at 6-month follow-up of 2 standard deviations (SDs) below the baseline mean of study population (22.65; *SD* = 5.63) (19).

Quality-adjusted life years

Quality-adjusted life years (QALYs) were used as a health outcome in the cost–utility analysis (CUA). QALYs were based on 35 items version of the Assessment of Quality of Life (AQoL-8D) assessed at baseline and 6-month follow-up, which is a reliable and validated instrument (20). Eight dimensions of health-related quality of life were covered (i.e., independent living, relationships, mental health, coping, pain, senses, self-worth, and happiness) and preference-based valuations of health states (utilities) on a scale of 0 (death) to 1 (perfect health) were generated, using the time trade-off method (21). Cumulative QALYs gains over the study's follow-up time of 6 months were estimated by calculating the area under the curve (AUC) of linearly interpolated AQoL-8D utilities between measurement points to cover the whole follow-up period.

Costs

Resource use and costing

We used the Trimbos and Institute for Medical Technology Assessment "Treatment Inventory of Costs in Patients with psychiatric disorders" questionnaire (TiC-P) to collect data on healthcare utilization, patient and family costs, and productivity losses (22). The TiC-P is a retrospective questionnaire with a 3-month recall period and has been used in a similar study (15). Costs were expressed in Euro and indexed from 2011 to 2013, the year the study was conducted, based on the German consumer price index (index factor 1.04) (23). Costs were converted to pound sterling (£) using the purchasing power parities reported by the Organization for Economic Cooperation and Development (24). For the reference year 2013, €1 was equated to £0.85.

Intervention costs

At the time of conducting the study, the market price of the digital intervention provided by the GET.ON Institute, a commercial health-care service provider, was €99 (£84) per participant, including costs for text messages, costs for website maintenance and hosting, technical support, and overheads.

Healthcare costs

We used two German guidelines for calculating health care costs (25,26). Health-care costs on a per-participant level were based on available lists of unit costs(26). Unit costs were as follows: €20.92 (£17.78) for a visit to the general practitioner, €46.55 (£39.57) for a session with a psychiatrist and €81.44 (£69.22) with a psychotherapist, respectively. Costs per contact for allied health services (e.g., physiotherapist) were valued at €17.08 (£14.52). Hospital stays were computed at €335.52 (£285.19) for an in-patient day in a psychiatric hospital and €306.41 (£260.45) for an in-patient day in a hospital for psychosomatic medicine and psychotherapy. Costs were estimated by multiplying the units of resource use with corresponding unit costs. The costs of prescribed medication were based on the LauerTaxe (27).

Patient and family costs

Out-of-pocket payments were directly obtained from participants. Costs for travelling were valued at €0.30 (£0.27) per kilometre. Productivity losses from unpaid work (e.g. household chores, shopping, child care) and informal care were valued using the proxy good method (e.g., price of a close market substitute: domestic help). The average gross wage of domestic help per hour was estimated at €18.33 (£15.58) per hour.

Productivity costs

Costs due to absenteeism (i.e., days not worked) were valued according to the human capital method (28). Lost working days due to absenteeism were valued at the gross average income of participants per day. Lost working days due to presenteeism (i.e., reduced efficiency while at work) were computed by taking into account the number of working days for which the participant reported a reduced work performance weighted by an inefficiency score for those days (Osterhaus method) (29).

Statistical analysis

Health-related outcome, quality-adjusted life years and costs

Analyses were conducted according to the intention-to-treat principle using Stata version 16 (StataCorp) (30). Missing data were imputed using multiple imputations by chained equations (MICE) using predictive mean matching to account for the skewed distribution of cost and utility data. The imputation model was stratified by study arm and included demographic data (e.g., age, gender, marital status, education) alongside health-related outcome variables at baseline (e.g., utility values, perceived stress). The number of imputed datasets was at least equal to the percentage of incomplete cases (i.e., m = 30). Analyses as described below were performed on each dataset separately and results were pooled using Rubin's rules.

Economic evaluation: Societal perspective

Disaggregated and total costs from the employer's and societal perspectives as well as QALYs per study group were assessed with a set of ordinary last square regression equations, the latter adjusted for baseline utility values. Group differences in symptom-free status were tested using logistic regression.

From a societal perspective, the incremental cost-effectiveness ratio (ICER) was calculated as the extra costs per additional symptom-free participant or QALY gained, respectively. We bootstrapped seemingly unrelated regression equations (SURE) models to generate 2500 simulations of incremental cost and effect pairs while allowing for correlated residuals of the cost and effect equations and adjusting for potential confounders (e.g., initial utility values in the effect equation). Based on the bootstrapped SURE models, bias-corrected and accelerated 95% CIs were obtained for incremental costs and effects. Bootstrapped cost and effect pairs were plotted on cost-effectiveness planes to graphically represent the uncertainty surrounding the ICERs. Cost-effectiveness acceptability curves (CEACs) were created to depict the probability of the intervention being cost effective compared to the control condition for varying willingness-to-pay (WTP) thresholds.
To determine subgroups in which the intervention was particularly cost-effective net-benefit regression framework (NBRF) was used (31). In the NBRF, the treatment dummy, prognostically relevant baseline characteristics, and their interactions are regressed on net-benefit. Net-benefit (NB) is defined as: $NB = (E*\lambda)–C$, where E are the effects per participant (e.g., QALYs), C are the costs per participant and λ is the willingness-to-pay for a unit of effect (i.e., €20,000 per QALY gained). Analyses were conducted using gender, age, education, marital status, work experience, previous health trainings / psychotherapy, level of perceived stress, resilience, agreeableness, psychological strain, and self-regulation competencies as independent variables.

Economic evaluation: Employer's perspective

From the employer's perspective, cost-benefit analyses were performed using two metrics: (1) net benefits (NB = benefits - costs; amount of money gained after costs are taken into account) and (2) return-on-investment (ROI = [(Benefits–Costs)/Costs]*100%; percentage of profit per Euro invested), where costs are defined as intervention costs and benefits as the difference in productivity costs between the iSMI group and the control condition. The metrics were estimated by

bootstrapping linear regression models (N = 2500). The probability of a positive financial return was assessed by the proportion of positive estimates (e.g., NB > 0, ROI > 0%).

Sensitivity analyses

To test the robustness of the base case findings, we performed three sensitivity analyses. First, we applied Winsorizing, where extreme values of cost outliers (e.g. those above the 95 percentile) were replaced by the value at the 95th percentile. Second, we varied the costs of the intervention (i.e., €299) to reflect uncertainties about the actual market price. Third, we used another instrument, the EQ-5D-3L (32), to assess health-related quality of life instead of the AQoL-8D. While the first two sensitivity analyses were applied to both the societal and employer's perspective, the latter was only done in the societal perspective.

Results

Health related outcomes and quality-adjusted life years

Participants in the iSMI condition had a statistically significantly higher probability for symptom-free status at 6-month follow-up with an Odds Ratio (OR) of 5.14 (95% CI 3.23 – 8.18) compared to WLC based on bootstrapped data. The mean of the cumulative QALYs were higher in the iSMI condition (0.321 QALYs: 95% CI 0.316 – 0.326) compared to the WLC (0.306 QALYs: 95% CI 0.302 – 0.310). Adjusted incremental differences in QALYs between the iSMI condition and the WLC were statistically significant (Δ(e) = 0.015 QALYs, 95% CI 0.009 – 0.022).

Costs

Baseline costs were slightly higher in the iSMI condition (€2283, 95% CI 1916-2650) but comparable to the WLC (€1936, 95% CI 1569-2303). The imputed mean 6-month cumulative per-participant costs (in €) separately for various cost categories by study condition are presented in Table 1. Direct medical costs as well as patient and family costs were similar in both groups. In the iSMI group, costs for absenteeism were higher than costs due to presenteeism. The opposite was seen in the WLC. Employer's costs were slightly higher in the WLC compared to the iSMI (incremental difference of €76, 95% CI -667−515). Average total costs were comparable in both groups with €3195 (95% CI 2661−3729) in the iSMI condition and €3233 (95% CI 2722−3744) in the WLC resulting in an incremental difference of €38 (95% CI -771−695) in favor of the iSMI group.

Table 1. Imputed mean cumulative per-participant costs (in €) by condition over a 6-month follow-up period.

	Intervention group (n = 198)		Control group (n = 198)		Incremental difference	
	Mean, €	95% CI	Mean, €	95% CI	Mean, €	95% CI
Direct medical costs						
Intervention costs						
	99	–	–	–	99	–
GP						
	52	42–62	50	41–58	2	-11–16
Mental health care						
	126	67–185	227	168–286	-101	-184–-18
Antidepressants						

	4	-5–14	15	5–25	-10	-24–4
Allied health services[a]						
	41	23–60	30	13–46	11	-13–36
Patient and family costs						
Over the counter drugs						
	20	13–28	26	19–34	-6	-16–5
Out of pocket expenses[b]						
	106	56–156	104	61–148	2	-63–66
Travel						
	11	6–16	15	10–20	-4	-11–4
Unpaid work						
	159	90–229	187	122–252	-28	-125–70
Informal care						
	330	195–466	194	92–297	136	-35–307
Domestic help						
	168	89–248	133	44–223	35	-88–159
Productivity costs						
Absenteeism						
	1217	897–1538	884	584–1184	334	-102–770
Presenteeism						
	859	616–1103	1368	1128–1609	-509	-852–-166
Employer's perspective						
Intervention costs + productivity costs						
	2176	1747–2605	2252	1841–2663	-76	-667–515
Societal perspective						
Total societal costs[c]						
	3195	2661–3729	3233	2722–3744	-38	-771–695

[a]For example, massage, physiotherapist, occupational therapist.
[b]For example, allied health services without prescription.
[c]Includes all cost categories based on a bootstrapped (n = 5000) linear regression model. Columns may not add up correctly due to rounding. CI = confidence interval.

Economic evaluation

Societal perspective

Cost-effectiveness

Table 2 shows the incremental costs, effects, mean ICERs and the distribution of cost and effect pairs on the cost-effectiveness plane based on 2500 bootstrap simulations. Cost-effectiveness analysis revealed that the iSMI generated more symptom-free individuals (Δ[E]=0.39; 95% CI 0.29-0.48) at lower costs (Δ[C]=–€38 [£953]; 95%CI –€-705 to €692) relative to the WLC. With regard to the cost-effectiveness plane, 56% of the bootstrapped ICERs fell in the southeast quadrant, indicating a 56% probability that the intervention dominates WLC (Figure 1). The remaining 44% of ICERs fell

in the northeast quadrant, demonstrating a 44% probability that the intervention leads to greater health gains but at higher costs than WLC. At a willingness-to-pay of €1500 per additional symptom-free person, the iSMI showed a probability of 94% of being cost-effective compared to the WLC (Figure 2).

Cost-utility

Cost-utility analysis revealed similar results (Table 2). Again, the iSMI was likely to be dominant relative to the WLC with more QALY gains at lower costs resulting in a 55% probability that the iSMI is cost-effective at a societal willingness-to-pay threshold of €0 (Figure 3). This probability increased to 80% at a societal willingness-to-pay per QALY gained of €20,000 (Figure 4). Using NBRF, no subgroups were identified for which iSMI was significantly more (or less) cost-effective (all p-values ≥ .05 for both WTPs of 0€ and €20,000 per QALY gained, respectively).

Table 2. Results from the societal perspective (main and sensitivity analysis) based on 2500 bootstrap simulations.

Outcome	Incremental costs, € (95% CI)	Incremental effects, points (95% CI)	Incremental cost-effectiveness ratio, €/points (95% CI)[a]	Distribution over the cost-effectiveness plane (%)			
				North-east quadrant[b]	South-east quadrant[c]	South-west quadrant[d]	North-west quadrant[e]
Main analysis							
Symptom-free status (0/1)							
	-38 (-705-692)	0.39 (0.29-0.48)	Dominant	44	56	0	0
QALYs[f] (range: 0-1)							
	-38 (-735-687)	0.015 (0.009-0.022)	Dominant	45	55	0	0
Sensitivity analysis 1[g]							
Symptom-free status (0/1)							
	-110 (-652-477)	0.39 (0.29-0.48)	Dominant	34	66	0	0
QALYs[f] (range: 0-1)							
	-110 (-652-477)	0.02 (0.01-0.01)	Dominant	34	66	0	0
Sensitivity analysis 2[h]							
Symptom-free status (0/1)							
	162 (-505-892)	0.39 (0.29-0.48)	€418	89	11	0	0
QALYs[f] (range: 0-1)							
	162 (-505-892)	0.025 (0.011-0.039)	€6,515	89	11	0	0
Sensitivity analysis 3[i]							
QALYs[f] (range: 0-1)							
	-38 (-735-687)	0.011 (0.003-0.019)	Dominant	45	55	0	0

[a]In

accordance with ISPOR best practice guidelines on ‘Model Parameter Estimation and Uncertainty’, we do not report any negative incremental cost effectiveness
Ratios (ICERs) since they are meaningless. Instead, we use the term ‘dominant’ which means that the intervention has a higher impact and comparatively lower cost with the WLC.
[b]The north-east quadrant of the CE plane, indicating that intervention is more effective and more costly.
[c]The south-east quadrant of the CE plane, indicating that intervention is more effective and less costly.
[d]The south-west quadrant of the CE plane, indicating that intervention is less effective and less costly.
[e]The north-west quadrant of the CE plane, indicating that intervention is less effective and more costly.
[f]QALYs: quality-adjusted life years.
[g]Sensitivity analysis 1 analyses for winzorizing cost outlier to 95% percentiles.
[h]Sensitivity analysis 2 analyses adding intervention costs of €299 (instead of 99€).
[j]Sensitivity analysis 3 analyses for EuroQol for quality-adjusted life years.

Employer's perspective

The iSMI condition showed a net benefit per participant of €76 (£65) (95% CI = €-498–665) and a benefit-to-cost ratio of 1.77 (95% CI = €-4.03-7.72). The ROI was 77% (95% CI = -503–672%), respectively. The probability of a positive return on investment was 78% for the iSMI condition (Table 3).

Table 3. Results from the employer's perspective (main and sensitivity analysis) of adjusted cost-benefit analyses based on 5000 bootstrapped linear regression models.

	Costs[a]		Benefits[b]		Financial Return				
	Total	95 % CI	Total	95% CI	NB[c]	95% CI	ROI[d] (%)	95% CI	P[e] (%)
Main Analyses									
Unguided intervention									
	99	NA	175	-399 – 764	76	-498 – 665	77	-503–672	78
Sensitivity analysis 1[g]									
Unguided intervention									
	99	NA	217	-226 – 687	118	-325 – 588	120	-329–594	96
Sensitivity analysis 2[h]									
Unguided intervention									
	299	NA	175	-399 – 764	-124	-698 – 465	-41	-233–156	14

[a]Includes intervention costs.
[b]Benefits are the difference in productivity costs between the intervention group and the control condition.
[c]Net benefit (NB) linear regression models adjusted for baseline costs due to absenteeism and presenteeism.
[d]Return on investment (ROI) linear regression models adjusted for baseline costs due to absenteeism and presenteeism.
[e]Probability of positive return on investment.
[f]Intervention costs increased by 50%.
[g]Sensitivity analysis 1 analyses for winzorizing cost outlier to 95% percentiles.
[h]Sensitivity analysis 2 analyses adding intervention costs of €299 (instead of 99€).

Sensitivity analyses

Results of the sensitivity analyses are summarized in Table 2 and Table 3. Winsorizing cost outliers led to a slightly higher probability that the intervention produces higher health gains at lower costs than WLC with regard to symptom-free status (66%) and QALYs (65%) at a societal WTP threshold of €0. The net benefit increased when cost outliers were winzorized and the probability of a positive return on investment was 96% for the iSMI. Increasing intervention costs up to 3 times (€299 instead of €99) this probability decreased to 33% regarding symptom-free status and QALYs gained at a WTP of €0. However, at a WTP of €20,000 per QALY gained, the probability of being cost-effective was comparable to the main analysis (e.g., 78%). Return on investment became negative when intervention costs were increased up to 3 times and the probability of a positive financial return decreased to 14% for the iSMI. Using the EQ-5D-3L resulted in a probability of 55 % regarding QALYs gained at a WTP of €0, identical to the main analysis.

Discussion

Principal Results

This study evaluated the cost-effectiveness and cost–utility of a universal unguided digital stress management intervention for employees from a societal perspective and the cost-benefit from the employer's perspective compared to a waitlist control condition over a 6 months' time horizon. From a societal perspective, the iSMI had a high probability of being cost-effective (e.g. 80% at a WTP of €20,000 per QALY gained). From an employer's perspective, the iSMI had a high probability of a positive return on investment with 78%.

Comparison with Prior Work

Evidence for economic evaluations of universal digital prevention of mental disorders is scarce. To our knowledge, this is the first economic evaluation of a universal iSMI to reduce stress in employees using a societal and an employer's perspective. The results of our study are in line with other economic evaluations of the same iSMI for stressed employees in the field of indicated prevention (PSS ≥ 22) in which e-coaches provided personalized feedback throughout the intervention (15). Kählke et al. (15) demonstrated that more QALYs were generated for lower costs in the guided iSMI compared to a waitlist control condition indicating a similar probability of 76% compared to our study that the intervention was cost-effective compared to WLC at a societal WTP of €20,000 per QALY gained. A similar probability of 71% at a societal WTP of US $25,000 was also found by Lindsäter et al. (33) who evaluated therapist-guided iCBT for stress-related disorders compared to WLC.

Results from the employer's perspective are comparable to the study by Ebert et al. (16), who examined the cost-benefit of the same iSMI as Kählke et al. (15). The analysis of Ebert et al. (16) yielded a similar benefit-to-cost ratio of 1.6 (95% CI = €-1.2-4.5) compared to a benefit-to-cost ratio of 1.77 (95% CI = €-4.0-7.7) in this study. Our results from the employer's perspective are also in line with findings from a recent systematic

review indicating that addressing mental health in employees improves both their wellbeing and productivity (34). Regarding the ROI analyses, our findings compare favorably to a systematic review of face-to-face health promotion interventions at the workplace (n = 12 RCTs) that showed on average a negative ROI (ROI = –0.22, 95% CI = 0.27–0.16; min = −4.3; max = 5) (35). Van Dongen and colleagues (2017) also showed a negative return-on-investment of a combined social and physical environmental intervention in office employees (36).

Limitations

The following limitations have to be considered. First, contrary to the pharmaco-economic guidelines recommending treatment-as-usual as comparator (37), the iSMI was compared with a wait-listed control condition, albeit with unrestricted access to usual care. Second, due to the limited time horizon of 6 months, longer term costs and effects caused by chronic stress (e.g., onset of a new health disorder or staff turnover) could not be analyzed. Future studies should examine whether treatment effects and costs are sustained over a longer period of time or decline. Third, preference-based utility values were only evaluated at baseline and after 6 months and thus, an immediate treatment effect has not been assessed. Fourth, costs due to presenteeism were only assessed with the Osterhaus method. However, this method tends to overestimate costs because it assumes a 1:1 relationship between workhours lost and productivity losses, but that relationship might be better described as an elastic relationship, e.g., 100% to 90%. Future studies should also include alternative methods (e.g., Health and Labor Questionnaire method) to calculate costs due to presenteeism. Fifth, self-report questionnaires were used which may have led to effects related to social desirability and response bias (38). Future studies could consider claims data from health insurance companies.

Clinical implications

Evidence-based recommendations on the cost-effectiveness of interventions can help inform decision-makers from the societal and employer's perspective when choosing preventive stress interventions. The findings of this study support the hypothesis that a universal prevention approach could be a cost-effective strategy to reduce the adverse consequences of work-related stress. However, it must be taken into account that the participants in the study already had a rather high initial stress level on average. That is, we cannot say whether the cost-effectiveness results will hold up if increased numbers of participants with low levels of stress participate in the intervention. An unguided universal iSMI might be appropriate from an economic perspective, since there are no costs for screening compared to an iSMI for indicated prevention and additionally no costs for eCoach guidance, compared to guided interventions. Since health care professionals and available resources are often limited, unguided interventions have the potential to be implemented in routine occupational care on a large scale. Meta-analytic evidence shows that unguided interventions generate similar effects compared to guided interventions in individuals with low symptom severity (39). However, the evidence on this is heterogeneous (40). Therefore, future studies should directly compare cost-effectiveness of guided compared to unguided iSMIs. From a health economic point of view, no moderators were revealed in NBRF analyses. However, this could also have

been due to a too small sample size and should be further researched in an individual participant data meta-analysis in the future.

Conclusions

A universal unguided digital stress management intervention appears to be cost-effective (i.e., the health effects achieved represent good value for the invested money) as well as offering a favorable benefit-to-cost ratio (i.e., the financial gains outweigh the intervention costs, so the return on investment is positive). Further research is needed to examine the long-term effects on cost-effectiveness and comparing a digital stress management intervention with standard care. Unguided digital stress prevention carries the promise to be scalable, which would leverage the cost-effectiveness and positive return-on-investment of this type of universal stress prevention in the working population.

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Authors' contributions

BF and MB obtained funding for the study. DDE and DL designed the randomized controlled trial. DDE, DL, HR, and MB developed the intervention content. ACZ was responsible for recruitment of participants, data collection, and data curation, supervised by DL and DDE. CB developed the analysis plan for the health-economic evaluation, supported by FS. CB and JF accessed and verified the data. MB provided the analysis tool. CB conducted the analyses. CB, JF, and FS interpreted the data. JF drafted the manuscript, supervised by CB. All authors participated in the critical review of the manuscript and approved the final manuscript.

Role of the funding source

The funders did not have a role in study design, data collection, analysis and interpretation of results, or the decision to publish the study results.

Conflicts of Interest

BF and DDE are stakeholders of the GET.ON Institute/HelloBetter, which aims to implement scientific findings related to digital health interventions into routine care. MB is co-founder and stakeholder of mentalis GmbH, a provider of digital mental health care products and services. DDE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy.
JF, FS, AZ, HR, and CB report no conflicts of interest.

Data sharing

The health economic analysis plan will be made available on request by qualified scientific and medical researchers for legitimate research purposes. The data will be shared under a data sharing agreement once the results of the health-economic evaluation are published. Investigators are invited to submit study proposal requests detailing research questions and hypotheses to receive access to the data. Collected participant-

level data will be deidentified. Requests should be sent to the last author.

Abbreviations

AQoL-8D: Assessment of Quality of Life
AUC: area under the curve
CEA: cost-effectiveness analysis
CEAC: cost-effectiveness acceptability curve
CI: confidence interval
CUA: cost–utility analysis
EQ-5D-3L: European Quality of Life 5 Dimensions 3 Level instrument
ICER: incremental cost-effectiveness ratio
IG: intervention group
iSMI: (digital or) internet-based stress management intervention
MICE: multiple imputations by chained equations
NB: net-benefit
NBRF: net-benefit regression framework
OR: Odds Ratio
QALY: Quality-adjusted life year
PSS: Perceived Stress Scale
RCT: randomized controlled trial
ROI: return-on-investment
SD: standard deviation
SURE: seemingly unrelated regression equations
TAU: treatment as usual
TiC-P: Treatment Inventory of Costs in Patients with psychiatric disorders questionnaire
WLC: waitlist control condition
WTP: willingness-to-pay

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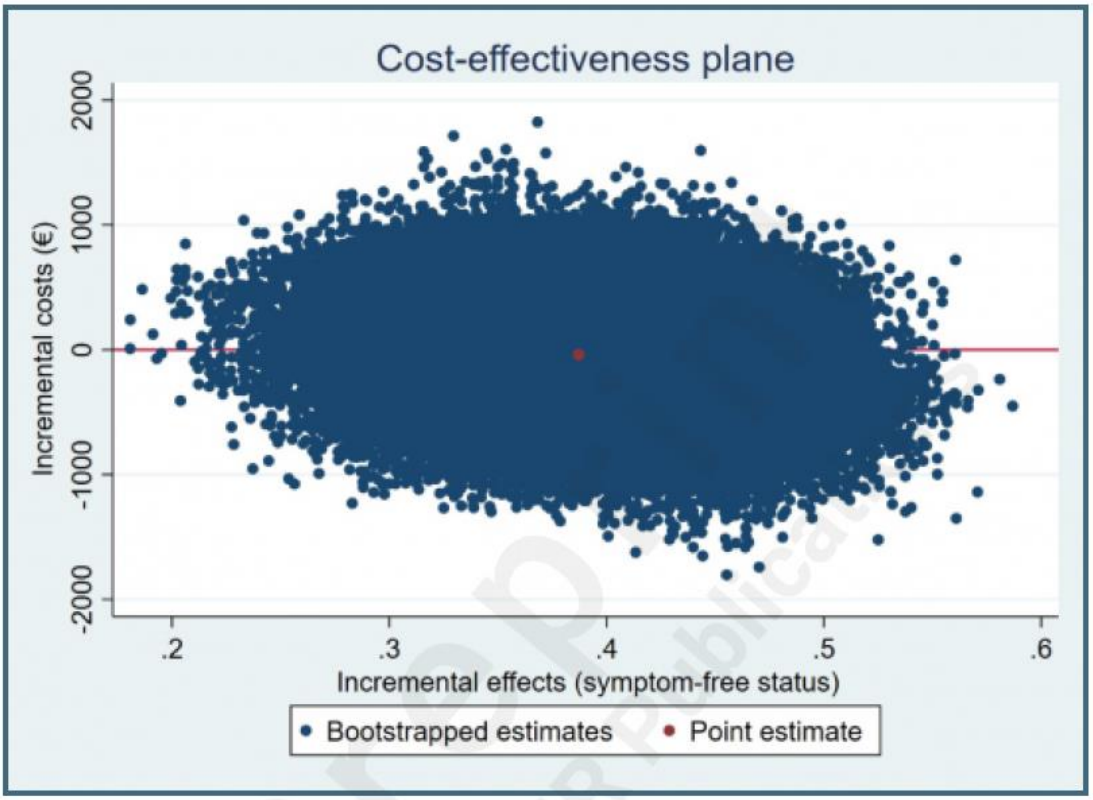
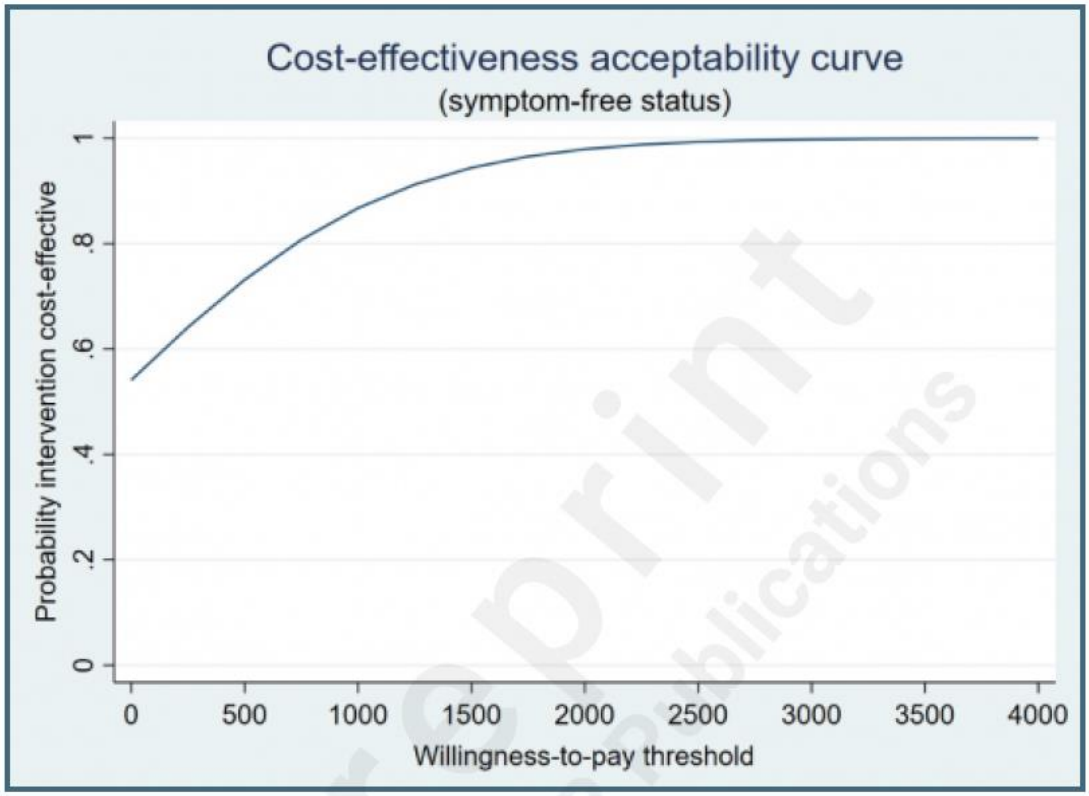
Supplementary Files

Figures

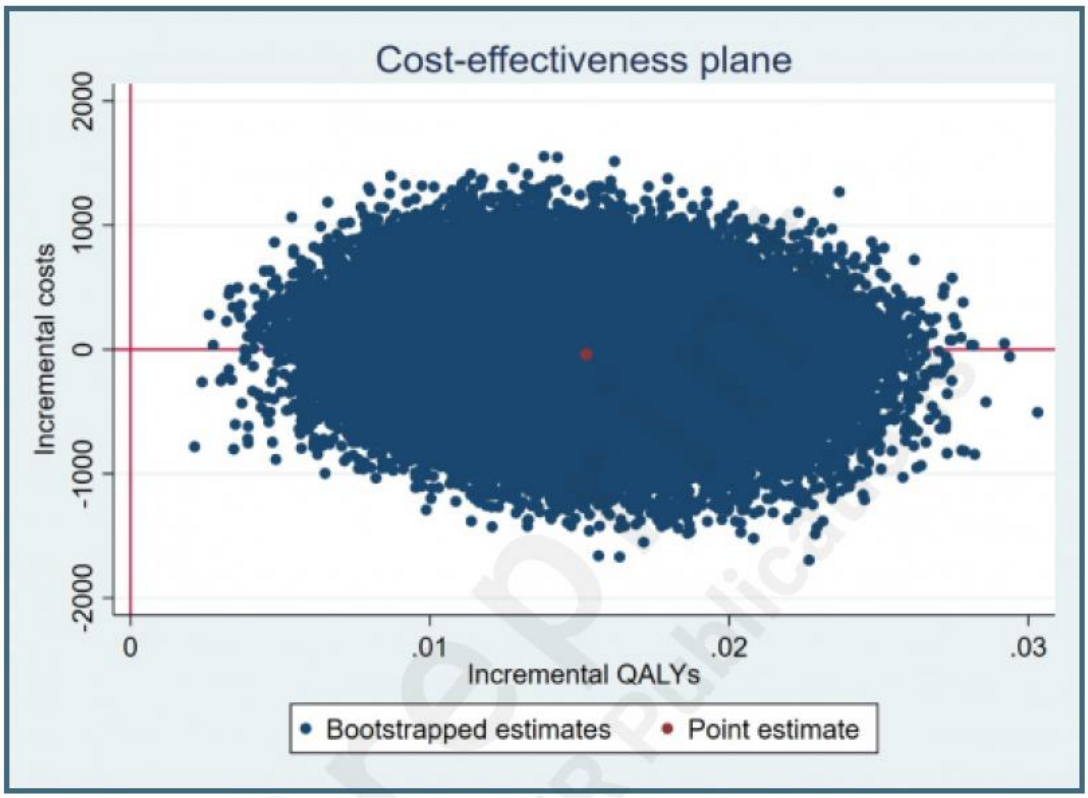
Scatterplot of 5000 replicates of the incremental cost-effectiveness ratio (mean differences in costs and symptom-free status) on the cost-effectiveness plane from the societal perspective: iSMI versus WLC.



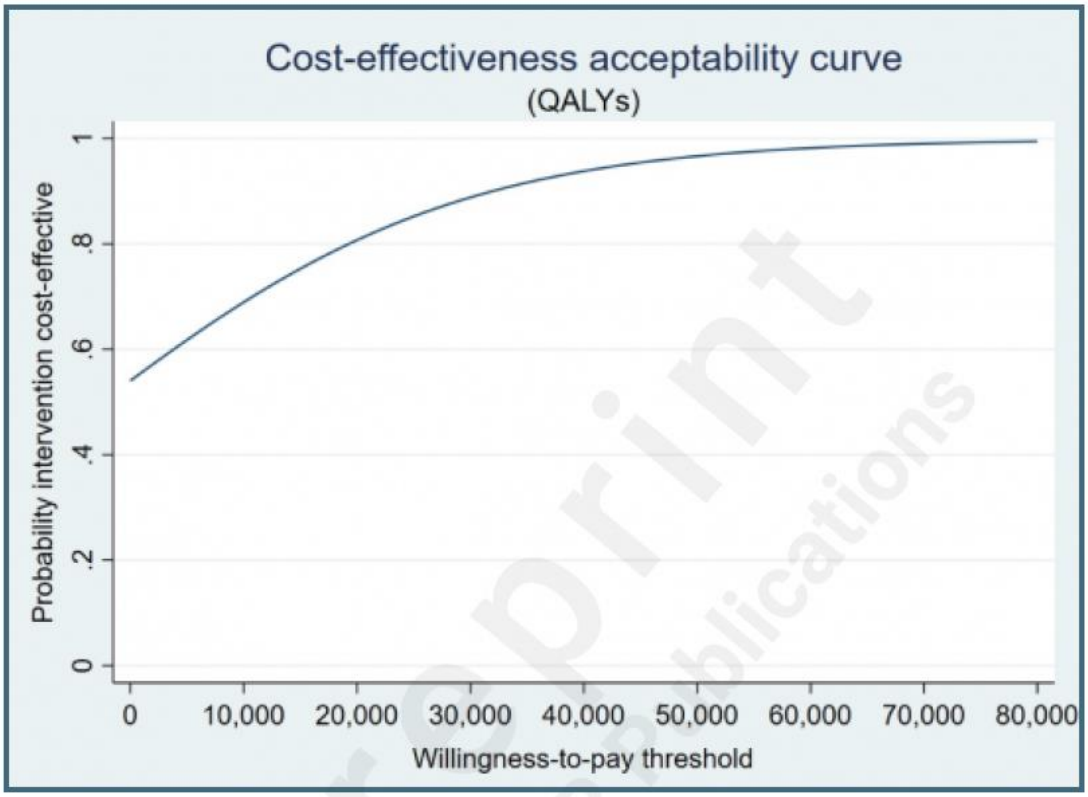
Cost-effectiveness acceptability curves (symptom-free status) from the societal perspective.



Scatterplot of 5000 replicates of the incremental cost-effectiveness ratio (mean differences in costs and QALYs) on the cost-effectiveness plane from the societal perspective: iSMI versus WLC.



Cost-effectiveness acceptability curves (QALYs) from the societal perspective.



4.2 Article 2

Authors: Claudia Buntrock, Johanna Freund, Filip Smit, Heleen Riper, Dirk Lehr, Leif Boß, Matthias Berking, David Daniel Ebert

Title: Reducing problematic alcohol use in employees: Economic evaluation of guided and unguided web-based interventions alongside a three-arm randomized controlled trial

Journal: Addiction

Doi: 10.1111/add.15718

Summary:

This study aimed to conduct an economic evaluation of guided and unguided DHIs to reduce problematic alcohol consumption in employees in comparison to a WLC condition. Over the course of 6 months, cost-effectiveness and cost-utility analyses were conducted from a societal perspective. Additionally, a cost-benefit analysis was performed from the employer's perspective. An open recruitment strategy for the German working population was used. The included employees (178 males, 256 females, mean age 47 years) consumed at least 14 (women) or 21 (men) SUAs per week and scored at least 6 (women) and 8 (men) on the Alcohol Use Disorders Identification Test. The DHI consisted of five modules and was provided with or without guidance. Participants were assigned to the guided intervention (n = 142), the unguided intervention (n = 146), or the WLC (n = 144). Online surveys were conducted to assess SUAs, quality of life (AQoL-8D), and resource use. Responder status (≤ 14 SUAs for women or ≤ 21 SUAs for men) was used as an outcome measure for the CEA and QALYs for the CUA. Net-

benefit regression was applied to estimate the cost-effectiveness for the three study arms. Bootstrapping and sensitivity analyses were performed to account for uncertainty. Taking the societal perspective, the guided DHI showed a 55% probability (54%) of being cost-effective at a WTP of €0 per responder (QALY) gained. The guided DHI showed the highest probability of being cost-effective compared to the other conditions. The probability rose to 78% at a willingness-to-pay of €20,000 per QALY gained. From an employer's point of view, the guided DHI had a higher probability of a positive return on investment (81%) compared with the unguided intervention (58%). Taken together, a guided DHI to reduce problematic alcohol consumption in employees appears to be both cost-beneficial and cost-effective.

The manuscript was submitted in December 2020, accepted in September 2021, and published in *Addiction* in October 2021. *Addiction* is an open-access and peer-reviewed journal on pharmacological and behavioral addictions.

Contribution:

Johanna Freund was the second author of this article. Dirk Lehr, Matthias Berking, and David Ebert obtained funding for the study. Claudia Buntrock conceptualized the study, supported by Filip Smit. Claudia Buntrock and Johanna Freund accessed and verified the data. Claudia Buntrock conducted the analyses. Claudia Buntrock and Johanna Freund interpreted the data, together with Filip Smit, and concluded from analyses. Johanna Freund and Claudia Buntrock drafted the manuscript and received feedback from the co-authors.

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RESEARCH REPORT

ADDICTION SSA

Reducing problematic alcohol use in employees: economic evaluation of guided and unguided web-based interventions alongside a three-arm randomized controlled trial

Claudia Buntrock[1] | Johanna Freund[1] | Filip Smit[2,3,4] | Heleen Riper[4,5] | Dirk Lehr[6] | Leif Boß[6] | Matthias Berking[1] | David Daniel Ebert[7]

[1]Department of Clinical Psychology and Psychotherapy. Institute of Psychology, Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany

[2]Trimbos Institute (Netherland Institute of Mental Health and Addiction), Utrecht, the Netherlands

[3]Department of Epidemiology and Biostatistics, Amsterdam Public Health Research Institute, Amsterdam University Medical Centers, Amsterdam, the Netherlands

[4]Department of Clinical, Neuro and Developmental Psychology, Amsterdam Public Health Research Institute, VU University, Amsterdam, the Netherlands

[5]Telepsychiatric Centre, University of Southern Denmark, Odense, Denmark

[6]Department of Health Psychology and Applied Biological Psychology, Institute of Psychology, Leuphana University Lüneburg, Lüneburg, Germany

[7]Department of Sport and Health Sciences, Technical University of Munich, Munich, Germany

Correspondence
Dr Claudia Buntrock, Friedrich-Alexander-University Erlangen-Nuremberg, Department of Clinical Psychology and Psychotherapy, Nägelsbachstrasse 25a, 91052, Erlangen, Germany.
Email: claudia.buntrock@fau.de

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Abstract

Aims: To perform an economic evaluation of guided and unguided internet-based interventions to reduce problematic alcohol consumption in employees compared with a waiting-list control condition (WLC) with unrestricted access to treatment-as-usual.

Design: A cost-effectiveness analysis (CEA) and cost–utility analysis (CUA) from a societal and a cost–benefit analysis from the employer's perspective with a 6-month time horizon.

Setting: Open recruitment in the German working population.

Participants: Employees (178 males, 256 females, mean age 47 years) consuming at least 14 (women) or 21 (men) standard units of alcohol (SUAs) per week and scoring ≥ 8 (men) or 6 (women) on the Alcohol Use Disorders Identification Test.

Measurements: On-line questionnaires administered to assess SUAs and assess quality of life (AQoL-8D) and resource use. Outcome measure was responder (≤ 14/≤ 21 SUAs) for the CEA and quality-adjusted life years (QALYs) for the CUA. Net benefit regression was used to estimate cost-effectiveness for each study arm. Bootstrapping and sensitivity analyses were performed to account for uncertainty.

Interventions: Five weekly modules including personalized normative feedback, motivational interviewing, goal setting, problem-solving and emotion regulation, provided with adherence-focused guidance [n = 142; responders: n = 73 (51.4%); QALYs = 0.364, standard error (SE) = 0.006] or without guidance [n = 146; n = 66 (45.2%); 0.359, 0.007]. Controls were on a waiting-list [n = 144; n = 38 (26.4%); 0.342, 0.007].

Findings: From a societal perspective, the guided intervention had a probability of 55% (54%) of being the most efficient strategy at a willingness-to-pay (WTP) of €0 per responder (QALY) gained, compared with the unguided intervention and the control condition. At a WTP of €20 000 per QALY gained, the probability was 78%. From an employer's perspective, the guided intervention had a higher probability of a positive return on investment (81%) compared with the unguided intervention (58%).

Conclusion: A guided internet-based intervention to reduce problematic alcohol consumption in employees appears to be both cost-beneficial and cost-effective.

KEYWORDS
Cost-effectiveness, cost–utility, economic evaluation, employees, internet-based intervention, problematic alcohol consumption, QALY

INTRODUCTION

Alcohol has a major impact on public health. Alcohol misuse leads to a large burden of disease, including cardiovascular diseases, mental health conditions, digestive diseases, cancer and injuries [1]. Worldwide, approximately 3.8% of all deaths and 4.6% of disability-adjusted life-years (DALYs) are attributable to alcohol [2]. By 2030, alcohol use disorders (AUDs) are estimated to be the fourth leading cause of disability in high-income countries [3].

Consequently, alcohol use is associated with substantial economic costs for society (e.g. health-care, law enforcement, social and indirect costs stemming from productivity losses). In middle- and high-income countries these costs account for approximately 1% of the gross domestic product (GDP) [2]. Approximately half the socio-economic costs (e.g. 0.64% of the GDP per country annually) are attributable to sick leave, reduced job performance, early retirement, involuntary unemployment and premature mortality [4].

Hence, programmes directed at employees to reduce problematic drinking can potentially benefit the employee, the employer and society as a whole. Problematic drinking refers to alcohol consumption that is likely to lead to physical or psychosocial harm and is defined as an average rate of consumption of more than 14 weekly standard units of alcohol (SUAs, 10 g of ethanol) for women and more than 21 weekly SUAs for men [5]. Evidence suggests that screening and brief interventions are effective at reducing excessive alcohol consumption [6]. However, it seems unlikely that brief interventions alone curb the prevalence of problem drinking [7].

Low-threshold internet- and mobile-based interventions (IMIs) seem to be a promising option, by which evidence-based interventions designed to reduce alcohol-related problems could be delivered less intrusively [8,9]. In addition, IMIs have the potential of attracting individuals who would otherwise not make use of traditional services due to practical concerns or time constraints [10]. In particular, IMIs can be anonymously accessed whenever required: two factors that are especially relevant for problematic drinking [11].

Based on an individual participant data meta-analysis [12], IMIs for adult problem drinking have been shown to be effective in reducing the weekly consumption of SUAs [−5.02 SUAs, 95% confidence interval (CI) = − 7.57 to −2.48, $P < 0.001$]. Guided IMIs seemed to yield better outcomes than unguided IMIs (−6.78 SUAs, 95% CI = − 12.11 to −1.45, $P = 0.013$) [12].

With respect to the economic merit of IMIs for problematic drinking, a modelling study revealed that the implementation of IMIs could substantially increase the cost-effectiveness of health-care systems for AUDs [13]. A recent systematic review on the cost-effectiveness of IMIs for substance use disorders suggested that IMIs for AUDs provide good value for money, from both a public health-care and a societal perspective [14]. The only study comparing an unguided and a guided IMI for problematic drinking in adults in a substance abuse treatment centre suggested that a guided IMI offered better value for money than an unguided IMI [15].

However, to the best of our knowledge, no study has yet evaluated the economic merit of (un-)guided IMIs for problematic drinking specifically in employees, from neither the societal nor the employer's perspective. Elsewhere we have reported the primary outcome with regard to the reduction of self-reported quantity of alcohol consumption in standard units of alcohol [16]. Here, we evaluated the cost-effectiveness and cost–utility of an unguided and guided IMI for problematic alcohol use in employees relative to a waiting-list control condition from a societal perspective and the cost–benefit from the employer's perspective, within a time horizon of 6 months.

METHODS

Study design

The execution and reporting of the health economic evaluation followed the declaration of the Consolidated Health Economic Evaluation Reporting Standards [17] and the guidelines of the International Society for Pharmacoeconomics and Results Research [18]. The economic evaluation was conducted alongside a three-arm pragmatic randomized controlled trial evaluating the effects of both an internet-based intervention with adherence-focused guidance and without guidance (i.e. self-help) to reduce alcohol consumption in employees compared to a waiting-list control group with unrestricted access to treatment-as-usual (TAU). Detailed information regarding the study design can be found elsewhere [16,19]. The study was approved by the University of Lüneburg (Germany) ethics committee (no. Boss201404_OT) and registered in the German clinical trial register for clinical studies (DRKS00006105).

Participants

Participants were recruited in Germany during the period from October 2014 to February 2016. An open recruitment procedure was used (e.g. print newspaper articles, open-access websites), which was supported by some German health insurance companies

(e.g. BARMER, KKH, BKK) via announcements in their membership magazines and on their websites). The recruitment strategy employed in this study is the same that will be employed when the intervention is delivered under real-world conditions, thus strengthening the ecological validity of the study.

Individuals (aged 18 years and above) were included into the study if they were (a) currently (self-)employed, (b) reported drinking at least 14 (women)/21 (men) standardized units of alcohol (SUAs) per week with (c) having a score of ≥ 8/6 for men/women on the Alcohol Use Disorders Identification Test (AUDIT) [20]. Exclusion criteria included (a) any past psychosis or drug dependence (self-disclosed); (b) notable suicidal risk, as indicated by a score greater than 1 on item 9 of the Beck Depression Inventory [21]; or (c) current treatment for alcohol-related problems or work-related stress. The Consolidated Standards of Reporting Trials (CONSORT) study flow-chart and participants' characteristics at baseline can be found elsewhere [16]. In brief, 434 employees were recruited into the trial. Two participants withdrew from the study and requested their data to be deleted. Thus, the final ITT sample consisted of 432 participants, with 146 randomized to the unguided intervention, 142 to the guided intervention and 144 to the waiting-list control condition. At post-treatment, 339 participants (78.5%) were still participating, whereas at 6-month follow-up, 270 participants (62.5%) completed the follow-up questionnaires. The three groups differed with regard to missing data on primary and secondary outcomes at T2 (P = 0.032), but not at T3 (P = 0.092) [16]. The average participant was female (n = 256, 59.5%; males: n = 178, 40.5%), 47 years of age [standard deviation (SD) = 19], full-time employed (69.7%), with an average working experience of 23 years (SD = 11) and drinking 29.6 SUAs weekly (SD = 15.8) [16].

Randomization and masking

Study participants were randomly assigned at individual level in a 1:1:1 ratio with a block size of three to the study groups by an independent researcher, who was not otherwise involved in the study, using an automated, computer-based, random integer generator (randomisation.eu). Detailed information about the randomization procedure can be found elsewhere [16]. During the randomization procedure, group allocation was concealed from participants, researchers involved in recruitment and eCoaches. After randomization, study participants were aware of their group allocation as they received immediate or delayed access to the internet-based intervention.

Interventions

All study participants had unrestricted access to TAU. The German S3-Guideline for Alcohol-related Disorders recommends brief interventions in outpatient settings for problematic drinking [e.g. general practitioners (GPs), psychotherapists] [22]. In our pragmatic study, we did not interfere in TAU. Instead, we maintained a naturalistic TAU condition to represent current routine care as best as possible. It should also be noted that health-care use was measured in detail (see Measures).

Web-based intervention

The web-based alcohol intervention (GET.ON Clever weniger trinken; CWT – be smart – drink less) consisted of five weekly modules which were based on evidence-based treatments of alcohol use disorders [23,24], e.g. motivational interviewing, methods to control drinking behaviour and relapse prevention. In addition, the intervention contained elements of emotion regulation [25]. A detailed description of the intervention can be found elsewhere [19]. Participants in the guided condition were supported by an eCoach (e.g. a trained psychologist). Guidance in this study was primarily based on the supportive-accountability model of guidance in internet interventions [26] and consisted of two elements: adherence monitoring and feedback on demand, which was provided within 48 hours. Participants in the guided intervention group completed three modules on average, while participants in the unguided intervention group completed 2.5 modules [16].

Outcome measurements

Health-related outcomes

Drinking outcomes were operationalized as the number of participants who complied with the low-risk guideline for problematic drinking at 6-month follow-up. Responders were defined as having consumed no more than 14 (for women) or 21 (for men) SUAs weekly.

Health-related quality of life was measured using the Assessment of Quality of Life (AQoL-8D) at baseline, post-treatment and 6-month follow-up. The AQoL-8D is a reliable and validated quality of life instrument [27]. It measures health-related quality of life across eight dimensions (independent living, relationships, mental health, coping, pain, senses, self-worth and happiness) and generates patient preference-based utilities on a scale of 0 (death) to 1 (perfect health), using the time trade-off method [28]. Quality-adjusted life-years (QALYs) gained were estimated by calculating the area under the curve (AUC) of linearly interpolated AQoL-8D utilities between measurement points to cover the whole 6-month follow-up period.

Resource use and costing

Costs were measured from both societal and the employer's perspectives. When the societal perspective was applied, all costs (i.e. intervention, health care, patient and family and productivity costs) related to the intervention were taken into account irrespective of who pays or benefits from them. When applying the employer's perspective, only costs and economic benefits pertinent to employers

were included (i.e. costs or cost reductions stemming from changes in absenteeism and presenteeism) plus intervention costs assuming that the latter would be paid for by the employer. We used the Trimbos and iMTA questionnaire for costs associated with psychiatric illness (TiC-P) [29], a retrospective questionnaire with a 3-month recall period, for collecting data on health-care use, patient and family costs and productivity costs. Accumulated costs were estimated using the AUC method to linearly interpolate 3-month costs as measured at each measurement point to cover the full follow-up period of 6 months. The TiC-P was adapted for use in Germany and has been used in a series of cost-effectiveness studies [30–32]. Costs were expressed in Euros and indexed from 2011 to 2015, the year the study was conducted, with an index factor of 1.05 based on the German consumer price index [33]. Costs were converted to pounds sterling (£) using the purchasing power parities reported by the Organization for Economic Cooperation and Development [34]. For the reference year 2015, €1 was equated to £0.89.

Intervention costs

At the time of conducting the study, the market price of the unguided internet-based intervention provided by the GET.ON Institute, a commercial health-care service provider, was €79 (£70) per participant, whereas it was €189 (£168) for the guided intervention including the time that eCoaches spent on coaching and administrative tasks, costs for website maintenance and hosting, technical support and overheads.

Health-care costs

We used two German guidelines for calculating health-care costs [35,36]. Health-care costs on a per-participant level were based on available lists of unit cost prices [36]. Unit cost prices were as follows: €21.06 (£18.74) for a visit to the GP, €46.96 (£41.79) for a session with a psychiatrist, €81.98 (£72.96) for a session with a psychotherapist and €17.14 (£15.26) for allied health services. Hospital stays were computed at €356.70 (£317.46) for an inpatient day in a psychiatric hospital (Supporting information, Table S2). Costs were estimated by multiplying the units of resource use with corresponding unit cost prices. The costs of prescribed medication were based on the German drug registry, Rote Liste [37].

Patient and family costs

Out-of-pocket payments were directly obtained from participants. Costs for travelling were valued at €0.30 (£0.27) per kilometre. Productivity losses from unpaid work (e.g. household chores, shopping, child care) were valued using the replacement cost method [38,39] with an estimated value of €19.25 (£17.13) per hour (i.e. the average gross wage of domestic help per hour).

Productivity costs

We followed the human capital approach to value costs due to absenteeism [40]. Lost working days due to absenteeism were valued at the gross average income of participants per day. Lost working days due to presenteeism were computed by taking into account the number of working days for which the participant reported reduced functioning weighted by an inefficiency score for those days (Osterhaus method) [41].

Statistical analysis

The study was not powered to statistically test differences in health economic outcomes. Therefore, we took a probabilistic decision-making approach to make health economic inferences (e.g. cost-effectiveness acceptability curves) [42] and did not test for statistically significant differences in costs between study groups. Due to the 6-month time horizon, we did not discount costs and effects.

Handling missing data

All findings were reported in accordance with the CONSORT [43], following the intention-to-treat principle. Little's overall test of randomness indicated that missingness in cost and outcome data occurred completely at random ($P = 0.57$). We employed a Markov chain Monte Carlo multivariate imputation algorithm as implemented in SPSS version 26, with 100 estimations per missing value. We did not impute costs due to inpatient care, because only six participants (1.6%) were hospitalized during the 6-month follow-up period leading to unstable imputations. Data were first aggregated over the 100-fold imputations and these aggregated data were used in the bootstrapped analyses.

Analyses of health-related outcomes and costs

We tested for group differences in the number of responders using Pearson's χ^2 analysis [16]. Total adjusted QALYs were estimated using ordinary least-squares regression analyses with robust standard errors controlling for AQoL-8D baseline scores [44]. Cost categories as well as costs from the employer's and societal perspectives per study group were assessed by bootstrapping ($n = 2500$) ordinary least-squares regression models. In addition, we estimated total societal costs with a generalized linear regression model. We used the modified Park's test [45] to determine the family distribution (i.e. gamma distribution). The model was adjusted for baseline costs [46], initial depressive symptom severity and alcohol consumption as associated factors of resource utilization. We used a link identity function providing additive effects of covariates [47].

Cost-effectiveness and cost–utility analyses from the societal perspective

Net monetary benefit (NMB) regression framework was used to obtain cost-effectiveness and cost–utility estimates for each condition from the societal perspective. All three conditions were included simultaneously in the NMB analyses, with no need to specify the comparator [48]. The NMB was calculated as $\lambda \times Ek - Ck$, where Ek is the arithmetic mean of health-related outcomes (e.g. responders, QALYs), Ck is the mean of costs for the kth comparator and λ is the willingness-to-pay (WTP) threshold. NMB values were calculated at each WTP (QALYs: €0–50 000 at €5000 intervals; responder: €0–5000 at €500 intervals). At each threshold, 2500 bootstrap model iterations of the linear regression models of the NMB adjusted for baseline cost, utility values (only when QALYs were used), initial depressive symptom severity and alcohol consumption as associated factors for health-related outcomes and resource utilization were performed. For an n-way comparison, the alternative with the highest net benefit has the highest probability of being cost-effective [49]. Cost-effectiveness acceptability curves (CEACs) were generated to assess for each condition the probability of being the most cost-effective alternative compared to the other two conditions over a range of willingness-to-pay thresholds [50]. CEACs were based on the bootstrapped regression models. In each of the bootstrap iterations, the probability that each intervention was the most cost-effective alternative was reported as the proportion of replicates, in which each intervention had the highest NMB.

Cost–benefit analyses from the employer's perspective

Two metrics were applied: (1) net benefits (NB = benefits – costs; amount of money gained after costs are taken into account) and (2) return-on-investment (ROI) [ROI = (benefits – costs)/costs × 100%; percentage of profit per Euros invested], where costs are defined as intervention costs and benefits as the difference in productivity costs between the intervention groups and the control condition. Both metrics were each estimated by bootstrapping a linear regression model adjusted for baseline costs due to absenteeism and presenteeism, and initial depressive symptom severity (n = 2500). The probability of financial return was estimated by the proportion of positive estimates (e.g. NB > 0, ROI > 0%).

Sensitivity analyses

To assess the robustness of the base case findings, six sensitivity analyses were performed. First, we repeated the main analyses but without covariate adjustments. Secondly, we applied a more conservative low-risk guideline for problematic drinking by defining responders as having consumed no more than seven (for women) or 14 (for men) SUAs weekly [51,52]. Thirdly, we performed analyses assuming reduced effects in both intervention groups (i.e. approximately the 95% CI of weekly alcohol consumption and QALYs). Fourthly, we applied winsorizing, where cost outliers (e.g. those above the 95th percentile) are not removed, but their extreme values are replaced by the value at the 95th percentile [53]. Fifthly, we assessed the impact of inpatient care on the results of the main analyses by excluding costs due to inpatient care from the analyses. Finally, we varied the costs of the intervention by plus 50% to reflect uncertainties about the actual market price, both in net monetary benefit regression analyses from the societal perspective and cost–benefit analyses from the employer's perspective.

RESULTS

Health-related outcomes

At 6-month follow-up, both intervention groups yielded statistically significant higher rates of response to the low-risk drinking threshold (unguided: n = 66, 45.2%; guided: n = 73, 51.4%) compared to the control group (n = 38, 26.4%; unguided: $\chi^2_{(1)} = 11.16$, $P = 0.001$; guided: $\chi^2_{(1)} = 18.85$, $P < 0.001$). Total adjusted mean QALYs were higher in the guided intervention group (0.364 QALYs: 95% CI = 0.359–0.369; SE = 0.006) compared to the unguided intervention group (0.359 QALYs: 95% CI = 0.354–0.364; SE = 0.007) and the control condition (0.342 QALYs: 95% CI = 0.337–0.357; SE = 0.007). Adjusted incremental differences in QALYs between the interventions groups and the control condition were statistically significant [unguided: Δ(e) = 0.018 QALYs, 95% CI = 0.010–0.025; guided: Δ(e) = 0.022 QALYs, 95% CI = 0.014–0.029].

Costs

Baseline costs were similar for the unguided intervention group [€992 (£883), SD = 1477] and the control condition [€917 (£816), SD = 1580] but higher in the guided intervention group [€1297 (£1154), SD = 2513]. Table 1 presents the bootstrapped (n = 2500) imputed mean cumulative per-participant costs (in €) by condition during the 6-month follow-up period. Direct medical and patient and family costs were comparable for all three groups. In both intervention groups, costs due to presenteeism were lower compared to costs caused by absenteeism. The opposite applied to the control condition. With regard to costs stemming from absenteeism, both intervention groups showed similar (unguided: €661, 95% CI = €462– 860; guided: €670, 95% CI = €467–872), but higher cost levels compared to the control condition (€561, 95% CI = €360–761). The guided intervention group generated the fewest costs due to presenteeism (€510, 95% CI = €352–667) compared to the unguided intervention group (€648, 95% CI = €492–803) and the control condition (€628, 95% CI = €472–785). The control condition and the unguided intervention group showed comparable cost levels [€1782 (£1586), 95% CI = €1435–2130 versus €1774 (£1579), 95% CI = 1429–2119]; however, both groups were less costly than the guided intervention group

TABLE 1 Bootstrapped (n = 2500) imputed mean cumulative per-participant costs (in €) by condition over a 6-month follow-up period

	Waiting-list control condition (n = 144)		Unguided intervention group (n = 146)		Guided intervention group (n = 142)	
	Mean, €	(95% CI)	Mean, €	(95% CI)	Mean, €	(95% CI)
Intervention costs	–		79	–	189	–
Direct medical costs[a]						
GP	40	34–47	42	35–48	43	36–49
Mental health care	64	37–92	46	18–73	70	43–98
Antidepressants	15	6–23	19	10–27	21	12–29
Allied health services[b]	36	19–53	30	13–46	48	31–65
In-patient care	183	56–310	27	0–153	126	0–253
Patient and family costs[a]						
Over-the-counter drugs	24	18–30	22	16–28	23	17–29
Out-of-pocket expenses[c]	42	24–59	19	1–36	34	17–52
Travel	8	5–10	7	5–10	4	2–6
Unpaid work	183	116–250	175	109–242	217	150–285
Productivity costs[a]						
Absenteeism	561	360–761	661	462–860	670	467–872
Presenteeism	628	472–785	648	492–803	510	352–667
Employer's perspective						
Intervention costs + productivity costs	1189	897–1481	1388	1098–1678	1368	1074–1662
Societal perspective						
Total societal costs[d]	1782	1435–2130	1774	1429–2119	1954	1604–2303

[a]Costs of cost categories were estimated based on bootstrapped (n = 2500) linear regression models.
[b]For example, physiotherapist, massage, occupational therapist.
[c]For example, allied health services without prescription.
[d]Includes all cost categories. Total societal costs were estimated based on a bootstrapped (n = 2500) linear regression model. Due to rounding, columns do not add up correctly. CI = confidence interval.

[€1954 (£1739), 95% CI = 1604–2303]. However, adjusted total costs were nearly identical for both intervention groups and lower compared to the control condition (Table 2).

Cost-effectiveness and cost–utility analyses from the societal perspective

The control condition yielded the smallest effects in terms of treatment response and QALYs gained and did so at higher costs compared to both intervention groups, reflected in the lowest mean NMBs (Table 2). The CEACs (Fig. 1) showed that the guided intervention tends to be the preferred alternative compared to the unguided intervention and the control condition, with a probability of 55 and 54% of being the most cost-effective strategy at a WTP of €0 per responder and QALY gained, respectively. The probability increases to 78% when increasing the WTP to €20 000 (£17 800) per QALY gained and 86% at a WTP of €5000 (£4450) per additional responder. Despite the 31 and 32% probability of the unguided intervention being the most cost-effective strategy at a WTP of €0 per responder and QALY gained, respectively, its probability diminishes with increasing WTPs (e.g. 22% at a WTP of €20 000 per QALY gained). The control condition has the lowest chance of being the most cost-effective strategy, with a probability of 14% for both health outcomes at a WTP of €0 that decrease to 0% as WTPs increase.

Cost–benefit analyses from the employer's perspective

The unguided intervention condition showed a net benefit per participant of €29 (£26) (95% CI = €23–34), which was €109 (£97) (95% CI= €105–114) in the guided intervention condition. The ROI was 36% (95% CI = 30–43%) and 58% (95% CI = 55–60%), respectively. The probability of a positive return on investment was 58% for the unguided and 81% for the guided intervention condition (Table 3).

Sensitivity analyses

Results of the sensitivity analyses are summarized in Supporting information, Table S1. Analyses based on linear regression models without covariate adjustments supported the conclusion that the guided intervention has the highest probability of being cost-effective at a WTP

TABLE 2 Results from the societal perspective of adjusted cost-effectiveness and cost–utility analyses based on 2500 bootstrapped net monetary benefit regression models

Study group	Adjusted mean total societal costs (€)[a]	95% CI	Treatment responder (*n*)	(%)	Adjusted mean QALYs[b]	95% CI	Adjusted mean NMB at WTP of €5000/treatment responder[c]	95% CI	Adjusted mean NMB at WTP of €20 000/QALY gained[d]	95% CI
Control	1942	1671–2213	38	26.4	0.342	0.337–0.357	464	−76 – 1004	4939	4661–5218
Unguided	1840	1583–2096	66	45.2	0.359	0.354–0.364	1498	943–2052	5367	5090–5643
Guided	1865	1592–2137	73	51.4	0.364	0.359–0.369	1852	1290–2413	5498	5217–5778

[a]Mean societal costs were estimated by a generalized linear regression model with gamma family distribution and link identity function adjusted for baseline costs, initial depressive symptom severity and alcohol consumption.
[b]Quality-adjusted life-years (QALYs) were estimated by an ordinary least-squares regression model adjusted for baseline utility values.
[c]Net monetary benefit (NMB) linear regression models were adjusted for baseline cost, initial depressive symptom severity and alcohol consumption.
[d]Net monetary benefit (NMB) linear regression models were adjusted for baseline cost, utility values, initial depressive symptom severity and alcohol consumption. CI = confidence interval; WTP = willingness to pay.

of €20 000 per QALY gained, however; the probability was lower (55%) compared to the adjusted analysis (78%) (Supporting information, Fig. S1). The application of stricter limits for problematic drinking led to converging probabilities for the guided (56%) and unguided intervention (44%) to be the most cost-effective preventive intervention at a WTP of €5000 (Supporting information, Fig. S2), assuming that reduced effects on health-related outcomes in both intervention groups did not influence the economic outcomes (Supporting information, Fig. S3). Winsorizing extreme values to the level at the 95th percentile did not affect cost-effectiveness outcomes (Supporting information, Fig. S4). Hospital costs were higher in the guided intervention group compared to the unguided group and the control condition, so excluding these costs increased the guided intervention's probability to be the most efficient option to 72% (85%) at a WTP of €0 (€20 000) per QALY gained (Supporting information, Fig. S5). Increasing intervention costs by 50% led to an almost equal likelihood that the unguided (46%) and guided interventions (41%) constitute the most efficient option from the societal perspective at a WTP of €0 per QALY gained. At a WTP of €20 000 per QALY gained, the probability of being cost-effective was higher for the guided intervention (64%) compared to the unguided intervention (36%) (Supporting information, Fig. S6). ROI was negative for the unguided intervention when intervention costs were increased by 50%, while the probability of a positive financial return was just greater than 50% for the guided intervention group (Table 3).

DISCUSSION

Main findings

Our study was designed to evaluate the cost-effectiveness and cost–utility of the unguided and guided intervention as adjunct to TAU to reduce problematic alcohol use in employees, in comparison with a waiting-list control condition (WLC) with unrestricted access to TAU from a societal and an employer's perspective. Statistically significant differences favouring both intervention groups compared to the WLC were found for both health outcomes (e.g. treatment response and QALYs). From a societal perspective, the guided intervention had the highest probability of being cost-effective (e.g. 78% at a WTP of €20 000 per QALY gained). From an employer's perspective, the guided intervention showed higher net benefits than the unguided intervention and the WLC. Probability of financial return ranged from 58% (unguided IMI) to 81% (guided IMI).

Comparison to previous research

A systematic review provided evidence that screening and brief interventions in primary care are cost-effective in relation to various comparators to tackle alcohol-related harms [54]. Although the effectiveness of IMIs for adult problem drinking is well established [12], there is a critical gap in health economic evidence for such

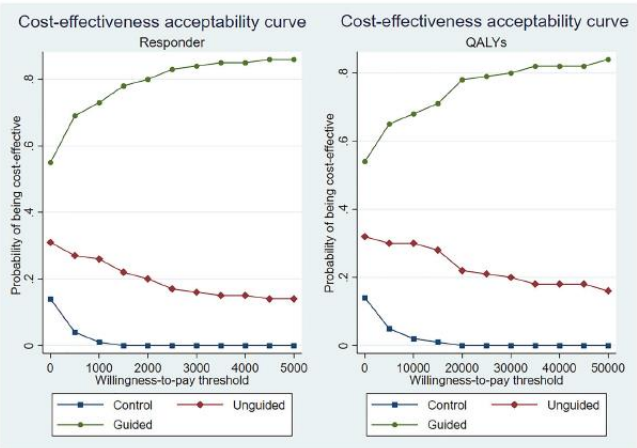

FIGURE 1 Cost-effectiveness acceptability curves from the societal perspective

TABLE 3 Results from the employer's perspective of adjusted cost–benefit analyses based on 2500 bootstrapped linear regression models (main and sensitivity analyses)

	Costs[a]		Benefits[b]		Financial return				
	Total	95% CI	Total	95% CI	NB[c]	95% CI	ROI[d] (%)	95% CI	*P*[e] (%)
Main analyses									
Unguided intervention	79	NA	108	102–113	29	23 to 34	36	30 to 43	58
Guided intervention	189	NA	298	294–303	109	105 to 114	58	55 to 60	81
Sensitivity analysis[f]									
Unguided intervention	118.5	NA	108	104–114	−10	−15 to −5	−8	−13 to −4	47
Guided intervention	283.5	NA	298	292–301	14	9 to 18	5	3 to 7	54

[a]Net benefit (NB) linear regression models were adjusted for baseline costs due to absenteeism and presenteeism and initial depressive symptom severity.
[b]Return on investment (ROI) linear regression models were adjusted for baseline costs due to absenteeism and presenteeism, and initial depressive symptom severity.
[c]Probability of positive return on investment.
[d]Intervention costs increased by 50%.
[e]Costs are intervention costs.
[f]Benefits are the difference in productivity costs between the intervention groups and the control condition. NA = not available; CI = confidence interval.

interventions. To our knowledge, this is the first trial-based economic evaluation of an unguided and guided intervention to reduce problematic drinking in employees using a societal and an employer's perspectives. As such, results from our trial add to the growing evidence pointing to the cost-effectiveness of IMIs for mental health disorders [14,55–57]. Blankers *et al.* (2012) compared an unguided and a guided IMI for harmful alcohol use in adults in a substance abuse treatment centre from a societal perspective. Results of the current health economic evaluation are in agreement with these findings. In parallel to our findings, the guided IMI provided better value for money than unguided self-help. Compared to our results, cost–utility analyses revealed a slightly lower probability (60%) of the guided intervention being cost-effective compared to the unguided IMI at a ceiling ratio of €20 000 per QALY gained [15]. In addition, our findings agree with available health economic evidence from a recent systematic review showing the health economic benefits of IMIs for alcohol use disorder. Probabilities that IMIs were cost-effective from a societal and a public health care perspective, respectively, ranged from 60 to 84% [14].

Our results from the employer's perspective are also in line with findings from a recent systematic review showing that targeting substance misuse in employees improves both employees' wellbeing and productivity [58]. Regarding the ROI analyses, our findings compare favourably to a systematic review on the costs and benefits of health promotion interventions at the work-place (n = 12 RCTs), which revealed on average a negative ROI (ROI = −0.22, 95% CI = 0.27–0.16; min = −4.3; max = 5) [59]. In addition, the percentages of profit per Euros invested of 37% (95% CI = 30–44%) and 61% (95% CI = 58–63%) for the unguided and guided intervention, respectively, are comparable to a study on a guided internet-based intervention targeting work-related stress in employees (ROI = 61%) [60].

Limitations

This study has some limitations. First, the time horizon of this study was limited to 6 months. It is possible that health effects were maintained after 6 months, but they also might diminish over time. The same holds true for decreased costs and productivity gains. As additional costs such as premature death or accidents were not taken into account, costs only reflect short-term costs. Further studies should thus assess the long-term clinical and cost-effectiveness of IMIs for problematic alcohol use to shed light on its longer-term cost-effectiveness. In addition, the societal perspective was incomplete by omitting crime and criminal justice, future medical and opportunity costs (e.g. time spent on using the intervention, travelling time). However, as this is a preventive intervention, crime and criminal justice costs might not significantly affect the results in this study. Secondly, although the sample size in this trial was sufficient to demonstrate clinical effectiveness, it needs emphasizing that much larger sample sizes are required for hypothesis testing in economic studies due to the large variance of costs relative to normally distributed health effects [61]. Therefore, future studies employing larger sample sizes are recommended to allow for robust evaluations of cost changes and sustainability of interventions such as IMIs. Thirdly, the IMIs were compared to a waiting-list control condition in the present trial. However, pharmaco-economic guidelines recommend standard care (e.g. brief face-to-face alcohol interventions) as comparator [62]. Future studies should thus directly compare the cost-effectiveness of IMIs versus face-to-face interventions. Fourthly, the trial participants were highly educated. Evidence suggests that better treatment adherence is predicted by higher education [63]. Attrition has been suggested to be an issue, especially in internet-delivered interventions [64]. Hence, we cannot predict the uptake of such an intervention in less educated people or among people with a lower socio-economic status. It is thus warranted to conduct economic evaluations in these specific population segments. Fifthly, we did not conduct diagnostic interviews to identify participants with alcohol use disorder. However, including participants with a wide range of consumed alcohol units reflect the real-life situation in the general population in high-income countries [65]. Finally, the research context may have led to self-selection of individuals who might be more motivated and committed to engage in IMIs than is assumed outside a research context [66]. As a result, findings might not be generalizable to the wider target population, but are likely to be representative for precisely those people willing to use IMIs in the first place.

Implications

The current study shows that an internet-based intervention may not only be effective in reducing weekly alcohol consumption, but also that achieving and maintaining a marked reduction in drinking is associated with significant increases in health-related quality of life. As the population segment targeted in the current study had a lower than average health-related quality of life when entering the study [67], this finding underscores the importance of offering this target group an eHealth intervention to curb their problematic alcohol use.

Internet-based interventions for mental disorders have often been touted as potential cost-saving alternatives to face-to-face individual or group therapy [55,56]. Findings from our study add to the evidence base that IMIs have indeed a high probability of being cost-effective in reducing problematic alcohol consumption among employees. The IMIs that we evaluated are cost-effective and even dominant, in the sense that for fewer costs better health gains were achieved. Furthermore, the outcomes of our ROI analyses could encourage employers and decision-makers in public health to offer IMIs to employees because there are favourable ROIs, as the IMIs led to increases in productivity (less absenteeism and less presenteeism), in particular via an IMI with adherence-focused guidance. All in all, the findings highlight the importance of promoting awareness and access to this type of intervention for problematic drinking.

Considering that only relatively few health-care professionals actually administer face-to-face brief alcohol interventions, and that only a small proportion of patients who might benefit accept those treatment offers [7], it would be worthwhile to integrate IMIs for problematic drinking into routine practice. However, some risks need to be considered when scaling-up IMIs. There are no guarantees that adherence and (by proxy) effectiveness found in a research context will be maintained if such an intervention is scaled-up in the general population, at the work-place or in primary care. In addition, the high-quality information and communication technology resources (e.g. stable and secure internet connections) may not be available to the same extent outside the research setting.

CONCLUSION

Findings suggest that internet-based interventions to reduce problematic alcohol consumption in employees are both cost-beneficial (i.e. the financial benefits exceed the intervention costs and thus the return on investment is positive) and cost-effective (i.e. the health effects gained present good value for the money invested). However, more studies with longer follow-up periods and standard care as comparator are needed to further substantiate these findings. Given the evidence for the effectiveness, feasibility and acceptance of internet-based interventions to reduce problematic alcohol consumption, their potential cost-effectiveness and scalability might strategically pave the way to alleviate the health and economic burden related to problematic alcohol use in an affordable manner.

DECLARATION OF INTERESTS

C.B., J.F., F.S., H.R. and L.B. have no competing interests to disclose. D.D.E., D.L. and M.B. are stakeholders of the GET.ON Institute, which aims to implement scientific findings related to digital health interventions into routine care. D.D.E. has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern,

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AUTHOR CONTRIBUTIONS

Claudia Buntrock: Conceptualization-Lead, Formal analysis-Lead, Methodology-Lead, Writing-original draft-Lead. **Johanna Freund:** Writing-original draft-Supporting, Writing-review & editing-Supporting. **Filip Smit:** Conceptualization-Supporting, Formal analysis-Supporting, Methodology-Supporting, Supervision-Supporting, Writing-review & editing-Supporting. **Heleen Riper:** Conceptualization-Supporting, Supervision-Supporting, Writing-review & editing-Supporting. **Dirk Lehr:** Conceptualization-Supporting, Funding acquisition-Equal, Project administration-Supporting, Supervision-Supporting, Writing-review & editing-Supporting. **Leif Boß:** Conceptualization-Supporting, Data curation-Lead, Investigation-Lead, Project administration-Lead, Writing-review & editing-Supporting. **Matthias Berking:** Conceptualization-Supporting, Funding acquisition-Equal, Writing-review & editing-Supporting. **David Daniel Ebert:** Conceptualization-Supporting, Funding acquisition-Equal, Supervision-Supporting, Writing-review & editing-Supporting.

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ORCID

Claudia Buntrock https://orcid.org/0000-0002-4974-5455
Johanna Freund https://orcid.org/0000-0002-0038-9330
Filip Smit https://orcid.org/0000-0001-9479-3600
Heleen Riper https://orcid.org/0000-0002-8144-8901
Dirk Lehr https://orcid.org/0000-0002-5560-3605
Leif Boß https://orcid.org/0000-0001-9012-0839
Matthias Berking https://orcid.org/0000-0001-5903-4748
David Daniel Ebert https://orcid.org/0000-0001-6820-0146

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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4.3 Article 3

Authors: Johanna Freund, Alexandra Piotrowski, Leah Buhrmann, Caroline Oehler, Ingrid Titzler, Anna-Lena Netter, Sebastian Potthoff, David Daniel Ebert, Tracy Finch, Juliane Köberlein-Neu, Anne Etzelmüller

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Summary:

Implementing EBPs in healthcare is a complex undertaking. Understanding and improving implementation through implementation theory can help close the gap between evidence and practice. The purpose of this study was to pilot and validate the German NoMAD questionnaire, an instrument derived from Normalization Process Theory, which can be used to investigate the implementation of EBPs. Survey data from four German research projects have been collected and combined (N = 539). Two versions of the G-NoMAD have been independently translated from the original English version by two research groups. A measurement invariance analysis was conducted to compare latent scale structures between the two groups of respondents to both questionnaire versions and various degrees of invariance (configural, metric, scalar) were tested across samples. The theoretical structure of the G-NoMAD was examined by performing a confirmatory factor analysis for three models (a four-factor, a unidimensional, and

a hierarchical model). In a consensus meeting, instructions, items, and scale format of a common G-NoMAD version were finalized. In the measurement invariance analysis, the results showed configural, partial metric, and partial scalar invariance, which indicates that the two questionnaire versions are comparable. The internal consistency of the G-NoMAD ranged from acceptable to good per subscale ($0.79 \leq \alpha \leq 0.85$). In the confirmatory factor analysis, the fit was similar in both the four-factor and the hierarchical model (CFI = 0.97, TLI = 0.96, SRMR = 0.08, RMSEA = 0.10). Therefore, priority should be given to the practical relevance of the hierarchical model due to its overall score and four subscale scores. The findings of this study support the further usage of the G-NoMAD in German implementation settings.

The manuscript was submitted in April 2023 and is currently under review in *Implementation Science Communications,* a multidisciplinary, open-access, and peer-reviewed journal that publishes research to promote the uptake of research evidence into healthcare practices. The preprint is published under a CC BY 4.0 license.

Contribution:

Johanna Freund was the first author of this article. David Ebert obtained funding. Johanna Freund developed the study design and organized monthly meetings in this collaboration with Anne Etzelmüller. She was responsible for the study coordination and data collection at the ImpleMentAll/GET.ON and ImplementIT studies, Anne Etzelmüller, Anna-Lena Netter, Alexandra Piotrowski, and Caroline Oehler at the study coordination of the three remaining studies. Johanna Freund conducted the analyses, supported by Leah Buhrmann. She drafted the manuscript and received feedback from the co-authors.

Validation of the German Normalization Process Theory Measure G-NoMAD: Translation, Adaptation, and Pilot Testing

Johanna Freund (johanna.freund@fau.de)
Friedrich-Alexander-Universität Erlangen-Nürnberg https://orcid.org/0000-0002-0038-9330
Alexandra Piotrowski
Witten/Herdecke University
Leah Bührmann
Northumbria University
Caroline Oehler
German Depression Foundation
Ingrid Titzler
Friedrich-Alexander-Universität Erlangen-Nürnberg https://orcid.org/0000-0002-8963-2324
Anna-Lena Netter
University of Marburg
Sebastian Potthoff
Northumbria University
David Daniel Ebert
Technical University of Munich https://orcid.org/0000-0001-6820-0146
Tracy Finch
Northumbria University
Juliane Köberlein-Neu
University of Wuppertal https://orcid.org/0000-0002-3451-7847
Anne Etzelmüller
Technical University of Munich

Method Article

Keywords: Implementation Science, psychometrics, normalization process theory, NPT, NoMAD, instrument development, implementation outcomes, validation

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Abstract

Background

Implementation of evidence-based healthcare practices (EBPs) is a complex endeavour and is often lagging behind research-informed decision processes. Understanding and systematically improving implementation using implementation theory can help bridge the gap between research findings and practice. This study aims to translate, pilot and validate the German version of the NoMAD questionnaire (G-NoMAD), an instrument derived from Normalization Process Theory, to be used to explore the implementation of EBPs.

Methods

Survey data has been collected in four German research projects and subsequently combined into a validation data set. Two versions of the G-NoMAD existed, independently translated from the original English version by two research groups. A measurement invariance analysis was conducted comparing latent scale structures between groups of respondents to both versions. After determining the baseline model, the questionnaire was tested for different degrees of invariance (configural, metric, scalar, and uniqueness) across samples. A confirmatory factor analysis for three models (a four factor, a unidimensional, and a hierarchical model) was used to examine the theoretical structure of the G-NoMAD. Finally, psychometric results were discussed in a consensus meeting and the final instructions, items, and scale format were agreed.

Results

A total of 539 health care professionals completed the questionnaire. The results of the measurement invariance analysis showed configural, partial metric and partial scalar invariance indicating that the questionnaire versions are comparable. Internal consistency ranged from acceptable to good ($0.79 \leq \alpha \leq 0.85$) per subscale. Both the four factor and the hierarchical model achieved a better fit than the unidimensional model, with indices from acceptable (SRMR = 0.08) to good (CFI = 0.97; TLI = 0.96). However, the RMSEA values were only close to acceptable (four-factor model: $\chi 2164 = 1029.84$, RMSEA = 0.10; hierarchical model: $\chi 2166 = 1073.43$, RMSEA = 0.10).

Conclusions

The G-NoMAD provides a reliable and promising tool to measure the degree of normalization among individuals involved in implementation activities. Since the fit was similar in both the four factor and the hierarchical model, priority should be given to the practical relevance of the hierarchical model which includes a total score and four subscale scores. The findings of this study support the further usage of the G-NoMAD in German implementation settings.

Trial registration

Both the AdAM project (No. NCT03430336, 06/02/2018) and the EU-project ImpleMentAll (No. NCT03652883, 29/08/2018) were registered on ClinicalTrials.gov. The ImplementIT study was registered at the German Clinical Trial Registration (No. DRKS00017078, 18/04/2019). The G-NoMAD validation study was registered at the Open Science Framework (No7u9ab, 17/04/2023).

Contribution to literature

- This study translates, adapts and validates the German version of the NoMAD questionnaire (G-NoMAD), a measurement instrument to assess normalization as an implementation outcome.
- The G-NoMAD provides a reliable and promising tool to measure the degree of normalization among health care professionals and other individuals involved in implementation activities in German implementation settings.

- Pragmatic quantitative measures to assess and monitor implementation processes are powerful tools facilitating implementation of evidence-based healthcare practices.

Introduction

Implementation of evidence-based healthcare practices (EBPs) is a complex endeavour (1) and is often lagging behind research-informed decision processes (2, 3). Successful implementation of EBPs depends on change processes on multiple levels (4) and occurs within specific context (5). Meanwhile, the successful implementation of EBPs is a necessary pre-requisite for optimal and state-of-the-art healthcare provision (6). Therefore, the successful implementation of new practices is a common goal on all contextual levels and across multiple stakeholder groups. Understanding and systematically improving implementation can support closing the gap between research findings and practice. Implementation processes and outcomes can be understood and, subsequently, improved by the use of implementation theory (7). Moreover, such theories can explain change processes in complex systems including a multiple stakeholder perspective (8).

Normalization Process Theory

As a vigorously developed and thoroughly tested and refined medium-range theory, Normalization Process Theory (NPT) (8–10) provides a basis for understanding relevant processes and work that needs to be done to implement an intervention (9). NPT can be used to understand the dynamics of implementing new practices or interventions in routine health care (9). The theory postulates that "practices become routinely embedded in social contexts ('normalized') as the result of people working, individually and collectively, to enact them" (Finch *et al.*, 2013, p. 2). NPT posits of four mechanisms – *coherence* (CO), *cognitive participation* (CP), *collective action* (CA), and *reflexive monitoring* (RM) – which promote or inhibit the implementation of complex interventions into routine health care systems (8–11), see details in Table 1. The theory has been widely used for qualitative analyses of implementation activities in a diverse range of health care contexts (8). The four mechanisms or core constructs of NPT have been found to be stable across contexts, EBPs, and stakeholders or users (12). As those constructs can also be used to investigate the potential of practices to become part of daily work (13), i.e., to normalize, NPT is a valuable basis to inform implementation outcome measurement.

Table 1
NPT mechanisms following Finch et al. (2018).

Construct	Definition: The process which promotes or inhibits...
Coherence	... the sense-making of an innovation to its users. These mechanisms are activated by participants' investments in meaning.
Cognitive participation	... users' engagement and legitimisation of a practice. These processes are fuelled by participants' investments of commitment.
Collective action	... the enactment of an innovation by its users. These processes are energized by participants' investments of endeavour.
Reflexive monitoring	... users' understanding of the implications of a practice. These processes are stimulated by participants' investments in assessment and valuation.

Validated instruments and the NoMAD

Pragmatic quantitative measures to reliably assess and monitor implementation processes are powerful tools facilitating the implementation of EBP (14). Specifically, the valid assessment and evaluation of implementation outcomes separate from the observed effect of an EBP can advance the understanding of underlying mechanisms of implementation (6). The

use of well-developed implementation outcome measures can also be helpful, if EBPs do not show the anticipated effect and the interest for an in-depth analysis of implementation process' quality grows.

Table 1. *NPT mechanisms following Finch et al. (2018).*

[Please insert Table 1 here]

NoMAD questionnaire

The "Normalization Process Theory Measure" NoMAD (11) is a questionnaire based on NPT to assess and monitor the implementation process. The development of the questionnaire which included consensus workshops, cognitive interviews, appraisal of item quality, and expert rating is described in detail elsewhere (10, 15). Following the initial development of the NoMAD, Finch et al. (11) conducted initial psychometric tests to establish its reliability and validity. Their results are based on 413 surveys, submitted by staff involved in one of six implementation projects across a range of interventions in different settings. A Confirmatory Factor Analysis (CFA) supported the theoretical structure of the four NPT constructs and a test of internal consistency supported the use of the 20 items to measure a general construct of normalization ($\alpha = 0.89$) as well as a measure of four related constructs ($\alpha = 0.65–0.81$). The NoMAD stands out among other measures in the field, whose psychometric properties are often rated as poor to moderate or lacking information on psychometric properties (16).

The questionnaire has been used and validated again in different languages and settings. A Dutch translation of the NoMAD questionnaire was validated within a sample of 262 healthcare professionals who were in the early stages of adopting e-mental health in their occupational tasks (17). The results showed an acceptable internal consistency ($0.62 \geq$ Cronbach's alpha ≤ 0.85) and the theorized four-factor structure could be mostly confirmed. To enable easier interpretation, they propose a hierarchical model that adds a second-level factor to account for the correlation among the four first-level factors. While this approach yielded marginally inferior results with regard to the model fit, it could be helpful in the practical application of the NoMAD as it enables researchers to also use a total score that combines the four NPT constructs.

In addition, the NoMAD has been translated and validated in Swedish. After exclusion of three items, the four-factor model could be successfully replicated and the four factors yielded good internal consistency ($0.78 \geq$ Cronbach's alpha ≤ 0.83) (18). Further NoMAD translations into Brazilian Portuguese (19) and Chinese (20) demonstrated good internal consistency for all constructs, confirming that translations into other languages are possible while maintaining the psychometric properties.

Research aim

The purpose of this study was to translate, adapt and validate the German version of the NoMAD questionnaire (G-NoMAD), a measurement instrument to assess normalization as an implementation outcome, in different German health care settings across four projects. Our aims were thus to: (1) assess the internal consistency and the relationships between NPT constructs, and (2) confirm a four factor structure with acceptable model fit according to the theoretical development of the measure along the four NPT concepts.

Methods

Research projects, data collection, and recruitment

Data were collected in four research projects across five organisations, and then combined to one validation data set. Of the four projects, one was conducted in the primary care setting (*AdAM*) and three in the context of mental health care (*iFightDepression Marburg, ImpleMentAll, and ImplementIT*). Data was collected through an online-survey (*ImpleMentAll,*

ImplementIT) or a survey via paper-pencil (*AdAM, iFightDepression Marburg*). Demographics and background information on the setting were captured to complement the NoMAD data.

Organisation 1: AdAM

In AdAM [*Anwendung digital-gestütztes Arzneimitteltherapie- und Versorgungs-Management*], a clinical decision support system (CDSS) addressing the medication management of patients with polypharmacy was implemented in primary care practices in Germany (21). The primary analysis was a stepped-wedge cluster randomized controlled trial (C-RCT) to examine the effectiveness of the intervention regarding patient-related outcomes (hospitality and death). The additional survey aimed to gather standardized information on the resources and characteristics of the primary care practices and how implementation was accomplished. General practitioners (GPs) from the C-RCT practices were asked to participate in the survey, after all practices had switched to the intervention group. Data were collected from September to December 2020.

Organisation 2: iFightDepression Marburg

In the "iFightDepression Marburg" project, the implementation of the internet-based self-management tool "iFightDepression (iFD; https://tool.ifightdepression.com/) was monitored. The tool is rooted in the principles of Cognitive Behavioural Therapy (22, 23) and can be applied as a supplement to regular depression treatment or to bridge the waiting period. The tool includes six weekly online workshops about specific topics regarding depressive symptoms, including written information, worksheets, exercises, and a mood rating (24). GPs and psychotherapists, who identified patients and provided access to the tool were eligible to participate in the study. The survey was conducted after six onetime information sessions on the iFD tool. Data collection took place from February to November 2018.

Organisations 3 and 4: ImpleMentAll project

The German institutions German Depression Foundation (DF) and GET.ON institute (www.geton-institut.de/www.hellobetter.de) were local implementation sites within the EU-project "ImpleMentAll" (www.implementall.eu) (25, 26). The aim of this project was to examine the effectiveness of tailored implementation (i.e., the ItFits-toolkit) compared to usual implementation of internet-based interventions (IBIs) based on Cognitive Behavioural Therapy in routine care in twelve sites from nine countries. Data from the two German trial sites at wave 2 (September to November 2018) were used for this analysis.

Organisation 3: German Depression Foundation. A nationwide implementation of iFD (see Organisation 2) was focused. In press releases, face-to-face and online training as well as through social media activities DF tried to inform guides and patients across Germany about iFD. Study participants were iFD guides who provided access to the tool in routine care as well as staff members of DF involved in the technical support and dissemination of iFD.

Organisation 4: GET.ON institute. Seven guided IBIs were implemented by the social insurance for agriculture, forestry and horticulture (SVLFG, www.svlfg.de) to prevent depression among their insured members in selected pilot areas as part of the project "With us in balance" (27). Staff involved in the counselling on the preventive services (e.g., field workers, in-house staff and call centre agents) were recruited via kick-off events and/or supervisors of the respective occupational group.

Organisation 5: ImplementIT

As part of the German national depression prevention program for farmers, gardeners and foresters, the SVLFG implemented guided, tailored IBIs and a personalised tele-based coaching for their insured members according to a stepwise rollout (27). The IBIs were provided by the GET.ON institute (www.geton-institut.de/www.hellobetter.de), the personalised tele-based coaching by the company IVPNetworks (www.ivpnetworks.de). Data was collected from April to June 2019.

Original NoMAD questionnaire

The original NoMAD in English language consists of three sections: section A assesses general information about the participant, section B includes three general items on the intervention answered on an 11-point Likert scale ranging from 0 to 10 with descriptive anchors at 0, 5 and 10 ((1)"How familiar does [the intervention] feel for you?"; (2) "Do you feel that [the intervention] is currently a normal part of your work?"; (3) "Do you feel that [the intervention] will become a normal part of your work?"). Section C) contains 20 items representing the four key constructs of NPT: *coherence* (4 items), *cognitive participation* (4 items), *collective action* (7 items), and *reflexive monitoring* (5 items). Section C items are answered on a 5-point Likert scale (Option A: 1 = strongly agree; 5 = strongly disagree) or, alternatively, as not relevant with three different answer options (Option B: "not relevant to my role", "not relevant at this stage", or "not relevant to the intervention"). Furthermore, the NoMAD shows a clear factor structure and a strong internal consistency supporting a measure to assess normalization in total (20 items, Cronbach's α = 0.89) as well as for the four subscales (Cronbach's α ranging from 0.65 to 0.81) (11).

Translation and adaptation process

Two slightly different versions of the German NoMAD existed, independently translated from the original English version (11) by two research groups (21, 25).

AdAM version. A German translation of the NoMAD was developed within three professional forward and backward translations, evaluated separately by three independent researchers using a scoring system. Indifferent points were then discussed within the research team. The resulting first NoMAD draft was reviewed by the project management team. In this step, project-specific adjustments were made to the wording of individual items without changing their meaning. This was followed by a pre-test with physicians, researchers, and members of family physician associations with the opportunity to provide feedback on understanding and wording. The final version was used in a written survey conducted as part of the AdAM project (21).

ImpleMentAll version. Another German translation of the NoMAD was developed in the ImpleMentAll study (25), and further used in two German implementation studies (27, 28). According to the translation protocol (29), this was done by using a forward-backward translation process by independent translators where discrepancies between the original English version and the back translated English version were analysed in a structured way and discussed with the original author Tracy Finch. Changes were then integrated in the target language version. All changes have been reported and explained.

Version comparisons. Despite different versions, the two translations largely match (see Additional file 1). While the ImpleMentAll version tended to use more technical and scientific terms and was formulated in a more general way, the language style used in the AdAM version is more colloquial and adapted to the specific context. The ImpleMentAll version was intended for use in various study sites and the terms were therefore formulated more generally. In both questionnaire versions, items are answered on a 5-point Likert scale (1 = strongly agree; 5 = strongly disagree) and, unlike the original questionnaire, do not include 'not relevant' response options.

Data analysis

All analyses were conducted using the statistical open-source program R (R 3.6.0 GUI 1.70 El Capitan build, and RStudio Inc., 2018, Version 1.1.463) with packages 'psych' (1.8.12) and 'lavaan' (0.6-5).

Descriptive statistics

Response to the questionnaire was analysed including the total number of responders, corresponding response rates, the total completion of NoMAD items (item 1–20), and the basic completion rate (i.e., all responders that completed one or more items). Respondents' demographics were calculated including age, gender, occupation, and work experience.

Mean scale scores were calculated for each NoMAD construct (coherence, cognitive participation, collective action, and reflexive monitoring) per study site. Internal consistency was assessed by computing Cronbach's alpha for each subscale. Cronbach's alpha was interpreted as acceptable if $0.7 \geq \alpha < 0.8$, good if $0.8 \geq \alpha < 0.9$, and as excellent if $\alpha \geq 0.9$ (30). Correlations were calculated between the NoMAD constructs for the pooled sample.

Confirmatory factor analysis

A CFA was performed to verify the factor structure of the NoMAD questionnaire. As theory suggests, the NoMAD has a four-factor structure including the factors coherence, cognitive participation, collective action, reflexive monitoring. Accordingly, the four-factor model was used in the CFA. Additionally, a unidimensional as well as hierarchical model were computed. The hierarchical model represents the idea of a global NoMAD score (i.e., a total normalization score) consisting of four sub scores. For all models, the data was fitted on the predefined model structure. For evaluating model fit, the fit indices Comparative Fit Index (CFI), Tucker Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA) and Standardized Root Mean Square Residual (SRMR) were interpreted. Conservative cut-off scores for acceptable fit were applied as suggested by literature (31–34). For evaluating the factor loadings, a cut-off value of 0.4 was chosen, where values below 0.4 indicated a low loading of the item on the latent construct (35) and items loading below 0.2 were considered insufficient.

Measurement invariance testing

We investigated whether the NoMAD instrument is measurement invariant across two samples representing data from respondents to two different versions of the German translation of the NoMAD. The analysis followed the 4-step approach of conducting measurement invariance testing with ordinal survey data as described by Bowen & Masa (2015). First, a CFA was performed aiming at estimating a baseline model in both groups (see above). Given the ordinal nature of the data, the robust option of the diagonally weighted least square (WLSMV) estimator was used to examine the expected dimensionality of the instrument scale (37). The Chi-Square test statistic ($\chi 2$) was reported, but due to its sensitivity to sample size and violation of the normality assumption (38) descriptive model fit indices were used to evaluate the model fit. The CFI, TLI, RMSEA, SRMR are reported and interpreted. After determining the baseline model, the questionnaire was tested for different degrees of invariance (configural, metric, scalar, and uniqueness*)* across samples. Parameters of the models (i.e., factor loadings, thresholds, and residuals) were progressively constrained across groups to investigate to what degree the instrument can be interpreted as invariant between groups (39). At *configural* invariance level, the form of the factor model was compared across groups (40). No parameters are restricted between groups beyond fixing the first loading of each factor to 1 as a referent indicator. If the unconstrained multiple group model meets fit criteria (41), the analysis continues to test the factor structure for *metric* invariance. Scales with *metric* invariance have statistically equivalent factor loadings across groups (40). All factor loadings are constrained to be equal and the resulting model fit is compared to the fit of the *configural* model. If the difference between the model fit is not significant ($\Delta CFI \leq 0.1$) (42), the testing will proceed to explore *scalar* invariance. If the difference between the models is significant ($\Delta CFI \leq 0.1$), the most variant parameters will be set free. If the number of freed parameters is below 20% of the total number of parameters, the testing is continued (40). In the next step, factor loadings as well as thresholds are constrained across groups. The same

criteria - i.e., ΔCFI ≤ 0.1 (42) and the 20% rule (40) - as applied in the previous steps are evaluated. *Scalar* invariance is generally considered the minimum level of invariance to be able to interpret scores equally across groups (36). *Uniqueness* invariance is investigated by constraining all residual variances across the groups. However, this level of invariance is usually not reached – and not deemed necessary - within measurement invariance testing (40).

Consensus meeting

A four-hour consensus meeting was held (1) to review the psychometric results of the questionnaire, (2) to review the two different versions of the German translation of the NoMAD, (3) to consent the final scale format, (4) to discuss instructions and (5) to decide whether the option "not applicable" should be used for the German NoMAD version as well, which would be in line with the original questionnaire. Researchers responsible for the survey instruments of each of the four projects were invited via email to participate. Due to the COVID-19 pandemic, the consensus meeting was held online. In total, ten researchers (AE, AP, CO, CS, IT, JF, JG, JK, LB, and SP) participated. Following the Nominal Group Technique (NGT), which is a structured group discussion led by one or more moderators (here: AE and AP), participant reflections on the above mentioned five topics were captured and discussions were provided. More particularly, after a brief introduction of each topic, participants were given time during which they listed their responses to a topic. Next, participants were asked to share their thoughts. Statements were documented in a condensed form and discussed. Finally, participants were asked to vote their preferred option for a topic discussed. A consented version was applied and documented for final approval by an independent lector after the consensus meeting. All sub-steps of item adaptation including discussions and rationale for decisions were documented (see Additional file 1).

Results

Response

Data from four projects across five organisations were used for the analysis (see Table 2). The mean response rate is 55.4% (539 respondents of 973 invited participants). A total of 539 surveys were used for the analysis.

Table 2
Response rates and item completion per organisation.

Organisation	Invited	Responded (≥ 1 NoMAD item)	Response rate	Total completion NoMAD items 1–20	Completion rate[a]
Organisation 1: AdAM	750	328	43.7%	292	96.7%
Organisation 2: iFD Marburg	78	77	98.7%	69	99.1%
Organisation 3: DF	21	16	76.2%	16	100%
Organisation 4: GET.ON	49	46	93.9%	46	100%
Organisation 5: ImplementIT	75	72	96.0%	72	100%

Notes. [a]Completion rate was assessed among responders (≥ 1 NoMAD item).

iFD: iFightDepression; DF: Depression Foundation

Table 2. *Response rates and item completion per organisation.*

[Please insert Table 2 here]

Sample

Table 3 provides an overview of participant characteristics per individual organisation. Most participants were between 51–60 years old (n = 237, 44.0%), male (n = 330, 61.2%), and worked as practice owners (n = 309, 57.3%) for a period of more than ten years in their current organisation (n = 333, 61.8%).

Table 3

Description of study participants.

Variable	Organisation 1: AdAM (n = 328)	Organisation 2: Marburg (n = 77)	Organisation 3: DF (n = 16)	Organisation 4: GET.ON (n = 46)	Organisation 5: ImplementIT (n = 72)	Full sample (n = 539)
Age, n (%)	0 (0.0)	17 (21.8)	4 (25.0)	1 (2.2)	2 (2.8)	24 (4.5)
Under 30 years	11 (3.4)	20 (25.6)	4 (19.1)	10 (21.7)	10 (13.9)	55 (10.2)
30–40 years	67 (20.2)	13 (16.9)	4 (25.0)	12 (26.1)	24 (33.3)	120 (22.3)
41–50 years	165 (50.3)	17 (21.8)	3 (18.8)	21 (45.6)	31 (43.1)	237 (44.0)
51–60 years	82 (25.0)	10 (12.8)	1 (6.3)	2 (4.35)	3 (4.2)	98 (18.2)
Over 60 years	3 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	5 (1.0)
NA						
Gender						
Male	203 (61.9)	37 (47.4)	4 (25.0)	33 (71.7)	53 (73.6)	330 (61.2)
Female, n (%)	125 (38.1)	38 (49.4)	12 (75.0)	13 (28.3)	19 (26.4)	207 (38.4)
Diverse	0 (0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NA	0 (0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
Occupation						
Practice owner	309 (93.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	309 (57.3)
Referrer	0 (0.0)	1 (1.3)	1 (6.3)	29 (63.0)	71 (98.6)	102 (18.9)
General practitioner	0 (0.0)	7 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.3)
Administrative employee	0 (0.0)	0 (0.0)	4 (25.0)	14 (28.6)	0 (0.0)	18 (3.3)
Psychologist, e-coach, psychotherapist	0 (0.0)	62 (80.5)	11 (68.8)	3 (6.1)	0 (0.0)	76 (14.1)
Employed doctor in training	14 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	14 (2.6)
Other health care worker	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.4)	2 (0.4)
Nurse	0 (0.0)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)

Variable	Organisation 1: AdAM (n = 328)	Organisation 2: Marburg (n = 77)	Organisation 3: DF (n = 16)	Organisation 4: GET.ON (n = 46)	Organisation 5: ImplementIT (n = 72)	Full sample (n = 539)
Employed (specialist) doctor	3 (0.9)	3 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.1)
Other practice staff	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
Support/information and communication technology (ICT) worker	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
Other employee	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
NA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Work duration in the organisation						
Less than one year	0 (0.0)	17 (22.1)	2 (12.5)	4 (8.7)	0 (0.0)	23 (4.3)
1–2 years	4 (1.2)	12 (15.6)	3 (18.8)	7 (15.2)	1 (1.4)	27 (5.0)
3–5 years	29 (8.8)	11 (14.3)	4 (25.0)	8 (17.4)	1 (1.4)	53 (9.8)
6–10 years	66 (20.1)	11 (14.3)	2 (12.5)	15 (32.6)	8 (11.1)	102 (18.9)
More than 10 years	229 (69.8)	25 (32.5)	5 (31.3)	12 (26.1)	62 (86.1)	333 (61.8)
NA	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

Table 3. *Description of study participants.*

[Please insert Table 3 here]

Measurement invariance

Two CFA were conducted for group 1 “AdAM version” and group 2 “ImpleMentAll version”, separately. Slightly better fit indices for the four-factor model are shown in group 1 (χ^2 = 525.754; df = 164, CFI = 0.978; TLI = 0.974; RMSEA = 0.082; SRMR = 0.068) compared to group 2 (χ^2 = 453.500; df = 164, CFI = 0.970; TLI = 0.965; RMSEA = 0.092; SRMR = 0.965). A measurement invariance analysis was performed to show whether the different questionnaire versions capture the same constructs and are therefore comparable.

Fit statistics of all invariance levels are illustrated in Table 4. First, we tested for configural invariance (Model 1, M1). The fit indices met our pre-specified criteria indicating that the two groups share the same configural model. Second, we tested for metric invariance based on a model with constrained factor loadings across the two groups (M2). A comparison of M1 and M2 showed a change of the CFI fit of more than 0.01 and thus, M2 was rejected. However, after freeing the factor

loadings for the second and third item within the factor collective action (CA.2, CA.3) since these thresholds differed between the groups, a partial metric invariance model (M2a) was tested. Due to a change in the CFI score below 0.01, M2a was accepted. Third, scalar invariance was investigated based on a model with constrained factor loadings and thresholds across the two groups (M3). A comparison of M2a and M3 showed again a change of the CFI fit of more than 0.01 and thus, M3 was rejected. After freeing the factor loadings for items "CA.2" and "CA.3" as well as the thresholds "RM.4|t2" and "CO.4|t3", a partial scalar invariance model (M3a) was tested indicating an acceptable model fit. Since the results of measurement invariance indicate that the questionnaire versions are comparable, the results are reported jointly for both questionnaire versions in the following.

Table 4

Results of the Measurement Invariance Analysis.

Model	χ^2	df	CFI	TLI	RMSEA	SRMR	$\Delta\chi^2$	Δ CFI	Model comparison	Decision
M1: Configural invariance	977.413	328	0.975	0.971	0.086	0.075	–	–	–	Accept
M2: Metric invariance	1363.908	344	0.960	0.956	0.105	0.105	386.495	0.015	M1	Reject
M2a: Partial metric invariance[a]	1163.615	342	0.968	0.964	0.095	0.095	186.202	0.007	M1	Accept
M3: Scalar invariance	1491.756	398	0.957	0.959	0.101	0.077	328.141	0.011	M2a	Reject
M3a: Partial scalar invariance[b]	1429.600	396	0.960	0.961	0.099	0.077	265.985	0.008	M2a	Accept

Notes. CFI: Comparative Fit Index; TLI: Tucker Lewis Index; RMSEA: Root Mean Square Error of Approximation; SRMR: Standardized Root Mean Square Residual.

[a] *freed: factor loadings for CA.2 and CA.3*

[b] *freed: factor loadings for CA.2 and CA.3 and thresholds RM.4|t2 and CO.4|t3*

Table 4. *Results of the Measurement Invariance Analysis.*

[Please insert Table 4 here]

Scale scores

The mean scale scores per organisation are presented in Table 5. In the pooled sample, item responses in the NPT constructs *coherence* and *cognitive participation* seem to have a tendency toward agreement, while *collective action* and *reflexive monitoring* rather received neutral answers. In addition, the responses to items vary the least for *collective action* and the most for *cognitive participation.*

Table 5
NoMAD-G mean scale scores per organisation.

	Organisation					Full sample
Scale	1	2	3	4	5	
N	328	328	16	46	72	539
CO	3.35 (0.98)	2.67 (0.53)	3.70 (0.70)	4.00 (0.72)	3.75 (0.68)	3.52 (0.92)
CP	3.44 (1.01)	2.57 (0.71)	3.98 (0.99)	4.25 (0.67)	4.00 (0.60)	3.48 (1.01)
CA	3.16 (0.73)	2.59 (0.49)	3.65 (0.69)	3.78 (0.70)	3.72 (0.53)	3.23 (0.75)
RM	3.07 (0.88)	2.60 (0.40)	3.86 (0.70)	3.56 (0.71)	3.55 (0.61)	3.14 (0.84)
Notes. CO: Coherence; CP: Cognitive participation; CA: Collective action; RM: Reflexive monitoring.						

Table 5. *NoMAD-G mean scale scores per organisation.*

[Please insert Table 5 here]

Internal consistency

Cronbach's alpha was computed for each subscale. The internal consistency ranges from "acceptable" for *collective action* and *reflexive monitoring* (each α = 0.79) to "good" for *coherence* and *cognitive participation* (each α = 0.85). Overall, the NoMAD scale comprising all 20 items is highly reliable (α = 0.93).

Relationships between NPT constructs

All correlations between the four NPT construct measures are shown in Table 6. The highest correlation between the NoMAD constructs could be identified for *coherence* and *cognitive participation* (r = .76), the lowest for *coherence* and *collective action* (r = .64). This indicates a high level of correlation for summated NoMAD scores (43).

Table 6
Correlations between NoMAD constructs (factors).

Scale	Coherence	Cognitive participation	Collective action	Reflexive monitoring
Coherence	1			
Cognitive participation	.76	1		
Collective action	.64	.72	1	
Reflexive monitoring	.69	.71	.76	1

Table 6. *Correlations between NoMAD constructs (factors).*

[Please insert Table 6 here]

Factor structure

The CFA results and related fit indices are presented in Table 7, including the first order four-factor model that defines normalization as four correlated constructs, the first order unidimensional model, and the hierarchical model. In the latter it is assumed that a second-level factor explains the correlations between the four first-level factors. Both the four factor model and the hierarchical model achieved a better fit than the unidimensional model with indices from acceptable

(SRMR = 0.08) to good (CFI = 0.97; TLI = 0.96). However, the RMSEA value of both models is only close to acceptable (four-factor model: χ2164 = 1029.84, RMSEA = 0.10; hierarchical model: χ2166 = 1073.43, RMSEA = 0.10). Since the fit is similar in both models, priority should be given to the practical relevance of the hierarchical model which includes a total score and subscale scores.

Table 7
Confirmatory factor analysis (CFA). Modified models are included in the CFA to explore potential improvements.

Model	χ^2	df	CFI	TLI	RMSEA	SRMR
Four-factor	1029.84	164	0.97	0.96	0.10	0.08
Unidimensional	1357.95	170	0.96	0.95	0.11	0.09
Hierarchical	1073.43	166	0.97	0.96	0.10	0.08
Hierarchical modified 1[a]	972.17	148	0.97	0.97	0.10	0.08
Notes. CFI: Comparative Fit Index; TLI: Tucker Lewis Index; RMSEA: Root Mean Square Error of Approximation; SRMR: Standardized Root Mean Square Residual.						
[a]Hierarchical model without item „RM1“						

Table 7. C*onfirmatory factor analysis (CFA). Modified models are included in the CFA to explore potential improvements.*

[Please insert Table 7 here]

Potential model improvements

Potential model improvements were investigated for the hierarchical model. Based on the factor loadings in the CFA, it can be assumed that item RM.1 (“*I am aware of reports about the effects of [the intervention].*”) has a weak relationship with the superordinate construct RM (λ = 0.12). Thus, the item RM.1 was removed and the modified four-factor model showed slightly better fit than the previous model (see Table 7).

Consensus version of the G-NoMAD

G-NoMAD instrument. A consensus version was produced, presenting the final German version of the NoMAD, termed G-NoMAD (see Additional file 2). Wording of the response scale was consented and the accompanying instructions were adapted. Finally, the consensus group agreed on the renewed inclusion of the option “not applicable”, which, contrary to the original NoMAD version, was not previously applied for in either German questionnaire versions. This decision was motivated by methodological discussions on advantages and disadvantages of this answer option (44–46) and the results showing that a tendency toward the middle (if an item was not applicable, the middle/neutral position “3” should still be chosen) was evident within the analysed data, which may bias interpretation.

G-NoMAD manual. In order to be able to use the G-NoMAD for different implementation contexts, we developed recommendations for its application and how to adapt the German instruction text to the respective study (see Additional file 3).

Discussion

The “Normalization Process Theory Measure” questionnaire (NoMAD) is a theoretically derived instrument for measuring factors relevant to the implementation of interventions that transform the existing work practices of individuals (11, 15). Since its development, the NoMAD has been translated from the English original and used in multiple languages across different cuntries, settings, and studies (17–20). The current study aimed to review several German translations and pilot

applications, to validate the instrument and to publish an official German-language version of the NoMAD questionnaire for research and practice purposes.

Main findings

The G-NoMAD instrument showed good psychometric properties to capture perceptions of individuals involved in implementation activities in different German speaking intervention studies and settings. Tests of internal consistency confirmed the validity of an overall measure of 'normalization' (20 items, α = 0.93), as well as the four separate NPT constructs coherence, cognitive participation, collective action, and reflexive monitoring (α = 0.79–0.85). Correlations between the four NPT construct measures can be considered as high (ranging from r = .64-.76). Using CFA, the hypothesized four-factor structure was largely confirmed, as all fit indices (with the exception of the RMSEA value) were found to be acceptable to good. Since the fit to the observed data was similar in the four-factor model and the hierarchical model, priority should be given to the practical relevance of the hierarchical model for users in research and practice, which includes a total score and four subscale scores.

Comparison with previous literature

In line with our findings, results from the original English NoMAD validation study (11) showed a clear factor structure and a strong internal consistency. The internal consistency and the correlations between construct measures were even slightly higher in the present study (Cronbach's α = 0.79–0.85; construct correlations r = 0.64–0.76) compared to the validation results of the original measure (Cronbach's α = 0.65–0.81; construct correlations r = 0.49–0.68) (11).

The current version of the NoMAD compares also favourably with regard to internal consistency and construct correlation against other translations of the measure into Dutch (17), Swedish (18), Brazilian Portuguese (19), and Chinese (20). In the Dutch NoMAD validation study (17), the four-factor model showed the best fit with the observed data. However, in this study, both the four-factor model and the hierarchical model achieved a similar fit.

While most fit indices in this study can be classified as acceptable (SRMR = 0.08) to good (CFI = 0.97; TLI = 0.96), the RMSEA value of both models was only close to acceptable (RMSEA = 0.10). In contrast to our study, the results of the English (11) and Chinese validation study showed acceptable psychometric properties across all fit indices (English version: CFI = 0.95, RMSEA = 0.08, SRMR = 0.03, TLI = 0.93; Chinese version: CFI = 0.92, RMSEA = 0.01, SRMR = 0.05, TLI = 0.91). In the Dutch validation study (17), all fit indices were outside the desired thresholds (CFI = 0.90, RMSEA = 0.12, SRMR = 0.11, TLI = 0.88), whereas in our study this only applied to the RMSEA value. It should be noted that there are only recommendations for model evaluation and no established guidelines for what constitutes an appropriate fit (38). Moreover, it is possible for a model to fit the data even though one or more measures of fit indicate a poor fit (38). In view of this, it can be considered a strength of the present study that, despite the different interventions and settings, largely good psychometric values could be achieved.

Limitations

First, two slightly different versions of the German NoMAD have been used to validate the questionnaire. While the ImpleMentAll version was formulated in a more general way to consider superordinate contexts of 12 different sites, the language style of the AdAM version is more colloquial and adapted to the specific context. Although the measurement invariance analysis confirmed that the two versions are comparable, this fact limits the validity of the results. At the same time, the results of this study provide a common basis towards a unified German NoMAD questionnaire for implementation research and practice in which the study results as well as the experiences from both research groups were taken into account.

Second, unlike the original English NoMAD (11, 15), participants in all involved projects were instructed that if an item was not applicable, the middle/neutral position “3” should still be chosen. This could have led to the confounding of answers with different meanings (e.g., question was not understood, skipped, interpreted as not applicable, response was refused or remained unanswered due to ignorance) and the bias of the overall results may be large (45). In the case of compulsory items, the checkbox might have been only ticked to move on to the next item and to be able to continue with the questionnaire, which could lead to an inflationary use of the “3”. This tendency toward the middle is evident in the ImpleMentAll study across 12 trial sites (mean scores in the range from 3.1 to 4.3, with the majority scattering between 3.5 to 3.7) (26) as well as in this G-NoMAD validation data (mean scores in the range from 2.6 to 4.0 per organisation, with the majority scattering between 3.1 to 3.5). Thus, in our suggested G-NoMAD version (see Additional files 2 and 3), we recommend in line with the original version of the NoMAD (11, 15) the use of the not applicable option for the items of the questionnaire and to statistically take this into account as a "missing item". We consider this fall back category useful to address those possible responders who may not have the ability or characteristic to answer a question, or to whom certain questions do not apply (e.g., persons as sole practitioners who cannot provide information on organisational or team-related aspects; persons who are not involved in the entire implementation process, but only in peripheral areas). This fall back category also provides a usable data point, which gives information about the non-processing of the task or non-answering of a question.

Third, as a further limitation it must be deducted that the use of NoMAD in a study setting may produce different results than in a routine setting without an accompanying evaluation. Fourth, NPT was developed using qualitative research of social processes and actions at an individual and collective level. NoMAD provides a tool to statistically explore the importance of NPT constructs relevant to achieving and maintaining practice change. However, to fully understand people’s perceptions of the complexities of implementation work it is likely to require a combination of quantitative and qualitative research methods.

Strengths

The used translation methodology, including forward and backward translation and the involvement of experts in the translation process, is a recommended method for translating instruments (47). Furthermore, a large sample size (N = 539) across five study sites was reached in this study providing a sufficient data basis for the psychometric evaluation of the G-NoMAD. Across all organisations, high response and completion rates have been reported indicating a high acceptance and usability of the questionnaire among participants.

The authors of the original NoMAD described the tool as a ‘pragmatic measure’ of implementation, encouraging users to tailor it to the demands of their respective implementation projects (11). The current study confirms the flexibility of the measure with regard to its application across a variety of implementation settings and projects, including a variety of interventions, stakeholders and implementation objectives.

Future research

Even if the results of this study support the broad usage of the G-NoMAD, the modified translation of the G-NoMAD should be further evaluated with regard to its psychometric properties. Additionally, the psychometric sensitivity of NoMAD to longitudinal change (26) and the verification of NoMAD with other instruments measuring implementation outcomes (longitudinally) are yet to be explored. Additionally, the think-aloud-method can be used to investigate user experience and thoughts when answering the questionnaire to understand deeper processes.

Results of the AdAM project indicate that the NoMAD questionnaire seems equally feasible/applicable for large organisations as well as individual settings (e.g. small physician practices with only one practice owner) in which implementation of EBPs is primarily done by one person and collective implementation activities are less obviously occurring. However, this issue should be further explored in future research.

Practical implications and use of the G-NoMAD

In order to be able to use the G-NoMAD for different implementation contexts, we provide detailed instructions for how to modify the questionnaire for different implementation contexts to improve its usability. We invite to adapt the instrument according to the instruction manual to increase the ease of use in routine settings and to enable higher external validity.

Conclusions

G-NoMAD provides a reliable and promising tool to measure the degree of normalization among health care professionals and other individuals involved in implementation activities. The findings of this study support the further usage of the G-NoMAD in German-language implementation settings. The measure can be used to statistically explore NPT mechanisms involved in achieving and maintaining practice change. It can also be used alongside qualitative studies. The practical relevance of the hierarchical model has to be emphasized, which includes a total 'normalization' score and four subscale scores.

In our various research projects, we have recognized the importance of such a measurement tool. Through the professional exchange over several projects and the possibility of a validation project, we are glad that we can now provide researchers and practitioners with a basis for further implementation and its evaluation.

The research and validation team with expertise in implementation science and practice is happy to be available to answer any questions at the following email address: german.nomad2022@gmail.com

Abbreviations

AdAM
Anwendung digital-gestütztes Arzneimitteltherapie- und Versorgungs-Management
CA
Collective action
CO
Coherence
CFA
Confirmatory Factor Analysis
CFI
Comparative Fit Index
CP
Cognitive participation
C-RCT
Cluster randomized controlled trial
DF
Depression Foundation
EBP
Evidence-based healthcare practice
G-NoMAD
German version of the NoMAD questionnaire
GP
General practitioner
ICT
Information and communication technology

iFD
iFight Depression
NGT
Nominal Group Technique
NoMAD
Normalization Process Theory Measure
NPT
Normalization Process Theory
RM
Reflexive monitoring
RMSEA
Root Mean Square Error of Approximation
SRMR
Standardized Root Mean Square Residual
SVLFG
Social insurance for agriculture, forestry and horticulture
TLI
Tucker Lewis Index
WLSMV
Diagonally weighted least squares

Declarations

Ethics approval and consent to participate

Written informed consent was obtained from all participants and stored at the respective organisation. AdAM was approved by the Ethics Commission of the North-Rhine Medical Association (approval date 26.07.2017, approval no. 2017184). Data collection by DF within the scope of the ImpleMentAll Project was approved by the Ethics Committee of the Saxonian state chamber of medicine (Sächsische Landesärztekammer) on 20.11.2018 (ref.: EK-BR-88/18-1). The Ethics Committee of the Friedrich-Alexander-Universität Erlangen-Nürnberg confirmed on the 30.05.2018 that no ethical approval is mandatory for the GET.ON institute within the ImpleMentAll Project. The ImplementIT study was approved by the Ethics Committee of the Friedrich-Alexander-Universität Erlangen-Nürnberg on 12.02.2019.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are available from Universität Erlangen-Nürnberg but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of all involved projects/institutions.

Competing interests

IT reports to have received fees for lectures/workshops in the e-mental-health context from training institutes and congresses for psychotherapists.

DDE is stakeholder of the GET.ON Institute/HelloBetter, which aims to implement scientific findings related to digital health interventions into routine care. DDE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy.

AE is employed by the GET.ON Institute/HelloBetter as research coordinator.

AN, AP, CO, JF, JK, LB, SP, and TF declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Authors' contributions

DDE obtained funding for the ImpleMentALL (trial site GET.ON) and ImplementIT study. AE and JF developed the study design. AE, LB, IT, JF, SP, and TF were involved in the translation process of the ImpleMentAll questionnaire version, AP and JK in the translation process of the AdAM questionnaire version. AE, AN, AP, CO, JF and IT were responsible for recruitment of participants, coordination and collection of data at the respective study site. JF was responsible for the analyses, supported by LB. JF drafted the manuscript, supported by AE, AP, LB, CO, IT, JK, and SP. AE, AP, CO, IT, JF, JK, LB, and SP participated at the consensus workshop for the further development of the G-NoMAD. All authors provided critical revision of the article and approved the final manuscript.

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Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1Questionnairedevelopment.xlsx
- Additionalfile2GNoMADmanual.docx
- Additionalfile3GNoMADquestionnaire.docx

4.4 Article 4

Authors: Johanna Freund, Ingrid Titzler, Janika Thielecke, Lina Braun, Harald Baumeister, Matthias Berking, & David Daniel Ebert

Title: Implementing internet- and tele-based interventions to prevent mental health disorders in farmers, foresters and gardeners (ImplementIT): Study protocol for the multi-level evaluation of a nationwide project

Journal: BMC Psychiatry

Doi: 10.1186/s12888-020-02800-z

Summary:

Farmers are a high-risk occupational group for developing depression and other mental health issues. Internet- and tele-based interventions for preventing depression represent an opportunity to expand the availability of treatment services and overcome barriers to mental healthcare. The German Social Insurance Company for Agriculture, Forestry, and Horticulture has implemented a guided internet-based intervention program and personalized tele-based coaching for their insured members in this occupational group. The present study aims to evaluate the nationwide implementation of internet- and tele-based interventions and to identify barriers and facilitators for the implementation of both interventions. Two types of participants are included in this study: a) insured members participating in the internet- and tele-based intervention, and b) staff participants involved in implementation activities, in the consultation and referral process of the services, or service delivery. The study follows a mixed-method approach to assess relevant outcomes, including qualitative interviews with

insured members (e.g., assessing intervention acceptance and satisfaction), focus groups with involved employees (e.g., barriers and facilitators), online surveys (e.g., organizational readiness, degree of normalization), and reporting data (e.g., implementation costs, dissemination activities). The evaluation will be based on the RE-AIM framework and the Consolidated Framework for Implementation Research. The findings will reveal to what extent the insured members and the healthcare workers accept digital prevention services. The identified barriers and facilitators in the implementation of the internet- and tele-based interventions will help to develop and improve appropriate implementation strategies.

The manuscript was submitted in March 2019, accepted in July 2019, and published in August 2019 in *BMC Psychiatry*. The journal focuses on mental disorders, including their prevention, diagnosis, treatment, and epidemiology. It is an international, open-access, and peer-reviewed journal.

Contribution:

Johanna Freund was a shared first-author of this publication. David Ebert, Harald Baumeister, and Matthias Berking obtained funding for this study. Johanna Freund developed the research aims and the study's mixed-method design with Ingrid Titzler. Johanna Freund was responsible for recruitment, trial coordination, questionnaire programming, and data collection, supervised by Ingrid Titzler. She drafted the manuscript and received feedback from her co-authors.

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BMC Psychiatry

STUDY PROTOCOL Open Access

Implementing internet- and tele-based interventions to prevent mental health disorders in farmers, foresters and gardeners (ImplementIT): study protocol for the multi-level evaluation of a nationwide project

Johanna Freund[1*†], Ingrid Titzler[1,2*†], Janika Thielecke[1], Lina Braun[3], Harald Baumeister[3], Matthias Berking[1] and David Daniel Ebert[1,2,4]

Abstract

Background: Farmers are a vulnerable population for developing depression or other mental health disorders due to a variety of risk factors in their work context. Beyond face-to-face resources, preventive internet- and tele-based interventions could extend available treatment options to overcome barriers to care. The German Social Insurance Company for Agriculture, Forestry and Horticulture (SVLFG) implements several guided internet- and mobile-based interventions and personalised tele-based coaching for this specific target group provided by external companies within a nation-wide prevention project for their insured members. The current study aims to evaluate the implementation process and to identify determinants of successful implementation on various individual and organisational levels.

Methods: The current study includes two groups of participants: 1) insured persons with an observable need for prevention services, and 2) staff-participants who are involved in the implementation process. The Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework and the Consolidated Framework for Implementation Research (CFIR) will be used to track and evaluate the implementation process. A mixed-method approach will provide insights on individual and organizational level (e.g. degree of normalization, readiness for change) and helps to identify determinants of successful implementation. In-depth insights on experiences of the participants (e.g. acceptance, satisfaction, barriers and facilitating factors of intervention use) will be yielded through qualitative interviews. Focus groups with field workers provide insights into barriers and facilitators perceived during their consultations. Furthermore, intervention as well as implementation costs will be evaluated. According to the stepwise, national rollout, data collection will occur at baseline and continuously across 24 months.

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* Correspondence: johanna.freund@fau.de; ingrid.titzler@fau.de
†Johanna Freund and Ingrid Titzler contributed equally to this work.
[1]Department of Clinical Psychology and Psychotherapy, Institute of Psychology, Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany
Full list of author information is available at the end of the article

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Discussion: The results will show to what extent the implementation of the internet- and tele-based services as a preventive offer will be accepted by the participants and involved employees and which critical implementation aspects will occur within the process. If the implementation of the internet- and tele-based services succeeds, these services may be feasible in the long-term.

Trial registration: German Clinical Trial Registration: DRKS00017078. Registered on 18.04.2019.

Keywords: Implementation, Internet- and tele-based interventions, RE-AIM framework, Prevention, Mental health, Farmers

Background

Depressive disorder is a common condition with a 12-month prevalence rate of 8.56% in European countries [1]. Previous research has shown that farmers [2–5] and employees in related occupations (e.g. forestry and fishery workers) [6] are at an increased risk for developing mental health problems, especially depression, compared to non-agricultural occupations. Risk factors for mental disorders associated with agricultural jobs include: work-related stress [7, 8], longer work hours [3], poor harvest and weather [2], financial problems [9], health problems [8, 10] and exposition to pesticides [8].

At the same time, farmers mainly live in rural areas with limited mental health care. In Germany, the availability of on-site psychotherapy is additionally restricted by long waiting times in rural areas [11, 12]. Furthermore, stigma surrounding mental disorders and resistance to mental health care are reported in rural areas [5]. Especially male farmers are often constrained to friends and family for mental health support, while professional face-to-face therapeutic treatments are rarely obtained [5]. Thus, alternative ways to deliver treatment might be beneficial for farmers [2].

Existing evidence-based treatments for mental disorders have shown to only reduce the burden of mental health disorders by a third [13]; however, symptoms of mental disorders can be effectively reduced with preventive interventions [14, 15]. As a recent meta-analysis showed, psychological interventions can prevent or delay the onset of Major Depressive Disorder (MDD) by focusing on individuals with increased risk (selective prevention) or with subclinical depressive symptoms (indicated prevention) [16].

Internet- and tele-based interventions

Easily accessible preventive interventions, as implemented in this study, could increase farmers' ability to overcome reported challenges. Internet- and mobile-based psychological interventions (IMIs) have been shown to be effective in working participants [17] as well as for preventing MDD onset and treating subthreshold depression in the general population [16, 18–21]. In a similar context, researchers have begun to evaluate online interventions in Australian farmers to reduce stigma surrounding suicide and to combat rural isolation for farmers [22].

Although access to the internet has increased significantly in Germany in recent years, rural areas still face problems using Internet services [23]. Therefore, tele-based coaching is an important addition to existing preventive programmes against depression, especially in rural communities. Evidence also suggests that tele-based coaching, in comparison to treatment-as-usual, is effective in reducing symptoms of depression [24].

Despite its effectiveness, the uptake of health care interventions in routine practice remains low and costly [25, 26]. Only 14% of evidence-based health care interventions are used in routine care [27]. While many studies focus on the implementation of interventions for the treatment of mental disorders, there is little research on the implementation of preventive interventions. The few studies relate to the prevention of eating disorders and depression in adolescents and young adults [28, 29].

Implementation in rural areas

Technology-based solutions appear to be an increasingly viable option as they have the potential to overcome disparities in access for rural mental health care services [30, 31]. In addition, computerised Cognitive Behavioural Therapy interventions for anxiety and/or depression seem to be acceptable among people living in rural and remote areas [32]. Moreover, barriers and facilitating factors for the implementation of health care interventions in rural areas have been studied: Current evidence suggests that close collaborations with professional institutions, training of employees and perceived credibility of the treatment may facilitate successful interventions [33]. These facilitating factors may be achieved by supporting government agencies, qualified program managers or empirical evidence of efficacy [33]. Furthermore, increased public awareness for mental disorders [34] as well as for the benefits of telehealth [35] might be beneficial.

In addition to the participants, perspectives of all people involved in the implementation and delivery of this treatment should be considered. For example, health care staff in rural areas may prioritise staff attitudes and beliefs towards treatment [36, 37] as well as the

leadership and organisational structures of the clinic and the community [37]. Likewise, organisational readiness within rural communities is imperative for the successful implementation of telehealth services [38].

Implementing mental health services in rural areas faces specific difficulties since existing studies disregard the diversity of rural settings, are rarely based on well-developed theories and show methodological weaknesses [39]. Studies exist regarding particular aspects of implementation in rural areas (e.g. acceptance of interventions). However, there is a lack of comprehensive, multi-level implementation research in routine care, especially with regards to the implementation of technology-based interventions for mental disorders in rural areas.

A nationwide pilot project

This study is part of a national depression prevention program for farmers, gardeners and foresters ("With us in balance") carried out by the German Social Insurance company for Agriculture, Forestry and Horticulture (SVLFG, www.svlfg.de). The study aims to evaluate the implementation of tailored IMIs and a personalised tele-based coaching as an extension to existing face-to-face group interventions. In addition to the implementation study, it is evaluated in parallel running, randomised controlled trials whether the internet- and tele-based interventions are (cost-)effective in reducing depressive symptoms and other mental health concerns as well as in preventing the onset of clinical depression in this specific target group of farmers, gardeners and foresters [40, 41].[1]

Evaluation frameworks

Implementation success is considered as a multi-dimensional construct. In this study, the evaluation is based on the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework [42] as it helps to structure this multifaceted evaluation on individual and organisational levels. The RE-AIM framework is one of the most used evaluation frameworks in the implementation setting and facilitates to assess the quality, speed and impact of implementation efforts. In addition, the use of the Consolidated Framework for Implementation Research (CFIR) enables a deeper understanding of the mentioned 'implementation' dimension, as CFIR offers a pragmatic structure for approaching compound and interacting states in the implementation of interventions [43].

[1]Terhorst, Y., Braun, L., Titzler, I., Buntrock, C., Freund, J., Thielecke, J., Ebert, D. D., Baumeister H. Clinical and cost-effectiveness of a guided internet-based Acceptance and Commitment Therapy to improve chronic pain related disability in green professions (PACT-A): study protocol of a 36-month follow up pragmatic randomized controlled trial (under review).

Staff are part of a dynamic interaction within the organisation and are a key component to successful implementation. Previous literature showed the importance to examine different levels, when implementing in rural areas, e.g. staff attitudes and beliefs [36, 37], management and organisational structures, and organisational readiness [38]. The following constructs focusing on the involved employees aim to capture different aspects of the implementation process:

- Degree of Normalisation: Normalisation refers to activities that people pursue to integrate an innovation into their everyday routine. According to the Normalisation Process Theory, normalisation is defined as the extent to which a new intervention is considered as a normal part of daily work [44].
- Determinants in the implementation process: The Theoretical Domains Framework (TDF) provides an integrative framework model to identify drivers of behavioural change that could influence determinants in the implementation process [45].
- Organisational leadership: Minimal attention is given in research to the organisational context, although it may have a significant impact on the implementation of evidence-based practices [46]. Therefore, this study collects information regarding implementation leadership which may have an impact on the program's ability to drive change and innovation [47].
- Organisational readiness for change: This construct refers to the extent to which employees of an organisation are willing to implement organisational change, with particular focus on psychological and behavioural aspects [48].

Research questions

The aim of this study is the multi-level evaluation of the implementation success and stepwise nationwide rollout of the following new preventive services: a) GET.ON online health trainings with 7 guided IMIs, and b) personalised tele-based coaching provided by external companies in addition to existing on-site group interventions offered by the SVLFG.

Our study seeks to address the following research questions:

- How successful is the implementation of internet- and tele-based interventions in terms of reach, effectiveness, adaptation, implementation and maintenance on an individual (participants, staff) and organisational level?
- How effective is the implementation in terms of intervention uptake, normalisation into everyday life, and implementation costs?

- What are the experiences and impressions of the participants receiving internet and tele-based interventions? In particular, to what degree do participants report: a) acceptance and use of the technology-based treatment, b) satisfaction with the intervention considering their expectations, and c) perceived barriers and facilitators to use the intervention?
- Which barriers and facilitating factors can be identified for advising on prevention services at staff level?
- What determinants for implementation success in rural areas can be identified by focusing on employees involved in the referral process?
- Which similarities and differences can be identified between internet- and tele-based interventions with regards to implementation success and other determinants metrics of implementation effectiveness?

Methods

Design of the study

This study is a prospective, longitudinal implementation study and is described according to the Standards for Reporting Implementation Studies (StaRI) checklist [49], see Supplementary material. A mixed-methods approach using qualitative interviews, focus groups, quantitative surveys and reporting data is utilised for a comprehensive understanding of the implementation process. The evaluation is based on the RE-AIM framework [42] and the CFIR [43].

The implementation follows a stepwise, nationwide rollout plan which determines the availability of the internet- and tele-based interventions and the enrolment of the insured persons in each rollout region. Each region (2–7 federal states of Germany) undergoes these implementation phases at different times, starting with a pilot implementation phase in Bavaria and Schleswig-Holstein for 1.5 years and following with three rollouts (A, B and C) over 2 years. The initial pilot implementation phase was extended for various reasons (e.g. additional time needed to implement internal structures at SVLFG such as the referral process and documentation of consultations with insurers, additional time to conduct trainings, and unforeseen delayed availability of the tele-based coaching). Based on the Conceptual Model of Implementation Phases [50], the study can be divided into the following phases: exploration, preparation, implementation (6–12 months) and maintenance (12–24 months). The duration of the phases was defined in accordance to the RE-AIM framework that recommends 6 to 12 months for the implementation phase and at least 2 years for the maintenance phase [42]. In addition, the enrolment plan of the SVLFG stipulates that the rollout area is expanded every 6 months and focuses on implementation in this region within these 6 months Fig. 1.

Enrolment

The insured individuals are advised on the preventive services by approximately 350 employed field workers and in-house staff of SVLFG during their consultations via phone or on-site. In addition, the prevention services are advertised widely through PR activities of the SVLFG (e.g. newspaper articles, radio reports, SVLFG member magazine, lectures and information events) in the federal states where the interventions have been implemented. Interested individuals receive detailed information regarding the offered prevention services and their eligibility at the SVLFG central call centre. Eligible insured persons can choose whether they prefer single (e.g. internet- or tele-based interventions) or group preventive services. The group interventions are delivered on-site and include various topics on mental health issues for this target group (e.g. dealing with stress, handing over the business to the next generation). The registration process is conducted by SVLFG.

Data collection starts with rollout A in April 2019 and is expected to be finished at the project end (April 2021).

Interventions

The internet- and tele-based interventions are described according to the *Template for intervention description and replication* (TIDieR) [51], see Supplementary material. They are briefly outlined below.

Tailored IMIs

Seven IMIs are provided by the GET.ON Institute (www.geton-institut.de). Their effectiveness in the prevention and treatment of mental disorders has been demonstrated in more than 30 randomised controlled trials [19, 20, 52–65]. The IMIs are individually tailored to the participants based on their symptoms, risk profile and needs, and follow the selective prevention approach (e.g. providing trainings for a group with increased risk for mental disorders). The different IMIs are addressing risk factors for the incidence of depression including subclinical depressive symptoms [66], insomnia [67], stress [68], anxiety [69], chronic pain [70], harmful alcohol use [71, 72] and subclinical depressive symptoms in the context of diabetes [73]. The IMIs are adapted to the target group of farmers, foresters and gardeners in terms of content (e.g. descriptions of mock individuals facing similar struggles) and graphics to meet the needs of the participants. Variation of content and duration of the seven IMIs is illustrated in Fig. 2.

To begin the intervention phase, the participant completes a computer-adaptive psycho-diagnostic assessment which is based on self-report questionnaires assessing mental health issues. The type of online training is chosen during the initial interview with the e-

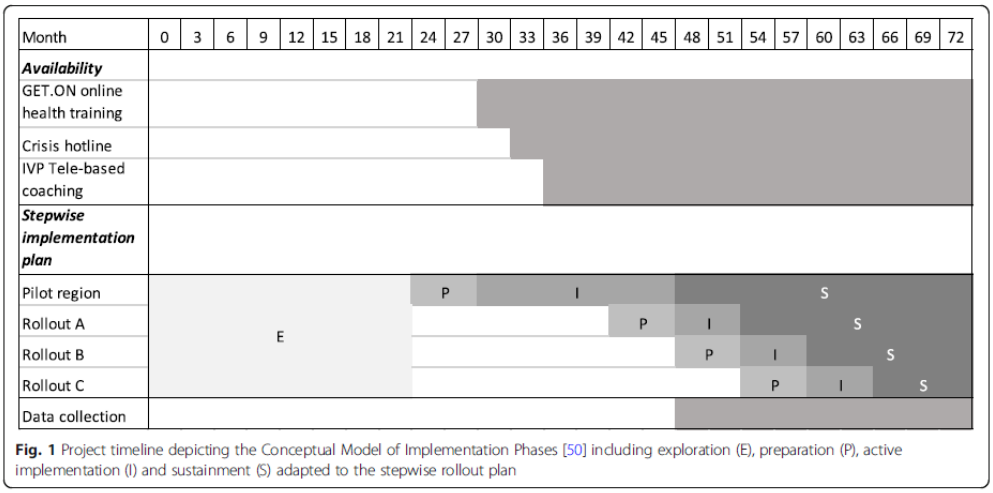

Fig. 1 Project timeline depicting the Conceptual Model of Implementation Phases [50] including exploration (E), preparation (P), active implementation (I) and sustainment (S) adapted to the stepwise rollout plan

coach depending on the participant's symptom profile, needs and preferences. The modules include psychoeducation, testimonials of mock individuals, in-depth exercises, a diary and homework to improve mental health and wellbeing. Depending on the training type, participants have access to additional modules. After each module, the participant receives individual feedback by email or by phone from the e-coach which helps to improve adherence of e-health interventions [74].

The e-coaches are psychologists with a university degree who have at least started a psychotherapeutic training. The training of the e-coaches consists of supervision by licensed psychotherapists in CBT training and information about IT-matters. A detailed description is published in the study protocols elsewhere [40, 75–80].

Personalised tele-based coaching

The personalised tele-based coaching is provided by the company IVPNetworks (www.ivpnetworks.de) and focuses on general mental health problems. The coaches are psychologists with trainings either in cognitive behavioural therapy, systemic therapy, psychodynamic psychology, hypnotherapy or other therapeutic trainings. Licensed psychotherapists are responsible for supervision. The coaches support participants in recognising and understanding conflict patterns in order to effectively cope with issues by activating their own resources.

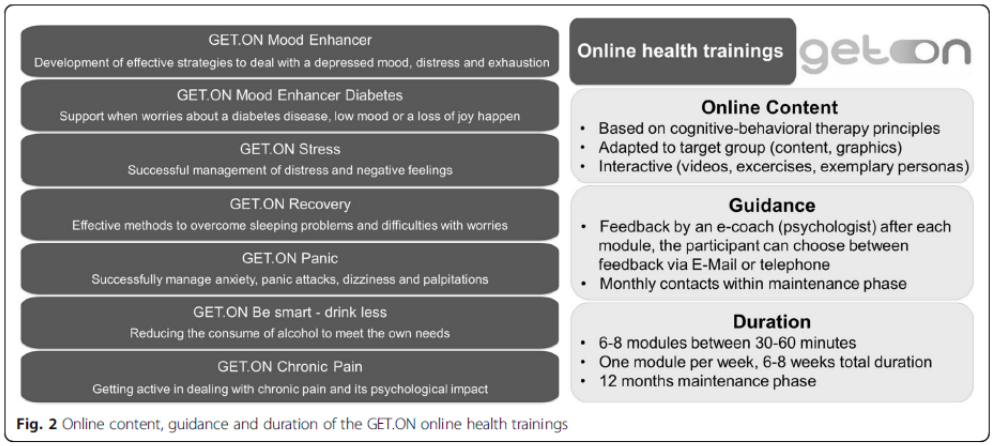

Fig. 2 Online content, guidance and duration of the GET.ON online health trainings

This is pursued by approaching the participant's personal situation and stressors (e.g., financial burden, family problems, work-related stress).

Participants are registered with their contact information in the IVPNetworks management and documentation platform (IVPnet 2.0). A case manager at IVPNetworks assigns the participant to a coach. The coaching is personalised in terms of amount, frequency and duration of the sessions, depending on the individual participant's needs. Personalised coaching means that there are no standardised manuals or fixed procedures for the coaching. Different therapeutic methods are used depending on the therapeutic background of the coach (which will be monitored in the study). If indicated, participants are supported in finding on-site social and health care services to complement the tele-based coaching (e.g., socioeconomic consultants, agricultural family counselling). Alternatively, on-site coaching can be arranged if a participant no longer prefers tele-based coaching. Common content and duration of the personalised tele-based coaching at IVPNetworks are illustrated in Fig. 3.

In addition to the personalised tele-based coaching, IVPNetworks offers a crisis hotline that can be used 24/7 by those insured at SVLFG. The crisis hotline is managed by trained psychologists and is a resource for acute psychological emergencies and crisis situations. As part of the crisis hotline, up to five follow-up contacts are possible.

Participants

The study design includes two groups of participants involved in the implementation process:

Group 1: insured persons at SVLFG

Inclusion criteria for insured persons at SVLFG includes: being an insured member of the health insurance scheme OR the pension fund of the SVLFG, being an agricultural contractor OR a collaborating spouse OR a family member or a pensioner, being over 18 years old, having access to the internet and/or a telephone, and providing informed consent.

Persons will be excluded if they currently suffer from a mental disorder and need extensive therapeutic service. Individuals may be excluded during the consultation in the call centre (if the interested insured person reports a mental disorder), during the assessment by the service provider or during their participation in case of a suspected mental disorder. If there is a suspicion, the external service provider advises the participant that a consultation with a general practitioner is recommended. The insured individual gets support in the search for further treatment options. In addition, people can be excluded for the tele-based intervention, if they have substantial hearing impairment or for the online interventions, if they have a visual impairment.

There are 465,000 eligible insured members of SVLFG nationwide, and the sample size is not capped. The number of participants enrolled in this study depends on the rollout stage of the implementation. Eligible insured persons can choose the specific intervention based on their preference and needs which reflects the conditions of routine care. A sample size of $N = 100$ per intervention is desirable to achieve reliable results. Based on previous experiences in the pilot phase of the implementation in two federal states, we expect a sample

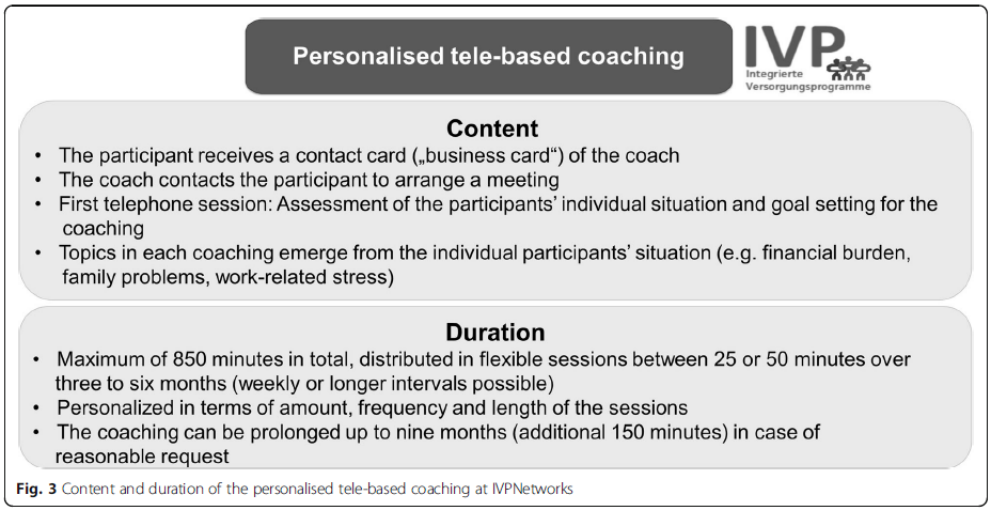

Fig. 3 Content and duration of the personalised tele-based coaching at IVPNetworks

size of approximately 500 to 800 participants for the national implementation area.

Group 2: staff-participants at SVLFG, GET.ON and IVPNetworks

Field worker, in-house staff and call centre agents at the implementing company SVLFG Approximately 350 field workers visit the insured members on-site. In-house staff counsel the insured persons by telephone. Both field workers and staff advise insured members on technical prevention, rehabilitation, etc. and additionally inform and advise members regarding the internet- and tele-based prevention services. They also forward interested persons to a nationwide call centre. Depending on the rollout phase (which includes a training on all health services offered by the SVLFG), the field workers begin advising members on the internet- and tele-based interventions at different times. Twenty-five call centre agents advise the insured individuals on various health offers including the newly implemented internet- and tele-based interventions. Additionally, call centre agents check the insurance eligibility criteria and are responsible for the enrolment in the prevention services.

Thus, implementation of internet- and tele-based interventions requires that these employees undergo changes to their work environment, especially at the behavioural level, by adapting their previous working routines to the new requirements.

Implementation team of SVLFG Members of the implementation team are responsible for the planning and realisation of the implementation activities. Employees who work in two or more roles (e.g. as a field worker, in-house staff and/or call centre agent) are excluded from the staff surveys for field workers, in-house staff and call centre agents to avoid conflation of the data, as such persons cannot perform both roles simultaneously without bias.

Coaches at GET.ON and IVPNetworks Coaches are involved in the delivery of the internet- or tele-based interventions and work as psychologists or therapists on a freelance basis or employment contract for GET.ON or IVPNetworks.

Approximately 150 staff-participants at GET.ON, IVPNetworks and SVLFG are expected to participate in the study. All employees of the described staff-groups who sign the informed consent are able to participate in the study. There are no specific eligibility criteria. If additional professional groups become involved in the future course of the implementation of these services, it will be decided whether these employees will be included in the surveys.

Measurements

The used measures are summarised in Table 1, followed by a description of each RE-AIM dimension and selected outcomes. Measurements include routine data, staff reviews of intervention consultations as well as usage of the interventions by insured individuals, online-assessments, qualitative interviews and focus groups.

Reach

To assess reach, the number and characteristics of the potentially eligible insured individuals at SVLFG, as well as exclusion, referral and uptake rates of the internet-, tele-based and on-site group preventive services will be reported. The following uptake levels will be considered in order to illustrate different levels of engagement:

- Referral rates: The absolute number of: a) referrals by the SVLFG field workers (operationalised as consultations about internet- and tele-based interventions), b) referrals by the call centre agents to the internet- and tele-based prevention services (IMIs: sending out a code for the registration at the online-platform, tele-based coaching: registration on the IVPnet platform), and c) the first contact with the external service provider (IMIs: first log in at online-platform to symptom screening; tele-based coaching: agreement for first tele-based coaching appointment).
- Uptake rates of internet- and tele-based interventions:
  - Intervention not started: The absolute number of referred persons who completed the assessment phase (IMIs: psycho-diagnostic assessment, tele-based coaching: first coaching assessment session) after the first contact with the external service provider, but have not started the intervention.
  - In treatment: The absolute number of persons who have started the intervention after assessment phase (IMIs: first login into first module; tele-based coaching: receive tele-based coaching at minimum second session).
  - Treatment not completed: Absolute number of persons who completed less than 50% vs. 70% of the intervention (IMIs: completed less than 50% vs. 70% maximal online modules within 13 weeks, have not logged in for at least 8 weeks or have interrupted the training for other reasons; tele-based coaching: completed less than 50% vs. 70% of the total call minutes, did not answer for at least 8 weeks or cancelled the coaching for other reasons).
  - Treatment completed: a) In previous e-mental health studies, the completer criteria differed between 50 to 100% of completed units [81–84].

Table 1 RE-AIM dimensions, measures and assessments

Dimension	Measure	Source	Assessment type	Time point
REACH (individual level)	Number and characteristics of potentially eligible insured individuals	SVLFG	Routine data	18 m
	Exclusion, referral und uptake rates; Completer rating from clinician's judgement (Helping Alliance Questionnaire)	GET.ON Institute / IVPNetworks / SVLFG; GET.ON and IVP coaches	Reportings; Online-Assessment	Every 3 months; after participant is defined as (non-) completer
	Estimated number of people exposed to the recruitment, recruitment response rate in general as well as specific recruiting strategies	GET.ON Institute / IVPNetworks / SVLFG	Reportings	Every 3 months
	Representativeness of participants compared to eligible insured individuals and interested, but not participating insured persons	SVLFG	Routine data	18 m
EFFECTIVENESS (individual level)	Depressive symptoms (Patient Health Questionnaire 9), perceived stress (Perceived Stress Scale 4), generalised anxiety disorder (Generalised Anxiety Disorder 7 scale), somatisation (Somatic Symptom Scale 8), health-related quality of life (Assessment of Quality of Life 4D), subjective capacity to work (Subjective Prognostic Employment Scale)	Insured person	Online-assessment	T0-T2[a]
	Patient satisfaction (Client Satisfaction Questionnaire adapted for internet interventions), side effects (Assessment of Negative Effects of Psychotherapy)	Insured person	Online-assessment	T1[a]
ADOPTION (organisational level)	Number, proportion and characteristics of involved employees per organisation, characteristics of federal states and rollout areas, characteristics of insured persons and type of agricultural holding	GET.ON Institute / IVPNetworks / SVLFG	Sociodemographics of employees, routine data	R0[b] Continuous
IMPLEMEN-TATION (individual + organisational level)	*Characteristics of the interventions:*			
	- Adaptations (TIDieR checklist)	GET.ON Institute / IVPNetworks	Reportings	Mid and end of the project
	- Usage of the intervention (e.g. adherence, duration and frequency of contacts)	GET.ON Institute / IVPNetworks	Reportings	Continuous
	- Credibility (Credibility Expectancy Questionnaire) and perceived (dis-)advantages	SVLFG staff- participants	Online-assessment	R0 / R1 / R2 / R3[b]
	- Costs for the intervention	SVLFG	Reportings	Every 3 months
	Outer Setting:			
	Acceptance, relevance, utility	Insured person GET.ON Institute / IVPNetworks	Online-assessment Interviews Reportings (e.g. adherence)	T1[a], T1[a] Continuous
	Inner Setting:			
	- Leadership support (Implementation Leadership Scale)	SVLFG staff-participants	Online-assessment	R0 / R1[b]
	- Organisational willingness to change (Organisational Readiness for Implementing Change questionnaire)	SVLFG staff-participants, implementation team	Online-assessment	R0 / R1 / R2 / R3[b]
	Characteristics of individuals:			
	- Degree of normalisation (NoMAD)	SVLFG staff-participants	Online-assessment	R0 / R1 / R2 / R3[b]
	- Determinants of Behavioural Change (Discriminant Content	SVLFG staff-participants)	Online-assessment	R1[b]

Table 1 RE-AIM dimensions, measures and assessments *(Continued)*

Dimension	Measure	Source	Assessment type	Time point
	Validation of the TDF Questionnaire)			
	- Barriers and facilitating factors at the consultations	SVLFG staff-participants	Focus groups	11/2017–02/2019
	Process:			
	- Evaluation of the implementation process (e.g. implementation activities, barriers and facilitating factors)	Implementation team	Interview	Every 6 months
	- Dissemination activities	SVLFG	Reportings	Every 3 months
	- Usage by employees	SVLFG staff-participants	Reportings	Every 3 months
	- Implementation costs	SVLFG	Reportings	Every 3 months
MAINTENANCE (individual + organisatonal level)	Sustainability of interventions (effectiveness)	Insured	Online-Assessment	T2[a]
	Referrals back to SVLFG and use of further offers	GET.ON Institute / IVPNetworks / SVLFG	Reportings	Continous
	Evaluation of the current implementation and further use of the technologies	SVLFG staff-participants	Online-assessment	R3[b]
	Sustainability of implementation (referral and uptake rates)	GET.ON Institute / IVPNetworks / SVLFG	Reportings	R3[b]

Notes
[a]time of insured-assessment depends on the date of intervention start
[b]time of employee-assessment depends on the date of the rollout in the specific area
Abbreviation: *m* month
Assessments: T0 (pre intervention), T1 (3 months after starting the internet-based training / 6 months after starting the tele-based intervention), T2 (12 months after starting the intervention)
Rollout: R0 (rollout start), R1 (6 months after rollout), R2 (12 months after rollout), R3 (18 months after rollout)

Research also indicates that a minimal treatment for subthreshold depression (e.g. six phone calls each with a maximum of 15 min) can also be effective in preventing MD [85]. Therefore, we defined two criteria with different treatment dosis as following: Absolute number of persons who completed at least 50% vs. 70% of online modules or call minutes. b) Clinical judgment by coaches at GET.ON Institute and IVPNetworks assessed with the Helping Alliance Questionnaire (HAQ) based on 11 items [86] in order to supplement the quantitative criteria for completion.

- Uptake of other services: This may include the crisis hotline, a second guided IMI, diagnostic clarification at IVPNetworks (via telephone or on-site), referrals to social or health service centres (e.g. socioeconomic or family consultants) during the tele-based coaching.

In addition, the estimated number of people exposed to recruitment materials and the associated response rate will be assessed. Specific recruiting strategies are tested to examine successful ways of addressing the target population. To provide representative information, interested but not participating individuals, and enrolled participants will be compared based on routine data. Differences in reach between the internet-, tele-based and on-site preventive services will be investigated as well.

Effectiveness

Effectiveness will be assessed at pre- and post-treatment (3 months after first log in on the GET.ON platform or 6 months after the registration at IVPnet) with online surveys consisting of frequently used and well validated self-report questionnaires. Depressive symptoms are assessed using the German Version of the Patient Health Questionnaire 9 (PHQ-9) [87] with high values on internal consistency ($\alpha = 0.88$) [88]. Generalised Anxiety Disorder severity is measured by the Generalised Anxiety Disorder 7 item self-report scale (GAD-7; $\alpha = 0.89$) [89, 90]. Perceived stress is assessed with the German Version of Perceived Stress Scale with 4 items (PSS-4; $\alpha = 0.84$) [91]. Somatisation tendencies will be measured by using the Somatic Symptom Scale based on 8 items (SSS-8; $\alpha = 0.81$) [92, 93]. The 12-item Assessment of Quality of Life instrument (AQoL–4D; $\alpha = 0.81$) [94] will be used to assess health-related quality of life. Subjective capacity to work will be assessed by using the Subjective Prognostic Employment Scale (SPE; Guttman scaling: rep = 0.99) based on 3 items [95]. Side effects attributed to the intervention are collected in the post-assessment period by the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP; 22 items; $\alpha = 0.86$) [96] adapted to internet- and tele-based interventions.

Adoption

Adoption will be assessed through the number and characteristics of the involved employees at SVLFG as well as at the external provider (GET.ON institute, IVPNetworks). Furthermore, metrics of the rollout regions and federal states, such as amount and characteristics of insured people and type of agricultural holdings will be described and compared to one another.

Implementation

After a broad literature search, questionnaires were selected that fit the study context as best as possible (e.g. can also be used for employees who are involved in the referral and not in the service delivery itself).

Intervention characteristics Potential adaptations to the existing interventions during the implementation process will be reported by the external service provider following the TIDieR checklist [51] halfway through the implementation and when concluding the project. Adaptations in the course of the implementation relate to referral and registration ways (e.g. to overcome barriers to participation). Furthermore, stakeholders' (e.g. field workers, in-house staff, call centre agents) perception of perceived (dis-)advantages of internet- and tele-based interventions and the treatment credibility will be assessed using the Credibility Expectancy Questionnaire (CEQ) with 6 items [96]. The psychometric properties of the CEQ are characterized by high internal consistency ($\alpha = 0.84–0.85$) and good values on test-retest reliability [97]. Intervention costs are recorded during the study as cost per participant for the respective intervention. Likewise, the use of the interventions by the insured individuals (including adherence, duration of intervention, number and duration of contacts, main topics, therapeutic background of coaches, etc.) will be monitored.

Outer setting Constructs including participants' needs and resources are related to the CFIR dimension 'outer setting' [43]. In assessing the outer setting, participant satisfaction is measured by using a German Version of the Client Satisfaction Questionnaire adapted for internet interventions (CSQ-I; $\alpha = 0.93$) based on 8 items [65, 98]. The participants are asked about the usefulness and relevance of the interventions. Acceptance of the interventions is indirectly recorded via non-completer rates (indicator, see above). Approximately 20 semi-structured interviews each with participants from GET.ON chronic pain, from the six remaining IMIs and from the tele-based coaching will supplement the data collection and provide insights into the participants' experience (e.g.

acceptance, satisfaction, barriers and facilitators for intervention usage) with the internet- or tele-based interventions. The interview guide is based on the Unified Theory of Acceptance and Use of Technology (UTAUT) model [99] and the Discrepancy Theory of Satisfaction [100] with regards to the dimensions: technical quality of care, psychosocial quality of care, organisational conditions, spatial and technical equipment, treatment outcome, continuity of care and financing [100].

Inner setting Constructs such as organisational culture and leadership engagement are related to the CFIR dimension 'inner setting' [43]. In assessing the inner setting, organisational readiness for implementing change for field workers, in-house staff, call centre agents and the implementation team at SVLFG is measured by using a German version of the Organisational Readiness for Implementing Change (ORIC) questionnaire with 12 items [101]. The ORIC questionnaire focuses on the degree to which employees are psychologically and behaviorally ready to implement organizational changes, which can be considered as a decisive factor for implementation success [101]. Good internal consistency (α = 0.88–0.92) is reported for the ORIC questionnaire [101]. Leadership of the implementation team as well as of the supervisors of field workers and call centre agents at SVLFG will be captured by using the Implementation Leadership Scale (ILS) based on 12 items [102]. The ILS can be seen as an efficient and short questionnaire which has been validated in settings of mental health with very high values on internal consistency (α = 0.93–0.97) [103].

Characteristics of the individuals The CFIR dimension of 'characteristics of the individuals' encompasses knowledge and beliefs about the intervention, self-efficacy and other personal attributes of the staff participants at SVLFG [43]. The degree of normalisation among staff-participants (e.g. field workers, in-house staff, call centre agents) is assessed by the German translation of the NoMAD and 3 additional normalization questions; the questionnaire (20 items) refers to the normalisation process theory and assesses the extent to which the new implemented service is a normal part of the daily routine at work [104]. The NoMAD questionnaire is characterized by a high internal consistency (α = 0.89) and has already been validated in heterogeneous samples [105, 106]. Determinants of behavioural change (e.g. knowledge, belief, self-efficacy) are assessed with the Discriminant Content Validation of the TDF Questionnaire (DCV) with 32 items [107] among field workers, in-house staff and call centre agents. The DCV helps to understand factors that influence the behaviour in health care settings and can therefore makes it possible to improve the implementation of innovations. Additionally, about 20 focus groups using an interview guide based on TDF [45] with field workers are conducted to identify barriers and facilitating factors for advising on prevention services. The aim of this mixed-method approach is the optimisation of the implementation process or interventions based on the findings.

Implementation process To capture the implementation process, the number and type of implementation and dissemination activities of SVLFG, GET.ON and IVP are reported every 3 months with an excel file (e.g. date, place, organisation, setting of the activity, target group, number of participants and content / aim of the activity). Implementation costs are reported every 3 months with an excel file and are defined according to the EU-project ImpleMentAll[2] project as the sum of personnel costs and other direct and indirect costs (indirect costs calculated at 20% of direct costs). In addition, the implementation team is interviewed every 6 months, particularly with regards to perceived effectiveness of the implementation in general and based on individual implementation strategies. These interviews also discuss barriers and facilitating factors in the implementation process and assessment of the current state of implementation. Quantitative (referral and uptake rates, barriers and facilitating factors in the implementation) and qualitative results (focus groups) about the progress and quality of implementation are prepared and delivered to the implementation team every 6 months to promote adaptions and improvements.

Maintenance

In assessing the maintenance of the implemented internet- and tele-based interventions, follow-up surveys with the insured participants will be conducted 12 months after first contact for the prevention project (e.g. 12 months after first login at the GET.ON platform or registration at IVPnet) to monitor the long-term impact of preventive interventions on mental health (see effectiveness measures, 60–65). Referrals to the SVLFG call centre are reported by the external service providers to capture all processes in the implementation that contribute to sustainable development. Uptake rates of the internet- and tele-based interventions are monitored in the maintenance phase of the respective rollout region. In terms of sustainability, we also record the use of a second IMI, the maintenance phase of the IMIs (e.g. monthly contacts for a year) or the prolongation of an

[2]Bührmann L, Schuurmans J, Ruwaard J, Genugten C van, Finch T, Rapley T, et al. Tailoring Implementation of Internet-based Cognitive Behavioural Therapy to Context-specific Needs across Europe and Australia. A Study Protocol for a Stepped-wedge Cluster Randomized Trial: the ImpleMentAll Project (under review).

IVP tele-based coaching and any other health care utilisation.

Normalisation is recorded in the maintenance phase using the questionnaire NoMAD [104] at the staff-level (e.g. field workers, in-house staff, call centre agents), and will be compared to the normalisation degree during the implementation phase. Additionally, the attitudes and experiences of the staff-participants involved in the implementation process are essential for sustained implementation. Therefore, a concluding survey with the staff-participants and important multipliers at SVLFG (e.g. management board) will be conducted at the end of the project to assess their professional view on the implementation and their intention to further use the internet- and tele-based prevention services. To ensure practical relevance, the item pool for this survey will go through an iterative feedback process with the initiators of the project.

Measuring implementation success

In line with the ImpleMentAll,[3] implementation success is defined as an increase in uptake of internet- and tele-based interventions (referral rates and levels of uptake, e.g. not started, in treatment, completer, non-completer), degree of normalisation among staff-participants (extent to which consultation to the internet- and tele-based interventions are perceived as a normal part of work) and efficiency outcomes (costs of implementation effort in relation to uptake and degree of normalisation).

Analysis

Reporting of implementation results will follow the StaRI [49] statement. To assess the implementation success and to illustrate a broad picture of the implementation process in the context of rural areas we will combine qualitative and quantitative methods in a summative way. Quantitative and qualitative data are collected simultaneously to evaluate the implementation process. Qualitative data are used to provide a deep understanding, while quantitative data are used to provide breadth of understanding [108]. In addition, the results of the qualitative analysis are then validated in a quantitative survey. Qualitative surveys are only carried out on a small part of the sample, while all participants are invited to the respective quantitative surveys. The database is therefore larger for quantitative surveys. The analysis is based on guidelines for mixed-methods research defined by the NIH Office of Behavioural and Social Sciences Research [109]. In addition, the Consolidated criteria for reporting qualitative studies (COREQ) [110] are used.

Quantitative analysis

The evaluation of the implementation follows the RE-AIM dimensions as described above. Descriptive analyses (frequencies, means and percentages) will be performed to assess outcomes across all RE-AIM dimensions. We will evaluate the implementation success of the internet- and tele-based interventions separately.

To assess the representativeness of the participants compared to the target group, t-tests or non-parametric tests will be used. To assess intervention effectiveness, we analyse for different groups of participants (e.g. participants who have started treatment or completed treatment) by using independent sample t-test and chi-squared analyses. We will use t-tests or non-parametric tests to analyse differences between pre-, post- and follow-up-measurements. In order to counteract the issue of multiple comparisons, Bonferroni correction is used. The statistical significance level is set to $p < .05$. Within-group effect sizes and 95% CIs will be reported at all measurement points. Implementation effectiveness is assessed by comparing uptake rates, the degree of normalisation among staff-participants and efficiency outcomes (costs of implementation effort in relation to uptake and degree of normalisation) at different time points.[4]

Furthermore, linear regression models are used to investigate differences between the interventions (guided IMIs, personalised tele-based coaching and on-site group workshops) regarding reach outcomes (referral and uptake rates) with intervention type as independent variable. By using further linear regression models we compare socio-demographic and clinical outcomes as dependent variables between the participants of the different prevention services (independent variable). Based on multiple linear regression models we analyse the influence of factors at staff level (credibility of the internet- and tele-based interventions, degree of normalisation, leadership support, organisational readiness to change and determinants of behavioural change) as independent variables on the number of referrals by field workers, in-house staff and call centre agents (dependent variables). Additionally, the implementation outcomes will be compared between the federal states and rollout areas at different phases of implementation.

[3] Bührmann L, Schuurmans J, Ruwaard J, Genugten C van, Finch T, Rapley T, et al. Tailoring Implementation of Internet-based Cognitive Behavioural Therapy to Context-specific Needs across Europe and Australia. A Study Protocol for a Stepped-wedge Cluster Randomized Trial: the ImpleMentAll Project (under review).

[4] Bührmann L, Schuurmans J, Ruwaard J, Genugten C van, Finch T, Rapley T, et al. Tailoring Implementation of Internet-based Cognitive Behavioural Therapy to Context-specific Needs across Europe and Australia. A Study Protocol for a Stepped-wedge Cluster Randomized Trial: the ImpleMentAll Project (under review).

According the intention-to-treat principle all observed data will be included. Patterns of missing data will be analysed and corrected. All analyses will be performed with R statistic software [111].

Qualitative analysis

Qualitative data is used for insights into the implementation process. Focus groups with field workers are conducted to understand barriers and facilitating factors of the consultation regarding the internet- and tele-based services. Interviews with insured persons enable insights in participants' experience (e.g. satisfaction, acceptance). All qualitative data will be audiotaped and transcribed verbatim using MAXQDA. The analysis is based on the qualitative content analysis by Mayring [112]. To establish reliability, two independent raters will code the same transcripts using a coding guide and coding rules. The focus groups are evaluated inductively as well as deductively, based on the TDF [45] in two different coding passes. The interviews with the insured individuals are evaluated with an inductive-deductive approach.

Discussion

This study provides novel and diverse information to the existing literature regarding the implementation of preventive treatments for depression. To our knowledge, this study is the first nationwide prevention project in Germany and the first comprehensive and multi-level implementation study in general that examines the implementation of internet- and tele-based interventions in farmers, gardeners and foresters in rural areas. The implementation process of different preventive services such as internet- and tele-based interventions will be compared. Insights into implementation of mental health services on an individual (participants, staff) and organisational level, within the context of rural areas, can be assessed. Additionally, the associated costs (implementation and intervention costs) will be considered. Furthermore, determinants for implementation success in rural areas can be identified by focusing on employees involved in the referral process. Based on these findings, recommendations for future interventions can be made.

The three parallel running RCTs [40, 41][5] will deliver results on the clinical effectiveness of the internet and tele-based interventions under randomized controlled conditions. Results of the implementation study will provide information about the implementation of the internet- and tele-based interventions from a routine care perspective in terms of a hybrid study design simultaneously examining the impact of the interventions in routine care (e.g. pre-, post- and follow-up comparisons at participant level) and the implementation itself. This enables results based on two different, complementary study designs. The results will show to what extent the implementation of technologies as preventive offers will be accepted by the participants as well as employees involved in the implementation process. If the implementation of the internet- and tele-based services succeeds, these services may be feasible in the long-term and health care in rural areas could be sustainably improved.

Trial status

Recruitment has been started in April 2019. Participants will be continuously included until the end of the study. Data collection is ongoing.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12888-020-02800-z.

Additional file 1. Standards for Reporting Implementation Studies: the StaRI checklist for completion

Additional file 2. Description of the GET.ON online health trainings

Additional file 3. Description of the personalised tele-based coaching (IVPNetworks)

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Authors' contributions

JF und IT share co-first authorship and contributed equally to this research and manuscript. DDE, HB and MB obtained funding for this study. IT, JF and DDE developed the design of the implementation study. IT, JF, JT and LB developed the design of the qualitative study with intervention participants. JF and IT drafted the manuscript and are responsible for recruitment, coordination of the trial and data collection. IT is supervising the trial management as operational lead of the project. All authors provided critical revision of the article and approved the final manuscript.

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Availability of data and materials

Results will be submitted for publication in a peer-reviewed journal and presented at conferences. Central results will be communicated to SVLFG and can be used to better understand insured persons, disseminate the information in health care campaigns and further improve health care services for farmers, foresters and gardeners. Access to the final trial dataset can be

[5]Terhorst, Y., Braun, L., Titzler, I., Buntrock, C., Freund, J., Thielecke, J., Ebert, D. D., Baumeister H. Clinical and cost-effectiveness of a guided internet-based Acceptance and Commitment Therapy to improve chronic pain related disability in green professions (PACT-A): study protocol of a 36-month follow up pragmatic randomized controlled trial (under review).

provided to fellow researchers upon request, depending on to be specified data security and data exchange regulation agreements.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Friedrich-Alexander-University of Erlangen-Nürnberg (12.02.2019) and registered in the German Clinical Trials Register (DRKS00017078, https://www.drks.de/drks_web/navigate.do?navigationId=trial. HTML&TRIAL_ID = DRKS00017078) on April 18th, 2019.

Prior to their involvement, written informed consent for participation in the study will be obtained from all participants (insured persons, employees). SVLFG confirmed that informed consent document for the insured individuals will be stored securely at SVLFG. Informed consent documents of employees will be stored at the Friedrich-Alexander-University Erlangen-Nürnberg. All participant information will be stored securely in locked file cabinets and/or password-protected with restricted physical access in a secured server at the Friedrich-Alexander-University Erlangen-Nürnberg. All reports, data collection, and administrative forms will be identified exclusively by a study ID number assigned to each participant to maintain confidentiality. All records containing names or other personal identifiers, such as informed consent forms will be stored separately from study records identified by ID numbers. The list that links participant ID numbers to other identifying information will be stored in separate, password-protected files on external hardware with limited access.

Consent for publication

Not applicable.

Competing interests

IT reports to have received fees for lectures/workshops in the e-mental-health context from associations and training institutes for psychotherapists. IT is project lead of the trial site GET.ON for the European implementation research project ImpleMentAll funded by the European Commission. DDE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. DDE and MB are stakeholders of the GET.ON Institute for health training online, which aims to implement scientific findings related to digital health interventions into routine care. HB has received consultancy fees and fees for lectures/workshops from chambers of psychotherapists and training institutes for psychotherapists in the e-mental-health context.

JF, JT, LB report no conflicts of interest.

Author details

[1]Department of Clinical Psychology and Psychotherapy, Institute of Psychology, Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany. [2]GET.ON Institute, Berlin, Germany. [3]Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University, Ulm, Germany. [4]Department of Clinical, Neuro- & Developmental Psychology, VU University Amsterdam, Amsterdam, Netherlands.

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Publisher's Note

4.4 Article 5

Authors: Johanna Freund, Claudia Buntrock, Janika Thielecke, Lina Braun, Harald Baumeister, Matthias Berking, David Daniel Ebert, & Ingrid Titzler

Title: Digital prevention of depression for farmers? A qualitative study on participants' experiences regarding determinants of acceptance and satisfaction with a tailored guided internet intervention program

Journal: Internet Interventions

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Summary:

The German project "With Us in Balance" aims to prevent depression in farmers and individuals in related occupations by examining a guided internet-based intervention program. Despite evidence on the effectiveness of internet-based interventions, little is known about participants' experiences. This qualitative study aimed to investigate participants' acceptance of and satisfaction with the guided internet-based program. Interviews were conducted with 22 out of 171 participants (13 %) in the intervention group of an RCT. The guide for the semi-structured interviews was developed based on the UTAUT model and the evaluation model of patient satisfaction. Two independent coders analyzed the interviews according to deductive-inductive content analysis and reached a substantial level of agreement (K = 0.73). 71 determinants for acceptance and satisfaction across ten dimensions (performance expectancy, organization, eCoach, usability, training content and structure, training usage, training outcome, financing, social influence, and behavioral intention) could be identified. Most

frequently, participants mentioned “location independence”, “positive relationship to the eCoach” (each *n* = 19, 86%), “personal eCoach guidance”, “expertise of the eCoach”, and “target group-specific adaptation” (each *n* = 18, 82%). The findings largely confirmed the acceptance of and satisfaction with the tailored internet-based program for depression prevention among farmers, forest owners, and gardeners. A significant proportion of positive factors identified surrounded the eCoach guidance, highlighting its importance in a preventive setting. Some negative factors were found, which helped to understand the potential weaknesses of internet-based interventions. As different needs related to intervention content and usage were identified, individualization might help to improve the program.

The manuscript was submitted in December 2021, accepted in August 2022, and published in September 2022 in *Internet Interventions*, which is an open-access and peer-reviewed journal publishing articles on all aspects of internet interventions.

Contribution:

Johanna Freund was the study’s principal investigator and the first author of this publication. She developed the qualitative study design and the interview guide under contributions from Lina Braun, Janika Thielecke, and Ingrid Titzler. She was responsible for the recruitment of participants, study coordination, interview data collection, and deductive-inductive qualitative analyses. Ingrid Titzler, Claudia Buntrock, and David Ebert provided feedback on the code system. Johanna Freund drafted the manuscript. All authors provided feedback on the manuscript.

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Digital prevention of depression for farmers? A qualitative study on participants' experiences regarding determinants of acceptance and satisfaction with a tailored guided internet intervention program☆

Johanna Freund [a,b,*], Claudia Buntrock [a,c,d], Lina Braun [c], Janika Thielecke [a,b], Harald Baumeister [c], Matthias Berking [a], David Daniel Ebert [a,b,1], Ingrid Titzler [a,1]

[a] Department of Clinical Psychology and Psychotherapy, Institute of Psychology, Friedrich-Alexander-University of Erlangen-Nürnberg, Erlangen, Germany
[b] Faculty TUM Department of Sport and Health Sciences, TU Munich, Munich, Germany
[c] Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University, Ulm, Germany
[d] Institute of Social Medicine and Health Systems Research, Faculty of Medicine, Otto von Guericke University Magdeburg, Magdeburg, Germany

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ABSTRACT

Introduction: Farmers, forest workers and gardeners have a higher risk of developing depression compared to other occupational populations. As part of the German pilot project "With us in balance", the potential of six guided internet- and mobile-based interventions (IMIs) to prevent depression among their insurants is examined. The IMI program is tailored to various risk factors of depression, individual symptoms, and needs. Although IMIs have been shown to be effective in reducing depressive symptoms, there is little qualitative research about the acceptance of digital preventive IMIs. The aim of this qualitative study is to gain insights into participants' experiences with the guided IMIs by focusing on determinants for acceptance and satisfaction.

Methods: Semi-structured interviews were conducted with 22/171 (13 %) intervention group (IG) participants of a randomized controlled trial. The interview guide was developed based on theoretical models of user acceptance (Unified Theory of Acceptance and Use of Technology) and patient satisfaction (evaluation model, discrepancy theory). The interviews were evaluated independently by two coders performing a deductive-inductive content analysis and attaining a substantial level of agreement ($K = 0.73$).

Results: The qualitative analysis revealed 71 determinants for acceptance and satisfaction across ten dimensions: performance expectancy, organisation, e-coach, usability, training content and structure, training usage, training outcome, financing, social influence, and behavioural intention. The most frequently identified drivers for the IMI use include "location independence", "positive relationship to the e-coach" (each $n = 19$, 86 %), "personal e-coach guidance", "expertise of the e-coach", "target group specific adaptation" (each $n = 18$, 82 %), "flexibility", "high willingness for renewed participation" (each $n = 17$, 77 %), "fast and easy availability", "training of health enhancing attitudes and behaviours" and "content with figurative expressions" (each $n = 16$, 73 %).

Discussion: The qualitative findings predominantly suggest the acceptance of and satisfaction with the IMI program for the prevention of depression in famers and related lines of work. Many identified positive drivers are related to the e-coach guidance, which emphasizes its importance in the preventive setting from the perspective of the participants. Nevertheless, some negative aspects have been identified which help to understand potential weaknesses of the IMI program. Participants indicated different needs in terms of IMI content and usage, which points towards the potential benefit of individualisation. The possibility of being able to use IMIs anonymously, flexibly and independently of location might be highly relevant for this specific target group.

☆ Trial registration: German Clinical Trial Registration: DRKS00014000 (April 9th, 2018).

* Corresponding author at: Friedrich-Alexander-University of Erlangen-Nürnberg, Institute of Psychology, Department of Clinical Psychology and Psychotherapy, Nägelsbachstraße 25a, 91052 Erlangen, Germany.
E-mail address: johanna.freund@fau.de (J. Freund).

[1] Shared last authorship

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1. Introduction

1.1. Background

The 12-month prevalence for depression worldwide is 4.4 % (World Health Organization, 2017), which leads to a high burden of disease at the individual and societal level. People affected by depression experience a significant loss in their quality of life (De Graaf et al., 2002) and have a higher risk for mortality (Chesney et al., 2014 Jun). Depression has a major impact on public health as it contributes most to global disability and accounts for 7.5 % of all years lived with disability worldwide (Vos et al., 2017). Consequently, depressive disorder leads to increased economic costs due to higher service uptake and productivity losses (Smit et al., 2006).

Because evidence-based psychotherapeutic treatments can decrease the burden of mental illness only by a third (Andrews et al., 2019), prevention of depression is becoming increasingly important (Muñoz et al., 2010). Preventive measures start before the onset of the disease and can effectively reduce the symptoms of mental disorders (Horowitz and Garber, 2006; Stockings et al., 2016). Based on the results of a recent meta-analysis, the occurrence of MDD in high risk groups can be prevented or at least delayed with psychological interventions indicated by a relative risk of 0.81 (95 % CI: 0.72–0.91) one year after the preventive measures (Cuijpers et al., 2021).

Preventive measures are important in the agricultural work setting. Farmers and those in related lines of work (e.g. forestry and fishery workers) are exposed to many risk factors for mental illnesses such as work-related stress, financial pressure, poor harvest and weather, health problems and exposure to pesticides (Sue et al., 1998; Sanne et al., 2004; Onwuameze et al., 2013; Roy et al., 2013; Logstein, 2016). Compared to other occupations, they have a higher risk of developing mental health issues (Roy et al., 2013; Sanne et al., 2003; Judd et al., 2006; Torske et al., 2016), especially depression, indicated by an odds ratio of 1.99 [95 % CI: 1.55–2.55] (Torske et al., 2016). However, mental health care utilization among farmers is low (Judd et al., 2006), among others due to stigma (Judd et al., 2006) and limited treatment availability in rural areas (Schang et al., 2016).

Therefore, new approaches to tackle the burden of depression in farmers are needed. A possible solution could be the usage of internet- and mobile-based interventions (IMIs), which are easily accessible and can be used independently of time and place (Ebert et al., 2018a). Meta-analytic evidence shows that IMIs are effective in reducing subthreshold depression (Hedges' $g = 0.39$ [95 % CI: 0.25–0.53] at post-treatment) as well as in preventing the onset of MDD (Hazard Ratio = 0.72 [95 % CI: 0.58–0.89]) (Reins et al., 2021). Little is known about the acceptance and utilization of IMIs by farmers.

As part of the nationwide pilot project ("With us in balance") of the German social insurance company for agriculture, forestry and horticulture (SVLFG), the preventive potential of IMIs is examined in different substudies: In addition to a pragmatic randomized controlled trial (RCT) on "Prevention of Depression in Agriculturists" (PROD-A) (Braun et al., 2019; Braun et al., 2021a; Braun et al., 2021b), an implementation study (ImplementIT) evaluates the implementation success of the guided IMIs in routine care (Freund et al., 2020). The IMI program includes various IMIs focusing on risk factors for depression (i.e. interventions for subclinical depressive symptoms, insomnia, stress, anxiety, harmful alcohol use, and subclinical depressive symptoms in the context of diabetes). The effectiveness of the IMIs have been demonstrated in >30 RCTs (Buntrock et al., 2016; Buntrock et al., 2015; Boss et al., 2016; Ebert et al., 2015; Ebert et al., 2017; Nobis et al., 2015 May; Thiart et al., 2015 Mar; Thiart et al., 2016; Ebert et al., 2018b; Boß et al., 2018; Ebert et al., 2018c; Ebert et al., 2016a; Heber et al., 2016; Buntrock et al., 2017; Nobis et al., 2018; Ebert et al., 2016b). For this project, the guided IMIs have been adapted to the specific target group, i.e. farmers, forest workers and gardeners.

Results of PROD-A showed a small effect on the reduction in depressive symptom severity at 9-weeks post-treatment ($d = -0.28$, 95 %-CI: −0.50 to −0.07) (Braun et al., 2021a) and at 6-month follow-up ($\beta = -0.30$, 95 %-CI: −0.52; −0.07), while no significant differences between the groups could be found at 12-month-follow-up (Braun et al., 2021b). Authors discussed that the effectiveness of the IMI program was restricted by low adherence to the interventions (22 %/56 % of participants completed 80 % of the modules at 9-weeks/12-months follow ups). More insight into the needs and experiences of the participants is essential, as described in the study protocol of ImplementIT (Freund et al., 2020). The focus is on the acceptance of and satisfaction with the IMI program which can affect intervention uptake (Philippi et al., 2021 Dec) and represent an essential criterion for health care quality (Samartzis and Talias, 2020).

Previous qualitative studies on patients' experiences with internet-based treatment for depression reported a lack of applicability of the intervention, difficulties due to inadequate computer skills, or poor equipment (Gerhards et al., 2011) and feelings of being left alone when using unguided IMIs (Holst et al., 2017). The findings point to the potential benefit of a higher degree of individualisation (Darvell et al., 2015) and more therapeutic contact (Gerhards et al., 2011; Holst et al., 2017; Darvell et al., 2015) in the IMI design. At the same time, participants appreciate anonymity and flexibility during the usage (Gerhards et al., 2011; Holst et al., 2017) and a well working technology (Holst et al., 2017).

However, qualitative research on depression prevention with IMIs is limited to the target group of adolescents (Iloabachie et al., 2011; Santesteban-Echarri et al., 2017), relapse prevention (Santesteban-Echarri et al., 2017; Boggs et al., 2014) or on postnatal depression (Shorey and Ng, 2019). A first recently published study of an internet-based intervention to prevent depression focused on adults in a workplace setting and explored barriers to intervention use and adherence (Eccles et al., 2021). Both personal (e.g. time, stress level) and program-level factors (e.g. content, functionality) could be identified as barriers.

1.2. Research question

It is crucial to understand the perspectives and needs of the participants (Damschroder et al., 2009; Proctor et al., 2011; Kidholm et al., 2012) in order to be able to derive adjustments and thereby contribute to the implementation success of digital preventive IMI programs. Therefore, the aim of this qualitative study is to examine the experiences of farmers and related occupations with the guided preventive IMI program by focusing on determinants for the acceptance and satisfaction.

2. Methods

2.1. Study setting

The research design of this qualitative study was defined in the implementation study protocol ImpleMentIT, which evaluates the implementation success of the IMI program in routine care based on a mixed-methods design (Freund et al., 2020). Interview participants were recruited from the intervention group of PROD-A (Braun et al., 2019). The inclusion criteria for this trial comprised (a) being an agricultural entrepreneur, collaborating spouse, family member as well as pensioner with sufficient insurance status, (b) an age of 18 or above, (c) an indication for at least subthreshold depression (determined by PHQ-9 ≥ 5), (d) access to internet, (e) no current psychotherapy and (f) in case of indications of suicidality, the ability to distance from suicidal ideation (e.i. by providing a non-suicide contract). Study participant enrollment occurred from April 2018 to April 2019.

PROD-A was approved by the ethics committee of the University of Ulm and registered in the German Clinical Trial Registration (DRKS00014000) on April 9th, 2018.

2.2. Intervention

The implemented IMI program, the GET.ON online health trainings, is provided by a service company (www.geton-institut.de/www.hellobetter.de) and consists of three phases with various measures for personalizing and tailoring the intervention (see Fig. 1): (1.) The participant completes a *psycho-diagnostic assessment* consisting of self-report questionnaires. During an initial call with the e-coach, a training type is jointly determined based on the assessment results and individual preferences of the participant. (2.) In the guided *active training phase*, the participant accesses the IMI on an online-based intervention platform via computer. All trainings are based on cognitive behavioural therapy (CBT) principles except "GET.ON stress" which is based on the transactional model of stress and coping (Lazarus and Folkman, 1987). The 6–8 weekly standard modules of the IMIs include psycho-educative material, exercises, and homework assignments as well as statements from exemplary people. In addition, there are interactive elements such as auditory material and videos clips. (3.) All trainings are completed with a *maintenance phase* consisting of monthly e-coach contact up 12 months. The IMI program is described according to the Template for intervention description and replication (TIDieR) (Hoffmann et al., 2014), see Supplementary material 1, and in the study protocols elsewhere (Braun et al., 2019; Freund et al., 2020).

2.3. Participants and recruitment

Since in the study by Francis et al. (2010) data saturation could be achieved in interview 17, the recruitment aim in this study was to reach a sample size of at least 20 participants. The sample composition should be representative of the entire participant sample of the intervention group, especially with regard to intervention status (not started; started, but not completed; completed), type of selected training (one of six IMIs) and usage of a second training.

In the first step, participants (who had not withdrawn the study participation in the meantime and who had registered on the online platform at the time of recruitment) were contacted in August 2019 by email and invited to the interview ($N = 161$). In order to reach a representative group of participants, participants that fit the relevant missing characteristics were reminded after 6 and 8 weeks ($N = 70$) until the necessary sample size with the desired distribution of characteristics was reached.

In total, we received 27 signed informed consents. Due to scheduling difficulties or lack of feedback on proposed interview dates, a total of 22 interviews were conducted in the period from September to November 2019. The time of the interview was on average 431 ($SD = 127$) days after the first login on the platform.

2.4. Qualitative method

2.4.1. Data collection

Data were collected by phone using a semi structured interview guide integrating elements from theories of technology acceptance and patient satisfaction. Acceptance of technology was operationalized following the Unified Theory of Acceptance and Use of Technology (UTAUT) model (Venkatesh et al., 2003), which includes the dimensions *performance expectancy*, *effort expectancy*, *social influence*, *facilitating conditions*, *behavioural intention* and *use behavior*. The dimension *use behavior* was assessed quantitatively via logins at the platform as supposed by Davis (1989). Patient satisfaction was operationalized according to the evaluation model after Ware et al. (1978). In this theory, patient satisfaction is seen as a positive or negative evaluation by the patient of a medical treatment, a medical facility or a medical service provider and mainly refers to eight dimensions (e.g. *art of care*, *technical quality of care*, *organisation/accessibility*, *financing*, *physical environment*, *availability*, *continuity* or *regularity of care* in the same facility and *outcomes of care*). All dimensions are included in the interview guide except for the *continuity of care* dimension that is less relevant in an online setting. Furthermore, we considered the participant's level of demands and expectations as well as the individual evaluation of care according to the discrepancy theory (Lawler, 1971). The latter theory postulates satisfaction when the treatment-independent expectations and demands of the patient correspond with the perceived treatment quality. Patients are satisfied when the actual experiences at least meet their own expectations and demands (Blum, 1998). To examine satisfaction according to Lawler (1971), the participants were asked to quantitatively rate questions on a scale of 0–100 with 100 indicating 100 % of their expectations were met.

The interview guide consisted of open questions including 60 main questions assigned to the previously mentioned theories (acceptance: 20 questions, satisfaction: 40 questions, both: 4 questions) as well as additional guided prompts to promote the narrative flow if needed. Exemplary questions from the interview guide are shown in Table 1. The instructions varied depending on the type and status of the intervention in which the interviewee participated. All participants received the same questions except non-starters who obtained a shortened version.

The semi-structured interviews ($N = 22$) were conducted by two

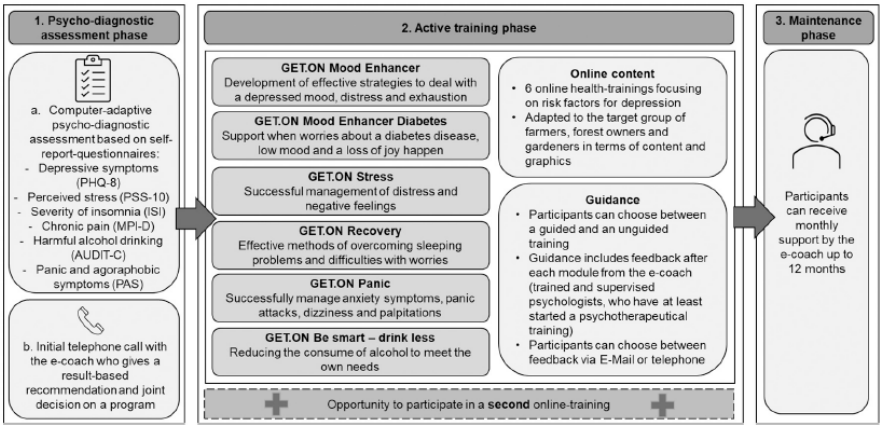

Fig. 1. Measures for personalizing and tailoring the intervention in the course of the participation.

Table 1
Example questions of the interview guide and their theoretical basis.

Theory background	Interview questions
UTAUT model – dimensions	
Performance expectancy	If you think back to the beginning of the coaching: What expectations did you have on what the coaching should change for you?
Effort expectancy	How did you imagine the time and effort involved in the online training in advance?
Social influence	What role did the support of friends and family for participation in the training play for you?
Facilitating conditions	The content and graphics of the online training were adapted to the green professions. To what extent was this adaptation helpful to you?
Behavioural intention	If at some point you would find yourself in a similar situation to the one you were in when you started the online training: How willing would you be to participate in another online training course?
Use behavior	-assessed quantitatively at the platform (e.g. completed modules)-
Evaluation model of patient satisfaction – dimensions	
Technical quality of care*	To what extent did you feel that your coach gave you competent advice?
Art of care*	How would you describe your relationship with your e-coach?
Accessibility*	To what extent were you satisfied with your registration on the intervention platform?
Finances	Would you have done the online training even if it would have cost you money?
Physical environment	What technical difficulties were encountered during the online training?
Availability	What does it mean to you that you were able to do the online training from home?
Outcomes of care*	What exactly has changed in your everyday life as a result of the online training?
Discrepancy theory (*with regard to the above four marked dimensions)	
Outcomes of care	Please think about the expectations on your coach that you mentioned before. To what extent were these met?

master's degree candidates (AR, MG) who each conducted half of the interviews by telephone between September to November 2019. Pilot tests with the first two interviews did not require any major changes of the interview guide. The average duration of the interviews was 46 min (SD = 23, Min = 30, Max = 62).

Qualitative data was audiotaped and transcribed verbatim using the software tool MAXQDA (VERBI software, 2017) according to a transcription guide. Numbers instead of names were used to ensure the anonymity of the data. For Consolidated Criteria for Reporting Qualitative Studies (COREQ) (Tong et al., 2007) see Supplementary Table 1.

2.4.2. Analysis

The analysis followed the qualitative content analysis by Mayring (2010). The process of the data analysis is illustrated in Fig. 2.

First, analysis units were determined in the coding rules. Second, main categories were derived deductively by the UTAUT model (Venkatesh et al., 2003) and the evaluation model of patient satisfaction (Ware et al., 1978). Third, according to a deductive-inductive approach codes were created and further material was added successively. During this process, new codes were created or previous codes were changed to match the data. Furthermore, a text passage could contain several meanings and thus be coded with several codes.

Fourth, the preliminary code systems and the coding rules were then checked in further feedback loops. It was decided unanimously in the expert team that the main categories were partially resolved because deductive satisfaction dimensions (Ware et al., 1978) were not suitable for the context of digital interventions. Due to the systematic overlap between the theoretical constructs (e.g. expectations, usability, facilitating conditions), a joint coding system for acceptance and satisfaction was developed in a synergetic way.

Fifth, the final coding run was prepared by familiarizing two independent raters with the analysis method through a coding test run and discussion. Sixth, two independent raters coded all 22 transcripts based on the final code system and the final coding rules by using MAXQDA (VERBI software, 2017).

Seventh, there was a substantial level of agreement between the two raters, as shown by Kappa according to Brennan and Prediger (1981) with k = 0.73 (Landis and Koch, 1977). Data saturation was sufficient as all 71 themes were identified by at least 2 participants. In order to ensure validity, the participants were asked about their individual agreement on the identified themes via an online-survey (N = 17, 77 %). The agreement rate per theme was on average 61 % (SD = 4 %, Min = 54 %, Max = 68 %) indicating a sufficient level of agreement (see Supplementary Material 3).

2.5. Quantitative method

2.5.1. Data collection

Quantitative data were collected within PROD-A (Braun et al., 2019). Depressive symptoms were assessed at baseline using the Quick Inventory of Depressive Symptomology (QIDS-SR16) (Rush et al., 2003). The 16-item inventory is characterized by high internal consistency of α = 0.86 (Rush et al., 2003). Participant satisfaction was assessed at 9-weeks follow-up by using a German version of the Client Satisfaction Questionnaire for Internet Intervention (CSQ-I; α = 0.93) (Boss et al., 2016; Schmidt and Wittmann, 2002) adapted to IMIs based on 8 items. Side effects of the IMI program were measured by using the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP; 22 items; α = 0.86) (Ladwig et al., 2014) adapted to online-trainings at post-treatment phase.

2.5.2. Analysis

Quantitative analyses were conducted to compare the interviewed sample (N = 22) with the remaining sample of the IG of the RCT which was not interviewed (N = 149). We used Fisher's Exact Test for categorical variables (due to cell frequencies <5) and t-Test or Mann-Whitney-U Test for continuous variables. Due to unequal sample sizes, the non-parametric U Test was applied when both assumptions of the normality distribution and of variance equality were not met. It was also used for verification when the data was not normally distributed. The analyses were carried with an alpha-level of 5 %, two-sided. The software tool SPSS (IBM SPSS Statistics, 2017) was used for quantitative analysis.

3. Results

3.1. Participants and intervention use

Sociodemographic and clinical characteristics of the interview participants are presented in Table 2. Participants were on average 53.27 years old (SD = 8.14) and evenly distributed across both sexes (M = 11, F = 11). Most participants were married (n = 18, 82 %), half worked as an entrepreneur in their own company (n = 10, 45 %), and about one third reported a middle-educated level (n = 6, 36 %) (International standard classification of education (ISCED), 2012). The participants reported on average a mild depressive symptom severity at baseline, indicated by the QIDS-SR16 with a mean value of 10.09 (SD = 5.21), with 7 participants displaying mild (32 %), 13 (59 %) moderate and 2 (9 %) severe depressive symptoms.

The training "GET.ON Stress" was chosen most frequently among the interview participants (n = 11, 50 %), followed by "GET.ON Mood Enhancer" (n = 5, 23 %) and "GET.ON Recovery" (n = 2, 9 %). No participant changed the type of training and one participant (5 %) started a second training. Participants had completed an average of 5.27 modules (SD = 2.51, 78 % of all modules) at the time of recruitment for

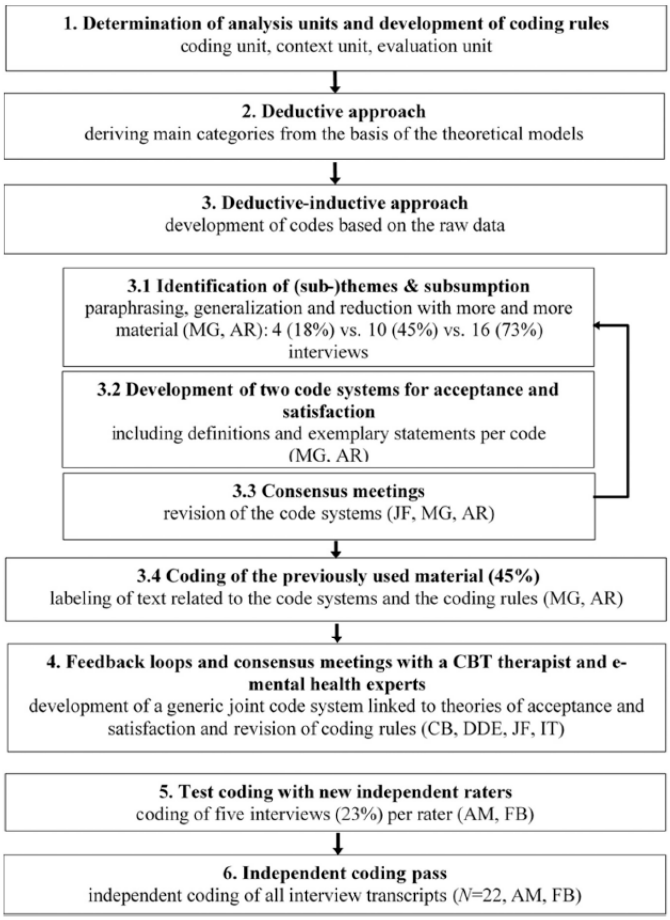

Fig. 2. Process model of qualitative data analysis based on the qualitative content analysis by Mayring (2010).

the qualitative study, while 64 % of the participants (n = 14) had a completion rate of 100 %. It took on average 90.07 days to complete the training (SD = 50.14). Satisfaction with the IMIs was reported as high (M = 25.86; SD = 6.83). 32 % of the participants (n = 7) reported negative effects attributed to the IMIs.

The interview participants did not significantly differ from non-interviewed IG participants regarding sociodemographic and clinical characteristics, although the interviewed sample completed on average more modules than the non-interviewed RCT participants. But these differences did not reach statistical significance (see Table 2).

3.2. Qualitative findings

The deductive-inductive analysis identified 71 determinants across the ten dimensions *performance expectancy* (N = 4 themes), *financing* (N = 2), *organisation* (N = 8), *e-coach* (N = 11), *usability* (N = 5), *training content and structure* (N = 15), *training usage* (N = 12), *training outcome* (N = 7), *social influence* (N = 4), and *behavioural intention* (N = 3) that were derived by the UTAUT model and the evaluation model of patient satisfaction (see Fig. 3).

Except the dimensions *performance expectancy* and *financing*, the qualitative content analysis of the other dimensions suggested to divide their results into positive and negative drivers to better represent aspects that guide the evaluation of acceptance and satisfaction. Overall, more positive drivers (N = 38, 58 %) of acceptance and satisfaction were identified compared to negative drivers (N = 27, 42 %). Positive drivers were also mentioned more frequently, as 12 positive themes yielded the highest consensus and were identified by >45 % (N = 10) of all participants. The dimension of *training content and structure* were assigned most of the determinants (N = 15, 21 %) including nine positive drivers (13 % of all 71) and six negative drivers (8 %).

Each dimension is explained in more detail in the following. All determinants are described alongside a definition and supporting quotation illustrating the participants' experiences in Table 3 in relation to acceptance (*performance expectancy, social influence*, and *behavioural intention),* in Table 4 in relation to both acceptance and satisfaction (*organisation, usability, training content and structure*, and *training usage)* and in Table 5 in relation to satisfaction (*e-coach*, *training outcome*, and finances).

Table 2
Characteristics of interviewed, non-interviewed and full sample intervention group participants.

Characteristics	IG, interviewed ($n = 22$)	IG, not interviewed ($n = 149$)	P-value[a]	IG, full sample ($n = 171$)
Age	53.27 ± 8.14	49.54 ± 9.70	0.09	50.02 ± 9.58
Gender				
Female	11 (50 %)	91 (61 %)	0.36	102 (60 %)
Relationship			0.41	
Single	1 (5 %)	6 (4 %)		7 (4 %)
In partnership	1 (5 %)	9 (6 %)		10 (6 %)
Married or registered civil partnership	19 (86 %)	125 (84 %)		143 (84 %)
Divorced or separated	1 (5 %)	5 (3 %)		6 (4 %)
Widowed	0	4 (3 %)		4 (2 %)
Level of education			0.52	
Low	7 (32 %)	66 (44 %)		73 (43 %)
Middle	8 (36 %)	41 (28 %)		49 (29 %)
High	7 (32 %)	42 (28 %)		49 (29 %)
Employment status			0.24	
Entrepreneur	10 (46 %)	81 (54 %)		91 (53 %)
Contributing spouse	6 (27 %)	42 (28 %)		48 (28 %)
Contributing family member	3 (14 %)	14 (9 %)		17 (10 %)
Pensioner or spouse of pensioner	1 (5 %)	10 (7 %)		11 (6 %)
Incapacitated for work	2 (9 %)	2 (1 %)		4 (2 %)
QIDS-SR16 score baseline	10.09 ± 5.21	9.71 ± 4.74	0.87	9.76 ± 4.79
Training type			0.10	
GET.ON Stress	11 (50 %)	90 (60 %)		111 (65 %)
GET.ON Mood Enhancer	5 (23 %)	36 (24 %)		41 (24 %)
GET.ON Recovery	2 (9 %)	13 (9 %)		15 (9 %)
GET.ON Be smart – drink less	2 (9 %)	0		2 (1 %)
GET.ON Panic	1 (5 %)	5 (3 %)		6 (4 %)
GET.ON Mood Enhancer Diabetes	0	1 (1 %)		1 (1 %)
No training selected	1 (5 %)	5 (3 %)		6 (4 %)
Number of modules completed at recruitment time	5.27 ± 2.51	4.19 ± 2.66	0.08	4.33 ± 2.66
Intervention status				
Not started	2 (9 %)	4 (3 %)	0.17	6 (4 %)
Intervention completion[b]	14 (64 %)	72 (48 %)	0.25	86 (50 %)
Treatment duration (days)	88.00 ± 91.47	78.50 ± 89.19	0.31	79.72 ± 89.27
Change of training type	0	2 (1 %)	1.00	2 (1 %)
Choice of a second training	1 (5 %)	6 (4 %)	1.00	7 (4 %)
CSQ-I ($n = 124$, total score 8–32)[c]	25.86 ± 6.83	24.94 ± 6.14	0.34	25.10 ± 6.24
INEP[c]	7 (32 %)	40 (27 %)	0.62	47 (27 %)

Note. Values are means ± SD or (%). IG = Intervention group. QIDS = Quick Inventory of Depressive Symptomology. CSQ = Client Satisfaction Questionnaire for Internet-based Interventions. INEP = Inventory for the Assessment of Negative Effects of Psychotherapy.

[a] We used Fisher's Exact Test for categorical variables and *t*-tests for continuous variables. If the normality of the data distribution and the equality of variance were not given in both samples, the Mann-Whitney *U* test was used instead.

[b] Completion is defined as completion of all modules.

[c] Assessment at 9-weeks follow-up.

3.2.1. Determinants of acceptance

Performance expectancy.

This dimension refers to the degree to which an individual believes that participation in the intervention is profitable to their occupational or private situation. Most frequently, the participants ($N = 10$, 45 %) expected that the training would enable them to better assess and improve the individual life situation. Further expectations of the participants refer to reducing stress and psychological symptoms ($N = 8$, 36 %), learning to deal with burdening situations ($N = 8$, 36 %) and improving well-being ($N = 4$, 18 %).

Social influence.

This dimension refers to the degree to which caregivers or the social environment of the participants accept and support IMI participation. More positive ($n = 3$) than negative drivers ($n = 1$) could be identified. It was found that half of the participants ($n = 11$) were actively supported by their social environment. Further positive drivers are related to acceptance of IMI participation by the social environment ($N = 4$, 18 %) and help in case of technical difficulties ($N = 4$, 18 %). The negative driver is related to no social support or rather negative reactions ($N = 6$, 27 %) were reported.

Behavioural intention.

This dimension refers to a reuse of the IMI. Two positive and one negative drivers could be determined. A high willingness to participate in the training again could be identified among most of the participants as most indicated to have had positive experiences during the participation ($n = 17$, 77 %). However, two participants (9 %) each reported a low willingness for renewed participation or renewed participation would depend on external factors (e.g. time, workload).

3.2.2. Determinants of acceptance and satisfaction

3.2.2.1. Organisation. It includes aspects regarding the access and activation of the training and its lessons, appointments with the e-coach as well as the independent organisation of the participant in order to process the IMI. More positive ($n = 6$) than negative drivers ($n = 2$) could be identified. 73 % of the participants ($n = 16$) especially raised the quick and easy access to the intervention and its lessons which they experienced as satisfactory. Further positive drivers are related to uncomplicated scheduling ($n = 9$, 41 %), written contact ($n = 7$, 32 %), low time and effort ($n = 5$, 23 %), realistic indication of the processing time ($n = 4$, 18 %), and regular reminders from the e-coach and/or the system support to keep up with the online training ($n = 3$, 14 %). Among the negative drivers, participants reported high workload per module ($n = 11$, 50 %) as well as difficulties in accessing the training or activating the modules ($n = 9$, 41 %).

3.2.2.2. Usability. In this dimension, aspects of technical infrastructure and perceived usability are considered. More negative ($n = 4$) than positive drivers ($n = 1$) have been found. Automatic buffering of unfinished modules was perceived as helpful by the participants ($n = 3$, 14 %). Problems with moving on the platform was identified as the most frequent theme ($n = 5$, 23 %). Further problems appeared due to a lacking internet connection ($n = 4$, 18 %), the complicated structure of the platform training ($n = 3$, 14 %), and technical difficulties ($n = 2$, 9 %).

3.2.2.3. Content and structure of training. This dimension refers to IMI content that influences the training outcome. Nine positive and six negative drivers have been determined. The majority of participants identified the target group-specific adaption of content and graphics ($n = 18$, 82 %) and figurative expressions ($n = 16$, 73 %) as highly beneficial. Furthermore, a diary ($n = 13$, 59 %), psychoeducation ($n = 12$, 55 %), exercises to strengthen psychosocial competencies ($n = 12$, 55 %) as well as for reflecting questioning thinking and behavioural patterns ($n = 5$, 23 %) were described as helpful. The content was easy-to-understand

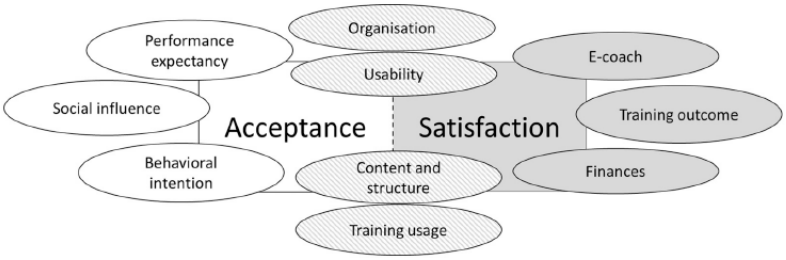

Fig. 3. Ten dimensions and their theoretical linkage with the UTAUT model for acceptance (Venkatesh et al., 2003) and/or the evaluation model of patient satisfaction (Ware et al., 1978).

(n = 11, 50 %). Positive drivers regarding the structure include the maintenance phase for after-care (n = 12, 55 %) and a small-stepped structure and success monitoring (n = 3, 14 %). Some of these aspects were identified positive drivers as well as negative ones, including psychoeducative content (n = 5, 23 %), exercises for strengthening psychosocial competencies (n = 4, 18 %), and the diary (n = 3, 14 %). Additionally, participants reported a lack of individual fit (n = 12, 55 %) and tips for transfer in daily routine (n = 5, 23 %), and described the content as complicated and lengthy (n = 3, 14 %).

3.2.2.4. Training usage. This dimension describes the degree to which the participant believes that organizational, technical, or social conditions support the use of the online training. The relationship between positive (n = 7) and negative drivers (n = 5) is relatively balanced. Participants stated that the location independence (n = 19, 86 %), the flexibility (n = 17, 77 %), as well as anonymity (n = 11, 50 %) of IMIs represent beneficial aspects with regard to training usage and costs and time could be saved (n = 9, 41 %). Training usage was facilitated by a technical support (n = 12, 55 %) as well as self-discipline and prioritization (n = 9, 41 %) and the online format seemed to be appropriate for prevention (n = 7, 32 %). Among the negative drivers, many aspects are related to personal factors, including a lack of motivation, perseverance and self-discipline (n = 11, 50 %), time (n = 10, 45 %) computer skills (n = 4, 18 %), and inhibitions about using the internet (n = 4, 18 %). Furthermore, participants experienced a lack of monitoring whether the training contents were implemented in daily life (n = 5, 23 %).

3.2.3. Determinants of satisfaction

3.2.3.1. e-Coach. In this dimension, all non-therapeutic aspects between participant and e-coach (e.g. appearance towards the participant, emotional support) as well as the expertise of the e-coach or its performance quality were taken into account. The number of positive (n = 6) and negative drivers (n = 5) is relatively similar. The majority of the participants described the relationship to the e-coach as positive and trusting (n = 19, 86 %), and emphasized the importance of a personal e-coach guidance (n = 18, 82 %), the expertise of the e-coach (n = 18, 82 %), and the support and motivation by the e-coach (n = 14, 64 %). They received individual feedback (n = 11, 50 %) and described the e-coach as empathetic (n = 4, 18 %). Among the negative drivers, participants described that the written contact prevents the therapeutic relationship building (n = 6, 27 %). The participants experienced a lack of personal contact (n = 5, 23 %), not sufficient therapeutical support (n = 4, 18 %), an objective and distant relationship (n = 3, 14 %), as well as a negative change of the relationship to the e-coach over time (n = 3, 14 %).

3.2.3.2. Training outcome. This dimension refers to the success of the IMI on the intended training goal, whether and to what extent the IMI has contributed to the improvement of the complaints. More positive (n = 5) than negative drivers (n = 2) have been determined. Training of health supporting attitudes and behaviours was mentioned here most often (n = 16, 73 %). Furthermore, participants described an increase of wellbeing (n = 14, 64 %), an improved handling of burdening situations (n = 7, 32 %), the realization of occupational changes and goals (n = 4, 18 %), and an improvement of contact with the social environment (n = 2, 9 %). The two negative drivers were related to the judgement of IMIs as insufficient in case of severe mental problems or crisis (n = 7, 32 %) and to the usage in one's own problematic environment (n = 2, 9 %).

3.2.3.3. Financing. This dimension includes factors related to the financing of training service. While some interviewees would participate at a financial effort depending on certain circumstances like the amount of costs, income, etc. (n = 8, 36 %), others would rather not participate in an IMI at a financial effort (n = 6, 27 %).

3.2.4. Discrepancy theory of patient satisfaction

Overall, 80 % of the expectations were met. The highest agreement rate was identified in the dimension *e-coach* with 89 %, followed by *organisation* with 83 %. The lowest agreement was with regard to *training outcome* with 69 %.

4. Discussion

This qualitative study investigated the experiences of farmers, forest workers and gardeners with a tailored IMI program for the prevention of depression by focusing on determinants for the acceptance of the technology and satisfaction with guided internet interventions. Results allow conclusions to be drawn about dimensions that are linked to one or both constructs.

4.1. Main findings

Summarized, 71 themes could be assigned to 10 dimensions: *performance expectancy*, *organisation*, *e-coach*, *usability*, *training content and structure*, *training usage*, *training outcome*, *financing*, *social influence*, and *behavioural intention*. Except for the dimensions of *performance expectancy* and *financing*, all dimensions were divided into positive and negative drivers that represent beneficial or hindering aspects for the acceptance of and satisfaction with IMIs.

Overall, participants mentioned more frequently positive drivers in comparison to negative drivers. The five most frequently identified drivers include 'location independence', 'positive and trusting relationship to the e-coach', 'personal e-coach guidance', 'expertise of the e-coach', and 'target group specific adaptation'. Altogether, the willingness for participating again in an IMI was high as reported by the majority of the participants. The experiences with the IMI largely correspond with the participants expectations representing an essential aspect of satisfaction according to the discrepancy theory (Lawler, 1971). At the recruitment time, 64 % of the interview participants had a

Table 3
Determinants of acceptance with the IMI program.

Dimensions	Participants (N = 22)		Definition	Supporting quotations
	N	%[a]		
Performance expectancy (N = 4) [acceptance]				
Assess/improve life situation	10	45	The participants expect that the training would enable them to better classify and improve their personal situation.	*"I've simply just hoped that I maybe find suggestions to be able to better classify the situation and simply can deal better with the situation." (P10)*
Reduce stress/ psychological symptoms	8	36	The participants expect that the IMI can reduce stress and psychological symptoms.	*"I had the expectation that I would get out of the brooding." (P15)*
Learn to deal with burdening situations	8	36	The participants expect to learn strategies to solve problems independently and to deal with stress and burdening situations.	*"I had just thought, you might be strengthened from within, that you, when push comes to shove, have the tools to help yourself." (P05)*
Improve well-being	4	18	The participants expect that their well-being (including a spirit of enterprise, mood) will improve.	*"And that I feel like doing activities again, well - what do I know - going out in the evening or something like that." (P06)*
Social influence (N = 4) [acceptance]				
Positive drivers (N = 3)				
Support from social environment	11	50	Participants experience their social environment as supportive, understanding and/ or it joins positive activities.	*"[…] That they simply took part in positive activities. […] And on the other hand they encouraged me that you are/I am in a better mood, that I am happier again […]." (P11)*
Acceptance of IMI participation by the social environment	4	18	Friends and family accept the participation in the training and give participants the necessary space they need.	*"They have accepted it that I do something like that." (P18)*
Help in case of technical difficulties	4	18	Participants receive support from family and friends in case of technical difficulties.	*"Exactly that person who I generally turn to when I have technical difficulties with the PC. That's my son-in-law in that case." (P16)*
Negative drivers (N = 1)				
No social support or rather negative reactions	6	27	Participants do not receive any support or rather negative reactions from the social environment.	*"What hindered you from trying out and implementing ideas from the online training in daily life? B: My environment here, they are not as open for stuff like that." (P05)*
Behavioural intention (for participating again) (N = 3) [acceptance]				
Positive drivers (N = 1)				
High willingness for renewed participation	17	77	The willingness to participate in the training again if needed is high among participants.	*"[…] I would do it again anytime." (P10)*
Negative drivers (N = 2)				
Low willingness for renewed participation	2	9	Participants do not want to participate in an IMI again.	*"I wouldn't participate in it again, but this doesn't mean I think it's bad, it just doesn't fit for me!" (P05)*
Renewed participation depending on external factors	2	9	The willingness to participate again if needed depends on external factors (e. g. time, workload) for participants.	*"[…] It depends on the circumstances. If there's a little more time then it could be, yes, come on, I'll try [the IMI] again." (P14)*

[a] The percentages give the proportion of all 22 interview participants who mentioned the theme.

completion rate of 100 % of all modules indicating a high behavioural use. These findings suggest a high level of acceptance of and satisfaction with the IMIs among the interviewees. Nevertheless, 27 (42 %) of the revealed themes in the study are related to negative drivers regarding to the acceptance of and satisfaction with the IMI program compared to 38 positive drivers (58 %). These are particularly important for presenting potential weaknesses of the intervention in a more differentiated way and making adjustments based on them.

Previous studies in the internet-based treatment of depression yielded inconsistent results with regard to acceptance. IMIs were often described as acceptable (Beattie et al., 2009; Schneider et al., 2014; Montero Marín et al., 2015), while other studies identified ambivalent findings regarding the acceptance of IMIs for depression treatment depending on the individual attitudes, preferences and needs of patients (Holst et al., 2017; Knowles et al., 2015). However, in this study within a preventive context, the internet-based format was perceived as appropriate. Although IMIs have been shown to be effective in severe depression (Karyotaki et al., 2018; Karyotaki et al., 2021), a number of participants (32 %) of this study considered IMIs as unsuitable for patients with severe mental illness which is consistent with the findings of Knowles et al. (2015).

In this study, some of the identified drivers appear contradictory, as they have been identified as both positive and negative. Written contact has been seen as beneficial because it can be easily integrated into everyday life, but might also affect the (building of a) relationship with the e-coach negatively. The diary was also described as beneficial as it helps to reflect one's own situation, but also as time-consuming and less helpful. Additionally, there were differences between the participants in terms of the perceived psychoeducational materials. Some of these were rated as helpful and, if already known, as less helpful. This shows the importance of a differentiated view of what IMI components can mean for participants with different needs. As Holst et al. (2017) stated, participants have diverse experience with internet-based treatment of depression.

Although the evaluated program was already tailored to individual risk factors of participants as well as adapted to agriculturists, the most frequently reported negative driver was still 'lack of individual fit'. That correspondents with previous qualitative research on patients' experiences with internet-based treatment for depression, who also reported a

Table 4
Determinants of acceptance of and satisfaction with the IMI program.

Dimensions	Participants ($N = 22$)		Definition	Supporting quotations
	N	%[a]		
Organisation ($N = 8$) [acceptance/satisfaction]				
Positive drivers ($N = 6$)				
Fast and easy availability	16	73	Participants experience a fast and easy access to the intervention platform or to the IMI modules as beneficial.	*"[…] This [the login to the intervention platform] went easy and uncomplicated. This was good." (P03)*
Uncomplicated scheduling	9	41	Date arrangements with the e-coach are easy and uncomplicated.	*"Date arrangement with the online psychologist. This worked out well actually […]" (P11)*
Written contact	7	32	The participants are able to integrate written contact well in their daily life. Date arrangements are not necessary.	*"[…] I mainly wanted written contact, because by phone, the distraction is quite high. […] or [I] didn't have the inner peace to get in contact by phone […]" (P15)*
Less time and effort required	5	23	The amount of time and work to process the training is low.	*"I had anticipated MORE amount of time, than it actually was afterwards." (P12)*
Realistic indication of the processing time	4	18	The amount of time and work required to conduct the training corresponds to the specified processing time per module.	*"It was already stated in advance how much time it would approximately take and that's how it was. Well, I didn't imagine it to be much different." (P21)*
Regular reminders	3	14	Regular reminders from the e-coach/system support participants to keep up with the online training.	*"In this respect, the reminder was also very helpful, if it [the module] was not yet complete. Otherwise I would certainly have needed a lot longer or I would not have gotten such a lesson over with so quickly." (P07)*
Negative drivers ($N = 2$)				
High workload per module	11	50	The time and effort required to carry out the training is high and a lesson can often not be completed in one session or in the designated time.	*"Though, with the timings, […] I haven't got there BY FAR. It was definitely three to four times as much time […]." (P16)*
Problems with IMI access	9	41	The participants report difficulties in accessing the training or activating the modules.	*"And to what extent were you satisfied with the activation of the training? B: […] So if you have to do it on your own as an older person, […], this is a little too complicated then." (P12)*
Usability ($N = 5$) [acceptance/satisfaction]				
Positive drivers ($N = 1$)				
Automatic buffering of unfinished modules	3	14	Participants experience automatic buffering of unfinished modules as helpful.	*"What I found very helpful is that you can save it in between and then say: Now I have no time or no more desire or whatever. I'll take a break now and continue tomorrow […]." (P07)*
Negative drivers ($N = 4$)				
Problems with moving on the platform	5	23	The participants have problems going through the modules, when clicking back or switching to other content.	*"What bothered me was that I, when I, within a module […] wanted to go to a site before then or two or three before that, it was always difficult to get there." (P19)*
Lacking internet connection	4	18	A poor internet connection, especially in rural areas, makes training use more difficult.	*"[…] I did not use this function. Because sometimes the transmission speed is part of it a little, which is sometimes not so good here in the countryside." (P17)*
Complicated structure of the platform	3	14	The platform structure is perceived as complicated. Hints regarding the use of the platform are missing.	*"[…] Maybe explanations about the program, where I have to click on, […]! I find everything so confusing. I couldn't cope with that." (P13)*
Technical difficulties	2	9	The participants have problems with downloading content or technical problems with the mobile use.	*"In between I had problems downloading these relaxation exercises, but then I managed to do it." (P03)*
Training content and structure ($N = 15$) [acceptance/satisfaction]				
Positive drivers ($N = 9$)				
Target group specific adaptation	18	82	A target group specific adaptation of IMI content increases the understanding and improves the identification.	*"That was nice to see: Oh, he's just the same as me. There was always someone where I thought it could be me too." (P01)*
Content with figurative expressions	16	73	Metaphors and figurative expressions are helpful as they increase understanding of IMI content.	*"[…] Yes, some [figurative expressions] were good. That helped to understand that."(P03)*
Diary	13	59	The diary is beneficial as a source of self-reflection.	*"[…] The decisive factor was actually being conscious, becoming conscious, consuming alcohol every day and then writing down […]." (P20)*
Psychoeducation	12	55	Training contents that contribute to knowledge building and psychoeducation are helpful for participants.	*"[…] [Psychoeducation] was VERY helpful, because you simply saw, you are not alone and […] it is no individual problem, but a disease." (P06)*
Exercises/techniques to strengthen psychosocial competencies	12	55	Exercises to strengthen psychosocial skills, such as mindfulness, relaxation or problem-solving techniques are helpful for the participants.	*"[…] the topic with the strength-giving exercises. So that it, that I personally CONSCIOUSLY should take a little time for myself every day. […] that was an important point. To take time for yourself, even when there is work all around."(P03)*
Maintenance phase for after-care	12	55	The maintenance phase with monthly contacts is helpful for participants' long-term implementation of learned training contents.	*"[…] it takes a long time until habits change. That's why it is important that there is aftercare." (P18)*
Easy-to-understand training content	11	50	The contents of the training are easy to understand.	*"[…] I was always able to take the subject matter and understand it and work through it." (P04)*
Exercises for reflecting/questioning thinking/behavioural patterns	5	23	Exercises that contribute to questioning and changing thinking and behavioural patterns are helpful for participants.	*"[…] where you should imagine that you can push away rumination, that you can push away bad thoughts a little or just pull*

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Table 4 (*continued*)

Dimensions	Participants (*N* = 22)		Definition	Supporting quotations
	N	%[a]		
				them out at a specific appointment. This was quite helpful certainly. […].” (P10)
Small-stepped structure and success monitoring	3	14	For the participants, a small-step approach and success control are helpful to change behavior and quickly gain a sense of achievement.	*“[…] That was actually quite helpful. And this step-by-step procedure always with the success control in between and also the reminder that you are sticking to it.” (P18)*
Negative drivers (N = 6)				
Lack of individual fit	12	55	The training content and the support provided by the e-coach are perceived as standardized and unsuitable for the individual situation.	*“What hindered you from implementing ideas from the online training into daily life? B: (exhales) Sometimes it just didn’t fit me.” (P01)*
Missing tips for transfer in daily routine	5	23	The participants lack implementation assistance/tips for the realization of the training contents into daily life.	*“What I find difficult […] is the point to express gratitude and appreciation towards others. I might have needed even more specific tips or specific,[…], help to get started there.” (P06)*
Psychoeducational contents already familiar	5	23	Psychoeducational contents were already familiar among participants and thus are less helpful.	*“[…] I believe that wasn’t new to me so I would say: Aha, this can be a depression, when you feel dull. No, well, less helpful […].” (P14)*
Not relevant exercises/techniques for strengthening psychosocial competencies	4	18	Participants describe exercises/techniques for strengthening psychosocial competencies as less helpful.	*“Partly also any exercises, for example how to handle such situations, when you have a panic attack, […] That wasn’t useful for me, because I have no trigger for these panic attacks.” (P01)*
Complicated, lengthy contents	3	14	The participants experience some training contents as complicated and lengthy.	*“You had to read some questions two-three times to understand them, because it was just, how do I say it was written too complicated, I would say.” (P12)*
Time-consuming or unhelpful diary	3	14	The diary is very time-consuming and less helpful.	*“[…] I kept up with the stress diary only on the first days […] It was too much effort for me then […].” (P03)*
Training usage (*N* = 12) [acceptance/satisfaction]				
Positive drivers (N = 7)				
Location independence	19	86	Location independence of the training facilitates participation.	*“Yes, in principle, the advantage is that you can do it from home.” (P05)*
Flexibility	17	77	The free and self-determined IMI usage is beneficial for the participants.	*“The self-determination. When I do it, when it suits ME, then I do that.” (P18)*
Anonymity	11	50	For the participants it is an advantage that the training can be used anonymously.	*“The fact that you’re more anonymous could be an advantage, that could mean a faster entry.” (P14)*
Technical support	11	50	In case of technical difficulties, participants have the possibility to contact the support or the e-coach.	*“How did you deal with these difficulties? B: I contacted the support and received help there.” (P21)*
Self-discipline and prioritization	9	41	Self-discipline and prioritization are helpful for participants to implement the training into daily life.	*“[…] That takes a portion of self-discipline. That you just say, only THAT is important now and the other thing I’ll leave for now.” (P18)*
Saving of costs and time	9	41	Participants see it as an advantage to save time by eliminating travel and waiting times as well as (fuel) costs.	*“We are in the countryside, where most of the time a ride is connected with a half hour drive one way. And that makes it so much easier.” (P21)*
Appropriate format for prevention	7	32	Due to the low threshold, the online format is suitable for a prevention offer.	*“[…] I did not have these really big problems […]. I had this problem, but for that I wouldn’t have gotten medical treatment or something.” (P02)*
Negative drivers (N = 5)				
Lack of motivation, perseverance and self-discipline	11	50	A lack of motivation, perseverance and self-discipline impede the implementation of the training contents in daily life.	*“[…] it was sometimes difficult for me to bring myself to do it then. […] that I can’t or couldn’t pull myself together.” (P16)*
Lack of time	10	45	Lack of time (due to workload among other things) is a barrier for implementing training contents into daily life.	*“What else hindered me […] That it simply doesn’t work, because you are still busy at work or have more appointments or had to work more at that time[…]”(P18)*
Lack of monitoring in the implementation of IMI content	5	23	Participants experience a lack of monitoring whether the training contents were implemented in daily life.	*“[…] You can intend to do something in the online training, write something down, but, it can’t or it won’t be revised, if you indeed did it.” (P15)*
Lack of computer skills	4	18	Participants report that a lack of PC skills makes it difficult to participate in the training.	*“I don’t have that much knowledge of computers now. It takes me a long time to understand that […].” (T13)*
Inhibitions about using the internet	4	18	Participants have concerns using the internet for the training or a negative attitudes towards the internet and/or data security.	*“With data protection, I have doubts, if that is guaranteed. Because the assignment of codes, they always allow that data can be traced again and again […].” (P14)*

[a] The percentages give the proportion of all 22 interview participants who mentioned the theme.

wish for more individualization (Darvell et al., 2015; Montero Marín et al., 2015; Knowles et al., 2015; Gega et al., 2013). However, whether a higher degree of individualization would lead to better adherence and/or outcomes remains an open research question and, to our knowledge, has yet to be examined in clinical trials. In addition, the findings of this study suggest that a ‘target group-specific adaptation’ before implementation might represent a way to increase the program’s fit with the participants.

Consistent with previous research on internet-based depression treatment (Holst et al., 2017; Darvell et al., 2015), the qualitative results point towards the importance of human guidance. The majority of participants described the relationship to the e-coach as highly positive and trusting. This is consistent with the findings of Beattie et al. (2009) where many patients were surprised about the quality of the relationships they were able to build online. Furthermore, some participants felt the need for more e-coach contact and described the therapeutic support as insufficient. This is consistent with the results of a study on guided internet-based depression treatment (Bendelin et al., 2011) where some participants needed more therapeutic support. However, too much therapeutic contact can also be experienced as negative if the contact is perceived as inappropriate and its extent might be of different importance for the patients (Bendelin et al., 2011). Therefore, future studies

Table 5
Determinants of satisfaction with the IMI program.

Dimensions	Participants (N = 22)		Definition	Supporting quotations
	N	%[a]		
E-coach (N = 11) [satisfaction]				
Positive drivers (N = 6)				
Positive and trusting relationship to the e-coach	19	86	The relationship to the e-coach is positive, amicable and trustworthy or rather became more intensive over time.	*"Well, that was good on the phone call! I had the feeling that I was in good hands there. That was good communication and that wasn't wrong!" (P13)*
Personal e-coach guidance	18	82	The participants describe the contact with the e-coach as an important part of the IMI.	*„[…] it was good that you had somebody […] PERSONALLY, I think, this is important. Just alone, this is not enough!" (P03)*
Expertise of the e-coach	18	82	The participants experience the e-coach as professional and competent.	*"And to what extent have you felt competently advised through your coach? B: There I felt advised in a very competent way." (P10)*
Support and motivation by the e-coach	14	64	The participants feel supported, encouraged and motivated by the e-coach.	*"[…] [the e-coach] Pointed out to me, gave me the COURAGE to continue and try it again anyway." (P03)*
Individual feedback from the e-coach	11	50	The e-coach gives individual feedback and addresses the personal situation. The e-coach has empathy and responds to the needs of participants.	*"[…] He responded to the questions, which I asked, and I find this is very positive […]." (P12)*
Empathy of the e-coach	4	18		*"[…] The empathy was certainly great. […]. How he [the e-coach] can also touch upon personal questions." (P18)*
Negative drivers (N = 5)				
Written contact prevents the therapeutic relationship building	6	27	In the case of written contact, it is difficult to establish a relationship with the e-coach.	*"It was an open contact [to the e-coach], but also a certain distance due to the writing." (P19)*
Lack of personal contact	5	23	Participants miss the personal contact.	*"[…] I could just imagine, not directly now, but indirectly, you just don't have personal contact […]" (P12)*
Therapeutical support not sufficient	4	18	Participants experience the therapeutical support as poor, not sufficient or even negative due to pressure from the e-coach.	*"[…] There have been two, three calls. I don't think it was much more, three, maybe four. […] I expected more. […]" (P11)*
Objective, distant relationship to the e-coach	3	14	Participants experience the relationship with the e-coach as factual or distant.	*"How would you describe your relationship to the coach? B: (.) objective, rational, short and brief." (P14)*
Negative change of the relationship to the e-coach	3	14	The relationship with the e-coach changed negatively over time, participant and/or e-coach were less motivated.	*"[…] I have to say, towards the end the coach wasn't that motivated anymore. […]" (P20)*
Training outcome (N = 7) [satisfaction]				
Positive drivers (N = 5)				
Training of health supporting attitudes/ behaviours	16	73	The training supported the participants in developing health-promoting attitudes and behaviours.	*"[…] I take more breaks, I consciously take more time for positive activities […]." (P06)*
Increase of wellbeing	14	64	Participants report an improvement in their wellbeing through the intervention.	*"[…] I also have more pleasure and driving force additionally. I got more energy to change things […]." (P06)*
Improved handling of burdening situations	7	32	Participants experience an improved handling of stress and burdening situations in daily life.	*"Life is as it is […]. That's why the summer was even worse than the ones before. But I got along better with it." (P19)*
Realization of occupational changes and goals	4	18	Participants succeeded in making occupational changes and implementing occupational goals.	*"[…] On the one hand we redesigned the company. […] What I had in mind for a long time actually, but what I achieved just now." (P06)*
Improvement of contact with the social environment	2	9	The contact or rather the communication of participants with their social environment improved.	*"And what changes do you notice in the private sphere? B: […] more relaxed or more friendly dealing with family and my fellows." (P06)*
Negative drivers (N = 2)				
Insufficient for acute problems	7	32	Participants judge the online training as insufficient in case of severe mental problems or situations of crisis.	*"[…] I believe, when someone somehow got into a specific crisis situation […], then I believe the contact would be too SLOW." (P06)*
IMI usage in one's own (problematic) environment	2	9	IMI usage at home reinforces avoidance behavior and prevents a distant view from the outside	*"However, the disadvantage is that you are in your own environment […]. I think, it is maybe MORE HELPFUL, if you can get out of your own environment […]." (P15)*
Financing (N = 2) [satisfaction]	8	36		

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Table 5 (*continued*)

Dimensions	Participants (N = 22)		Definition	Supporting quotations
	N	%[a]		
Willingness to pay for the IMI depends on circumstances			The willingness to pay for participation depends on the amount of costs, income, etc.	*"[…] [the willingness to pay] depends on how much it would cost and how my financial position would look like then." (P21)*
Low willingness to pay for the IMI	6	27	The willingness to participate in an IMI at a financial effort is either low.	*"[…] NO, I hadn't [pay for the IMI]. I have to say honestly. I hadn't." (P12)*

[a] The percentages give the proportion of all 22 interview participants who mentioned the theme.

should explore whether adherence and/or outcome might potentially be improved by individualising the intensity, format and function of guidance according to individual needs.

Likewise, location independence and saving of cost and time (Ebert et al., 2018a) were reported as very important for the interviewees who mostly live in rural areas with long waiting times for on-site psychotherapy (Bundespsychotherapeutenkammer, 2018). The anonymity of IMIs (Buntrock et al., 2014) was also stated as beneficial, which could possibly counteract the reported stigma surrounding mental disorders and resistance to mental health care in rural areas (Judd et al., 2006). At the same time, the use of IMIs is partially hindered by a lack of internet connection in rural regions according to the participants. Therefore, digitization initiatives are crucial in order to ensure the provision of a sufficient broadband network (Bundesvereinigung, 2017). Moreover, implementation of IMIs into clinical routine should carefully reflect on whether patients are forced to have on-site contact e.g. for diagnostic and monitoring reasons, as it may counteract patients' preference for anonymity as a driver for depression prevention uptake.

The flexible use of the training, an often reported benefit of IMIs for depression treatment (Gerhards et al., 2011; Holst et al., 2017; Beattie et al., 2009; Knowles et al., 2015; Bendelin et al., 2011), was found to be highly relevant for the majority of the interviewees. The results of the PROD-A RCT in this target group showed that the completer rate of the IMI was only 22 % after 9 weeks and increased to 51 % after 6 months and 56 % after 12 months (Braun et al., 2021a; Braun et al., 2021b). These results suggest that especially if farmers can participate in an IMI at their own pace, the utilization rate could be increased. This specific target population is particularly affected by seasonal workload, what limits a regular participation in duration and frequency of training use. However, a high degree of flexibility might both enable some participants to stick with the training or support procrastination tendencies in others.

Our qualitative findings provide new possible explanations for the reported low treatment adherence in this occupational group (Braun et al., 2021a; Braun et al., 2021b). Since the number of modules completed is likely related to treatment outcome (Donkin et al., 2011) and low adherence could have various reasons (Christensen et al., 2009), more insight into the needs and experiences of the participants is essential as examined in this study. These explanations based on this study include identified drivers regarding individual aspects, such as a lack of motivation, time, and computer skills, or inhibitions about using the internet in general that might have a negative effect on IMI usage. These results are in line with previous research on patients' experience as well as on adherence of IMIs for depression prevention and treatment where inadequate computer skills (Gerhards et al., 2011), a negative attitude towards computer use, personal circumstances, and time constraints (Eccles et al., 2021; Christensen et al., 2009; Waller and Gilbody, 2009 May) were reported. Other reported negative aspects regarding the acceptance and satisfaction of the implemented IMI program in this study are related to the intervention itself (e.g. high workload per session, problems with access, complicated and lengthy content, lack of clarity on the platform). Treatment length (Christensen et al., 2009), high workload (Halmetoja et al., 2014), content complexity and program functionality (Eccles et al., 2021) are in line with previous findings in the investigation of adherence in IMIs.

4.2. Limitations

The results should be interpreted in light of the following limitations. Firstly, the interview sample was self-selected, small, showed higher satisfaction with the IMIs as well as higher usage rates than the remaining participants of the intervention group (63 % vs. 48 % participants completed all modules). This limits the representativeness of the results. Participants with higher usage rates received more treatment and might tend to experience a higher level of acceptance and satisfaction and thus report more positive aspects. However, there was no significant difference in participant satisfaction between the interview sample and the intervention group (eventually due to limited power). Nevertheless, the focus on individuals with low adherence might have given more insight into why people might not completed the intervention.

Secondly, the sample was recruited from the intervention group of an RCT, which reduces the transferability to routine care. In the context of the RCT, the participants are paid more attention (e.g. through scientific surveys) than in routine care, which might affect their (response) behavior ("response bias") (Paulhus, 1991). Different recruitment procedures are used in routine care (Freund et al., 2020) compared to the RCT (Braun et al., 2019). In routine care, the participant can choose between seven different IMIs (Freund et al., 2020) while in the RCT, between six IMIs (Braun et al., 2019).

Thirdly, the deductive analysis approach led to difficulties when developing the code system. A generic joint coding system for acceptance and satisfaction was finally developed due to the overlapping of the dimensions of acceptance and satisfaction as the two constructs are closely related. User acceptance is often referred to as the process of accepting, experiencing and being satisfied with an intervention (Rost et al., 2017). Some dimensions of the satisfaction model did not fit into the IMI context, and therefore, the deductive main categories were partially resolved. As a result, a joint consideration of the dimensions across all theories appeared suitable from a methodological point of view. At the same time, a deductive-inductive approach is common in qualitative research (Schreier, 2014).

Fourthly, the intervention program consisted of different IMIs that were allocated based on the personal symptom profile in order to maximize individual fit. However, due to a limited sample size and an unequal frequency of use between training types, this study was unable to take into account the differences between the various trainings.

4.3. Implications

Based on the study results, various implications for intervention development, future research and clinical practice can be made. Intervention-related aspects can be used to improve the future development of the IMI program and facilitate its implementation into routine care. For this, negative intervention-related drivers should be reduced as well as positive drivers maintained. The different needs and preferences of the participants could possibly be taken into account through more individualization of the intervention (e.g. by asking for previous knowledge on psychoeducation, including diary as an optional element, adapting the extent of therapeutic guidance to the individual needs). The effects of these adaptations should in turn be examined in terms of outcomes such as satisfaction. Additionally, possible reasons for low adherence should be examined in more detail by focusing on

participants with less completed modules or conducting sub-group analysis to compare completer and non-completer (Braun et al., in press).

Theoretical implications for future research can also be derived. Acceptance is a very broad construct that is operationalized very differently in research. Methodological challenges in terms of defining user acceptance, distinct operationalization of concepts and measurements often limit the meaningfulness of research findings (Rost et al., 2017). A strong theoretical reference, as seen here in the study, can be helpful to approach acceptance and satisfaction. At the same time, previous theoretical models in clinical research are little tailored to the setting of internet interventions. The present study offers initial indications of how such an adjustment could succeed. In addition, little is known about the acceptance of and satisfaction with IMIs in a preventive setting. More research in the field of digital prevention of depression with diverse occupational groups is needed. Further research should investigate which measures can be used to improve tailoring in order to better meet participants' needs and to increase the context-fit. Future studies should also be conducted with a larger sample in order to gain insights into different IMI types. In addition, participant experiences with a second training should be given greater consideration.

5. Conclusion

The study provides new findings in the digital prevention of depression in the agricultural setting. The qualitative results predominantly suggest the acceptance of and satisfaction with the IMI program in this target group and therefore support the intention to implement IMIs in routine care in the long term. Nevertheless, some negative drivers have been identified which help to understand potential weaknesses of the intervention. The qualitative results can be used towards further development and adjustment of digital interventions. Many positive drivers are related to the e-coach guidance, which seems to be of great importance for participants. Since the interviewees report diverse experiences in terms of IMI content and usage, more individualization of the IMIs may be necessary.

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Ethics approval and consent to participate

PROD-A was approved by the ethics committee of the University of Ulm (No. 454/17) and registered in the German Clinical Trial Registration (DRKS00014000) on April 9th, 2018. The implementation study was approved by the ethics committee of the Friedrich-Alexander-University of Erlangen-Nürnberg (12.02.2019) and registered in the German Clinical Trials Register (DRKS00017078) on April 18th, 2019.

Written informed consent for participation in the study was obtained from all participants and is stored at the Friedrich-Alexander-University Erlangen-Nürnberg.

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CRediT authorship contribution statement

DDE, HB and MB obtained funding for the SVLFG evaluation project. JF, IT, JT and LB developed the study design and interview guide. JF was responsible for recruitment of interview participants from PROD-A, coordination and collection of interview data for PROD-A participants. LB was responsible for data collection of the PROD-A trial. JF and IT were responsible for the evaluation method. JF was responsible for the analyses and development of code system. IT, CB and DDE provided feedback on the code system. IT supervised the trial management, data collection and analyses as operational lead of the project. JF drafted the manuscript. IT supervised the further writing of the manuscript. All authors provided critical revision of the article and approved the final manuscript.

Declaration of competing interest

HB has received consultancy fees and fees for lectures/workshops from chambers of psychotherapists and training institutes for psychotherapists in the e-mental-health context.

DDE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy.

MB is scientific advisor of mentalis GmbH and GET.ON Institute/HelloBetter, both providers of digital mental health care products and services. MB is also co-founder and stakeholder of mentalis GmbH.

DDE is stakeholder of the GET.ON Institute/HelloBetter, which aims to implement scientific findings related to digital health interventions into routine care.

IT reports to have received fees for lectures/workshops in the e-mental-health context from training institutes and congresses for psychotherapists. She was the project lead for the research project ImpleMentAll (funded by the European Commission) at GET.ON which aimed to investigate the effectiveness of tailored implementation strategies compared to implementation as usual (11/2017–03/2021).

JF, CB, JT, LB report no conflicts of interest.

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4.6 Article 6

Authors: Johanna Freund, David Daniel Ebert, Janika Thielecke, Lina Braun, Harald Baumeister, Matthias Berking, & Ingrid Titzler

Title: Using the Consolidated Framework for Implementation Research to evaluate a nationwide depression prevention project (ImplementIT) from the perspective of health care workers and implementers: Results on the implementation of digital interventions for farmers

Journal: Frontiers in Digital Health

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Summary:

Depression is a major public health concern, and thus, preventive interventions are vital. Farmers and related occupations have a higher risk of developing depression compared to other occupational groups. The project "With Us in Balance" from the SVLFG evaluates the potential of digital interventions, including a guided internet-based program and personalized tele-based coaching, to prevent depression in an agricultural setting. While user outcomes (e.g., effectiveness) are promising, little is known about implementing digital interventions. This study aimed to evaluate determinants affecting the uptake and implementation of digital interventions from the perspective of healthcare workers and intervention implementers. This mixed-method study consisting of online surveys and focus groups was based on the CFIR. Many facilitating factors among participants (N = 93) were identified concerning the CFIR dimensions "intervention characteristics" (e.g., evidence and quality) and "inner setting" (e.g.,

the relative priority of the digital interventions compared to existing services). Barriers to implementation were revealed about the "outer setting" (e.g., patient needs and resources), the "inner setting" at the SVLFG (e.g., access to knowledge and information), and "characteristics of individuals" (e.g., self-efficacy). In the CFIR dimension "implementation process", facilitating and hindering factors were identified. Implementers and healthcare workers appeared to be widely accepting digital services for depression prevention. However, the findings also revealed barriers to implementation, which help to derive recommendations for future implementation strategies. Particular attention should be given to the "outer setting", such as increasing awareness of mental health problems among farmers, and barriers regarding the "inner setting".

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Contribution:

Johanna Freund was the study's principal investigator and the first author of the published article. She developed the idea and design for the study and the focus group guide. Johanna Freund selected the theoretical framework and measures and was responsible for the recruitment of participants, study coordination, data collection, and development of the code system. Johanna Freund conducted the analyses. She drafted the manuscript while receiving feedback from the co-authors.

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EDITED BY
Christiaan Vis,
VU Amsterdam, Netherlands

REVIEWED BY
Derek De Beurs,
Trimbos Institute, Netherlands
Maddalena Fiordelli,
University of Italian Switzerland, Switzerland

*CORRESPONDENCE
Johanna Freund
johanna.freund@fau.de

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Using the Consolidated Framework for Implementation Research to evaluate a nationwide depression prevention project (ImplementIT) from the perspective of health care workers and implementers: Results on the implementation of digital interventions for farmers

Johanna Freund[1,2]*, David Daniel Ebert[2], Janika Thielecke[1,2], Lina Braun[3], Harald Baumeister[3], Matthias Berking[1] and Ingrid Titzler[1]

[1]Department of Clinical Psychology and Psychotherapy, Institute of Psychology, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany, [2]TUM Department of Sport and Health Sciences, TU Munich, Munich, Germany, [3]Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University, Ulm, Germany

Introduction: Depression has a significant impact on individuals and society, which is why preventive measures are important. Farmers represent an occupational group exposed to many risk factors for depression. The potential of guided, tailored internet-based interventions and a personalized telephone coaching is evaluated in a German project of the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG). While user outcomes are promising, not much is known about actual routine care use and implementation of the two digital health interventions. This study evaluates the implementation from the perspective of social insurance employees to understand determinants influencing the uptake and implementation of digital interventions to prevent depression in farmers.
Methods: The data collection and analysis are based on the Consolidated Framework for Implementation Research (CFIR). Health care workers ($n = 86$) and implementers ($n = 7$) completed online surveys and/or participated in focus groups. The surveys consisted of validated questionnaires used in implementation research, adapted items from the CFIR guide or from other CFIR studies. In addition, we used reporting data to map implementation based on selected CFIR constructs.
Results: Within the five CFIR dimensions, many facilitating factors emerged in relation to intervention characteristics (e.g., relative advantage compared to existing services, evidence and quality) and the inner setting of the SVLFG (e.g., tension for change, compatibility with values and existing working processes). In addition, barriers to implementation were identified in relation to the outer setting (patient needs and resources), inner setting (e.g., available resources, access to knowledge and information) and characteristics of individuals (e.g., self-efficacy). With regard to the implementation process, facilitating factors (formal implementation leaders) as well as hindering factors (reflecting and evaluating) were identified.
Discussion: The findings shed light on the implementation of two digital prevention services in an agricultural setting. While both offerings seem to be widely accepted by health care workers, the results also point to revealed barriers and contribute to recommendations for further service implementation. For instance, special attention should be given to "patient needs and resources" by raising awareness of mental health issues among the target population as well as barriers regarding the inner setting.

Clinical Trial Registration: German Clinical Trial Registration: [DRKS00017078]. Registered on 18.04.2019

KEYWORDS

implementation, internet-based intervention, telephone coaching, consolidated framework for implementation research (CFIR), prevention, depression, mental health, farmers

1. Introduction

Depression is a highly prevalent disorder (1) and the leading cause of disability worldwide (2). Yet despite its high burden on individuals and society, depression often remains untreated due to stigma (3) inadequate mental health resources (4), and the preference to manage problems on one's own (5). Moreover, existing evidence-based treatments for mental disorders can reduce the burden of mental disorders by only one-third (6). Measures to prevent depression are therefore becoming increasingly important (7).

For depression treatment, there are increasing numbers of internet- and mobile-based interventions and research studies (8–12). Internet-based interventions (IBIs) may be widely used, and since they are easily accessible (13), they may help individuals overcome barriers to obtaining face-to-face mental health care (14). According to a recent meta-analyses, IBIs can effectively treat depression (15) as well as subclinical depressive symptoms and help to prevent the onset of major depressive disorder (16). Similarly, tele-based interventions offer many of the same advantages, such as easy access and flexibility (17). The effectiveness of telemedicine services for depression treatment has been demonstrated by a meta-analysis indicating that the outcomes of tele-therapy do not differ from those of face-to-face-therapy (18).

For depression prevention, the potential of digital interventions including guided, tailored IBIs and personalized telephone coaching (TC) is evaluated with several RCTs and implementation studies in the German project "With us in balance" of the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG). Farmers and related occupational groups are exposed to many risk factors for depression such as a high workload, financial worries, poor weather conditions, and health problems (19–23) and have a higher risk of mental health issues, especially depression, compared to other professional groups (22, 24–26). As their help-seeking behavior is often restricted due to its stigmatization (25) and limited mental health care in rural areas (27), the SVLFG introduced digital interventions for their insured members to compliment existing but limited onsite prevention services to overcome barriers to care.

The results of the "With us in balance" project based on a randomized controlled trial (RCT) showed a small effect on the reduction of depressive symptoms through guided IBIs at 9-weeks post-treatment ($d = -0.28$, 95% CI: −0.50 to −0.07) and at 6-month follow-up ($d = -0.35$, 95% CI: −0.57 to −0.14) compared to treatment-as-usual (TAU) (28, 29), while no effects could be found at 12-month-follow-up (28). First results on the effectiveness of the personalized TC demonstrated a small to medium effect on the reduction of depressive symptoms ($d = -0.39$, 95% CI: −0.15 to −0.64) at 6-month posttreatment in comparison to TAU (30). The implementation study "ImplementIT" (31) aims to evaluate the implementation of the digital interventions into routine care. First qualitative results regarding acceptance of and satisfaction with the digital intervention as well as barriers and facilitators for use from the perspective of participating farmers, forest owners, and gardeners have been explored (17, 32, 33). The results indicate that these offers could be suitable for the target group as interviewees reported that digital interventions helped them overcome barriers to treatment and brought specific benefits such as "flexible use", "anonymity", and "location independence" (32, 33). At the same time, "time-consuming work life" and "time-consuming private life" were the most often mentioned barriers regarding intervention use (32). However, besides RCT participation, in which low adherence regarding intervention use (28, 29) and recruitment difficulties (34) are reported for IBIs, not much is known about routine care use. Therefore, it is critical to understand the factors that influence the uptake and implementation of both digital health interventions.

As noted in a recent scoping review (35), there is little existing research on the implementation of digital interventions for depression in routine care and leadership and organizational factors have been largely neglected in previous studies on the implementation of digital interventions. Similarly, in the field of depression prevention, there is scant research on the implementation of digital interventions. The existing studies are limited to the internet-based prevention of eating disorders in young adults (36) and depression in adolescents (37). Therefore, further research on the implementation of digital interventions for depression prevention, especially regarding organizational aspects, is needed. In this project, health care workers are involved in the consultation and referral process to digital interventions and thus, play a central role as gatekeepers in the management of depression prevention at the social insurance company. In the broadest sense their working activity is comparable with the referral role of general practitioners (GPs), whose referral behavior can be influenced by skepticism and negative attitudes (38). Therefore, it is essential to understand determinants influencing professionals' attitudes and behavior. Furthermore, the implementation of the digital interventions leads to a behavioral change among health care workers who previously have not advised on digital health services or health services in general. As recommended in previous studies (39–41), behavioral change should be investigated on a theoretical basis to guide the selection of constructs.

The aim of this study is to evaluate the implementation process from the perspective of health care workers to understand the barriers and facilitating factors in the uptake and implementation of digital interventions to prevent depression in farmers, forest owners, and gardeners. Additionally, the use of dissemination and implementation strategies is examined.

2. Methods

2.1. Study design

As defined in the study protocol of ImplementIT (31), the implementation study follows a mixed-methods design with quantitative (surveys, reporting data) and qualitative approaches (focus groups, open questions). The stepwise implementation determining the availability of the digital interventions across all federal states in Germany is illustrated in Figure 1. According to the Conceptual Model of Implementation Phases (42), the study can be divided into the phases "exploration", "preparation", "implementation" and "maintenance". The evaluation is based on the established Consolidated Framework for Implementation Research (CFIR) (43), which has already been applied in a similar setting (44). The CFIR (43) unifies constructs from various implementation theories and offers a pragmatic structure to assess complex and interacting states in the implementation across five domains consisting of four to eight constructs. The first domain is related to characteristics of the implemented intervention and includes constructs such as "evidence strength and quality", "relative advantage", and "adaptability". The second domain is the outer setting and includes constructs from the cultural, political, and structural context (e.g., "patient needs and resources", "external policies and incentives") that influences the implementation. The third domain includes aspects with regard to the inner setting (e.g., "networks and communications", "culture", "readiness for implementation"). The fourth domain is related to characteristics of the individuals involved in the intervention/implementation (e.g., "knowledge and beliefs about the intervention", "individual stage of change", "other personal attributes"). The fifth domain is the implementation process and includes constructs such as "planning", "engaging", and "reflecting and evaluating". The study is described alongside Standards for Reporting Implementation Studies; see the StaR checklist (45) as supplementary.

2.2. Interventions

The SVLFG advertises its health services through public relation (PR) activities. In addition, insured persons are also advised on the health services by field workers and in-house staff. During consultations at the SVLFG call center, insured people who meet the eligibility criteria of SVLFG receive detailed information on what prevention services they can access. They can choose between digital interventions (e.g., IBIs, TC) or group preventive services delivered onsite. The call center agents carry out the registration process. The digital mental health interventions that are provided free of charge for the insured are described in detail in the study protocol (31) and summarized below.

2.2.1. Guided IBIs

After receiving an access code for the guided IBIs from the SVLFG call center, the participant can register on the service company's online platform (www.geton-institut.de). The IBIs consist of three intervention phases: (1) the participant completes a *psycho-diagnostic assessment* based on self-report-questionnaires. One of seven trainings is selected based on the assessment and the participant's individual preferences during the initial phone call with the e-coach. (2) The participant completes the IBI in the *active training phase* with personal e-coach (psychologist who has started at least psychotherapeutic training) guidance consisting of feedback *via* e-mail or phone. The IBI "GET.ON Stress" is based on the transactional model of stress and coping (46), the IBI "GET.ON Chronic Pain" on Acceptance and Commitment Therapy (47), and all other IBIs on Cognitive Behavioral Therapy (CBT) principles ("GET.ON Mood Enhancer", "GET.ON Mood Enhancer Diabetes", "GET.ON Recovery", "GET.ON Panic", "GET.ON Be smart—Drink less"). The IBIs consist of 6–8 weekly modules including psycho-educative information, exercises, interactive elements (e.g., auditory material, videos clips), and statements from exemplary people. Prior to implementation, all trainings were adapted to the agricultural setting and target group with regard to content and graphics. After completing the active training phase, participants have the option to conduct a second guided IBI in consultation with the e-coach. (3) The final *maintenance phase* enables monthly e-coach contact *via* text or telephone for up to 12 months.

2.2.2. Personalized tele-based coaching

Personalized tele-based coaching is provided by the company IVPNetworks (www.ivpnetworks.de). SVLFG call center agents register participants on the IVPNetworks management and

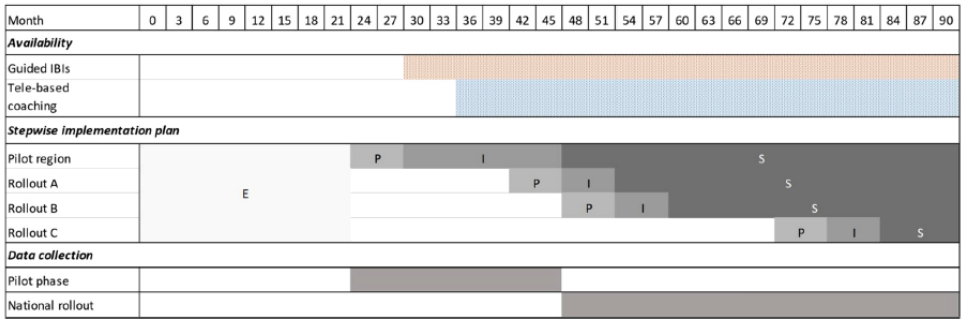

FIGURE 1
Project timeline including exploration (E), preparation (P), active implementation (I), and sustainment (S) phase per rollout area.

documentation platform (IVPnet 2.0), and a case manager at IVPNetworks assigns the participant to a coach. The coaches are psychologists with training in different psychological methods (e.g., systemic therapy, psychodynamic psychology, hypnotherapy, CBT) and supervision by licensed psychotherapists. There are no standardized manuals for the coaching. Coaching methods depend on the coach's professional and therapeutic background. According to the coaches, the TC can generally be described to entail an "initial phase" (e.g., contact bilding and problem definition), a "working phase" (e.g., problem solving) and a "stabilizing phase" (maintaining effects) (30). The coaching is personalized in terms of number, duration, and frequency of the sessions, depending on the individual participant's needs. A period of 850 min (or 6 months) is set as the maximum, with the possibility of an extension of another 150 min (or 3 months). Participants can be supported in finding onsite social care services (e.g., agricultural socioeconomic or family counseling) and, alternatively, if indicated, in using onsite coaching.

2.3. Recruitment and data collection

Employees from the following fields at the SVLFG were included in the study:

- Staff involved in the referral process who provide advice on and referral to health services including digital and onsite offers, such as field workers, in-house staff, and call center agents. Since the advice on health offers had to be newly introduced (field workers, in-house staff) or the previous advice had to be adapted or extended to include the digital offers (call center agents), these employees experienced changes in their daily work.
- Staff involved in the strategic planning and conduction of implementation activities (implementation team).

Employees who work as both call center agents as well as implementation team members were excluded from the staff surveys for employees involved in the referral process due to mixed roles, in order to avoid any bias in the data. These employees were only able to participate in the surveys for the implementation team.

Employees were recruited from March 2018 to June 2021 for study participation while engaging in one of six kickoff events in the respective rollout area (e.g., for field workers, in-house staff as well as call center agents) at which the digital offerings and the accompanying implementation study were presented. Since the training of the pilot rollout employees has already taken place in 2017/2018, they were invited to the study *via* their supervisors (by e-mail and at internal meetings) in spring 2019. In total, 365 employees involved in the referral process have been invited for study participation and received an informed consent. The study team sent about two reminder e-mails to the respective group of employees to increase the study enrollment and response rate. In total, 86 employees involved in the referral process (86/365, 23.6%; $n = 75$ field workers and in-house staff; $n = 11$ call center agents) and seven implementation team members (7/7, 100%) signed the informed consent.

An overview of employee surveys and response rates from May 2019 until May 2022 per occupational group and rollout area is illustrated in Table 1. The time of the survey varied depending on the employee group and rollout area (consisting of 2–7 federal states of Germany). Data collection occurred at regular 6-month intervals from May 2019 to May 2022. Employees in the pilot area (Bavaria, Schleswig-Holstein) and Rollout Area A (Bremen, Lower Saxony, Saxony-Anhalt) were surveyed from May 2019 to May 2021, and employees from Rollout Area B (Hesse, North Rhine-Westphalia, Rhineland-Palatinate, Saarland) from November 2019 to May 2021. Employees from Rollout Area C (Baden-Württemberg, Berlin, Brandenburg, Mecklenburg-Western Pomerania, Saxony, and Thuringia) received delayed training due to the COVID-19 pandemic and were therefore surveyed only from May 2021 to May 2022. Therefore, the data collection period was extended from 2 years to 3 and a half years. Across all measurement time points and occupational groups, the response rates varied between 79% and 100% with a mean of 91.1% (SD = 18.8). In addition to the quantitative surveys, the implementation team was interviewed as part of a focus group on the current status of service implementation, their perception on the effectiveness of implementation activities, as well as their perceived barriers and facilitating factors. For the aim of this study, only the answers on barriers and facilitating factors were included. In total, seven focus groups were conducted and recorded by the study coordinator (JF) every 6 months during the implementation study. The duration varied between 42 and 105 min ($M = 81.29$, SD = 20.21).

2.4. Outcomes

Table 2 summarizes the 30 of 37 (81.1%) selected CFIR constructs across all five CFIR dimensions, the evaluation methods (surveys, focus group, or reporting data) used for the analysis and the source of items. The CFIR construct selection was based on the research team's decision as to which constructs were relevant to the agricultural setting. Data from all the participants groups were included for most of the constructs. The surveys consisted of open and close questions from validated questionnaires used in implementation research, adapted items from the CFIR guide (48) as well as from other implementation studies based on the CFIR (44, 49, 53, 57–60) (see Table 2). "Readiness for implementation" among the implementation team as well as staff involved in the referral process was measured by using a German version of the Organizational Readiness for Implementing Change (ORIC; $\alpha = 0.88–0.92$; 12 items; scale 1–5) questionnaire (54). "Leadership engagement" was captured from the staff-perspective with the Implementation Leadership Scale (ILS; $\alpha = 0.93–0.97$; 12 items; scale 1–5) (55, 61) with regard to the implementation team as well as supervisors. The perception of the treatment credibility was assessed among staff involved in the referral process by using items from the Credibility Expectancy Questionnaire (CEQ; $\alpha = 0.84–0.85$, 6 items; scale 1–7) (56) adapted to the interventions and the employees' perspective within the construct "knowledge and beliefs about the intervention". Single items from the Discriminant Content Validation (DCV; 32 items; scale 1–7) questionnaire based on the Theoretical Domains Framework Questionnaire (52) were used to assess "access to knowledge and information" (DCV domains: knowledge, training), "compatibility" (DCV domain: compatibility with current working activities), (DCV domain: "self-efficacy"

TABLE 1 Overview of employee surveys and response rates from May 2019 until May 2022 per occupational group and rollout area ($N = 93$).

Time	Measurement point	Occupational group	Invited (*N*)	Responded (*N*)	Response rate (%)	Duration (min.)
May 2019	T0	Field worker/in-house staff (pilot rollout area)	17	17	100	38.6 (17.5)
	T0	Field worker/in-house staff (rollout area A)	21	19	91	45.1 (18.3)
	T0	Call center agents	11	11	100	28.0 (13.5)
	T0	Implementation team	6	6	100	14.0 (10.1)
November 2019	T0	Field worker/in-house staff (rollout area B)	26	25	96	29.0 (11.9)
	T1	Field worker/in-house staff (rollout area A)	20	16	80	50.5 (19.7)
	T1	Field worker/in-house staff (pilot rollout area)	17	16	94	26.7 (13.4)
	T1	Call center agents	11	11	100	41.9 (24.9)
	T1	Implementation team	6	6	100	12.2 (6.3)
May 2020	T1	Field worker/in-house staff (rollout area B)	27	22	82	53.7 (36.9)
	T2	Field worker/in-house staff (rollout area A)	17	15	88	26.3 (15.6)
	T2	Field worker/in-house staff (pilot rollout area)	18	18	100	17.9 (7.8)
	T2	Call center agents	11	10	91	24.4 (14.9)
November 2020	T2	Field worker/in-house staff (rollout area B)	27	24	89	21.2 (12.7)
	T3	Field worker/in-house staff (rollout area A)	16	14	88	21.8 (11.7)
	T3	Field worker/in-house staff (pilot rollout area)	18	15	83	18.4 (14.8)
	T3	Call center agents	10	10	100	17.2 (9.3)
May 2021	T0	Field worker/in-house staff (rollout area C)	17	14	82	31 (13.7)
	T3	Field worker/in-house staff (rollout area B)	24	19	79	35.7 (24.8)
	T4	Field worker/in-house staff (rollout area A)	16	14	88	38.4 (19.6)
	T4	Field worker/in-house staff (pilot rollout area)	17	15	88	31 (22.4)
	T4	Call center agents	10	8	80	18.6 (16.4)
November 2021	T4	Field worker/in-house staff (rollout area C)	17	15	88	58.3 (34.7)
	T5	Call center agents	10	10	100	13.9 (3.22)
May 2022	T2	Field worker/in-house staff (rollout area C)	17	14	82	43.7 (23.0)
	T2	Implementation team	7	6	87.5	12.7 (6.3)
	T6	Call center agents	10	10	100	26.1 (10)

Employees from rollout area C received delayed training due to the Covid-19 pandemic and were therefore surveyed only from May 2021 to May 2022. The duration of the survey also includes other items/measurement instruments that are not part of this study.

(DCV domain: beliefs about capabilities) and "other personal attributes" (DCV domains: skills, optimism, intentions) among staff involved in the referral process. Single items from a German version of the NoMAD questionnaire (51, 62) were used to assess "available resources" (NoMAD item: contextual integration) and "individual stage of change" (NoMAD items: interactional workability, skill set workability).

Furthermore, we used reporting data on dissemination activities documented by the SVLFG to measure "engaging". Open questions on barriers and facilitating factors in the implementation (see Supplementary Material) were asked from the second measurement time point (T1) every 6 months in the regular surveys given to staff involved in the referral process as well as to the focus groups with the implementation team whose responses could relate to all five CFIR dimensions.

2.5. Analysis

Descriptive analyses were performed to assess outcomes across the CFIR dimensions. The outcomes within the dimension "intervention characteristics" as well as CEQ and DCV questionnaires and single items of the evaluation survey were evaluated separately for the internet- and tele-based interventions. All other outcomes were analyzed jointly. Items with a 6- or 7-level Likert scale (e.g., DCV items, CEQ items 1–3 and 5, items regarding relative advantage) were transformed into a 5-level Likert scale based on linear transformation (63). As in another CFIR study (44), scores of 4 or above were interpreted as positive aspects in the implementation, while scores below 3 were classified as areas for improvement, and scores in between were considered as neutral. However, this does not apply to the cost and complexity items, where higher agreement suggests

TABLE 2 Overview CFIR domains and selected constructs (30/37), group of participants, evaluation methods and source of item.

Construct	Participants	Evaluation methods			Source of item
		Survey	Focus group	Reporting data	
I. INTERVENTION CHARACTERISTICS					
Intervention source	implementation team (T2)	x			CFIR guide (48)
Evidence Strength and quality	implementation team (T2)	x			CFIR guide (48)
Relative advantage	implementation team (T2), health care workers (T1)	x			CFIR guide (48)
Trialability	implementation team (T2)	x			CFIR guide (48)
Complexity	implementation team (T2)	x			CFIR guide (48), Kegler et al. (49)
Design quality and packaging	implementation team (T2)	x			CFIR guide (48),
Cost	implementation team (T2)	x			Pankratz, Hallfors and Cho (50)
II. OUTER SETTING					
Patient needs and resources	implementation team (T2)	x			CFIR guide (48)
External policy and incentives	implementation team (T2)	x			CFIR guide (48)
III. INNER SETTING					
Structural characteristics	implementation team (T2)	x			Created
Networks and communications	implementation team (T2)	x			CFIR guide (48)
Implementation climate	implementation team (T2)	x			CFIR guide (48)
Tension for change	implementation team (T2)	x			Created
Compatibility	implementation team (T2), health care workers (T1)	x			Finch et al. (51); Huijg et al. (52)
Relative priority	implementation team (T2)	x			CFIR guide (48)
Goals and feedback	implementation team (T2)	x			Helfrich et al. (53)
Readiness for implementation	implementation team (T1), health care workers (T1)	x			Shea et al. (54)
Leadership engagement	health care workers (T2, T4 or T6)	x			Aarons et al. (55)
Available resources	implementation team (T2), health care workers (T2, T4 or T6)	x			Finch et al. (51); Huijg et al. (52)
Access to knowledge and information	health care workers (May 2021: T0, T3 or T4)	x			Finch et al. (51); Huijg et al. (52)
IV. CHARACTERISTICS OF INDIVIDUALS					
Knowledge and beliefs about the intervention	health care workers (T1)	x			Huijg et al. (52); Devilly et al. (56)
Self-efficacy	health care workers (T1)	x			Huijg et al. (52)
Individual stage of change	health care workers (May 2021: T0, T3 or T4)	x			Finch et al. (51)
Other personal attributes	health care workers (T1)	x			Huijg et al. (52)
V. PROCESS					
Planning	implementation team (T2)	x			Hadjistavropoulos et al. (44)
Engaging	implementation team (T2)	x	x	x	CFIR guide (48), created
Opinion leaders	implementation team (T2)	x			CFIR guide (48)
Formally appointed internal Implementation leaders	implementation team (T2)	x			CFIR guide (48)
Champions	implementation team (T2)	x			Damschroder et al. (57)
External change agents	implementation team (T2)	x			CFIR guide (48)
Executing	implementation team (T2)	x	x		CFIR guide (48)
Reflecting and evaluating	implementation team (T2)	x	x		Helfrich et al. (53), Jaen et al. (58), CFIR guide (48), Sohng et al. (59)

Health care workers include field worker, in-house staff, and call center agents at the social insurance company. The constructs "adaptability", "cosmopolitanism", "culture", "individual identification with organization", "learning climate", "organizational incentives and rewards", and "peer pressure" were not captured.

higher cost or complexity. The analyses were performed per employee group. All observed data were included according to the intention-to-treat principle. Since the response rates (see Table 1) and data quality was relatively high in this implementation study, missing data was not imputed. The analyses were done with R statistic software (64).

Dissemination activities were categorized by two independent raters (JB, IW) according to the Cochrane Effective Practice and Organization of Care (EPOC) taxonomy (65). Each activity could contain multiple strategies. Inconsistent cases were discussed with the third researcher (JF) until all dissemination activities could be consistently assigned.

Answers to open questions on barriers and facilitating factors in the employee surveys were evaluated by two independent raters using a deductive-inductive approach with MAXQDA (66), a software for qualitative analysis. A code system with main categories based on the CFIR (deductive approach) and identified subthemes from the data (inductive approach) was created by a research assistant (JB) to match the data and developed further in feedback loops with two experts in e-mental health and qualitative research (JF, IT). As a text passage could consist of different aspects, it could be coded with several codes. The data were assigned to the code system and frequencies were calculated in relation to the mentions of the individual themes as well as per occupational group [i.e., (a) field workers and in-house staff or (b) call center agents]. The agreement rate between the two independent raters (JB, SM) can be characterized as high ($k = 0.86$) (67).

Based on the audio recordings of the focus groups minutes were taken for each focus group with the implementation team. Answers to open questions regarding barriers and facilitating factors were summarized and analyzed per focus group based on a code system following a deductive-inductive approach. The theoretically based superordinate categories formed the basic framework for the inductively identified topics. Frequencies of themes were analyzed at interview level. The analysis was performed by a research assistant (IW) in an iterative process with several feedback loops with input from clinical researchers (IT, JF).

3. Results

3.1. Participant characteristics

Most of the 93 study participants were involved in the referral process as field workers and in-house staff ($n = 75$, 80.6%) as well as call center agents ($n = 11$, 11.8%). Seven employees were part of the implementation team at the insurance company (7.5%). On average, the participants were 49.29 years old (SD = 8.6), mostly male ($n = 63$, 67.7%) and worked for more than 10 years at SVLFG ($n = 61$, 65.6%). Most of the field worker and in-house staff had experience with consultations on health offers ($N = 60$, 69.8%), however only 31.5% ($n = 29$) of them had experience with consultations on mental health services. Further characteristics of the study participants are shown in Table 3.

3.2. CFIR constructs

In the following, the findings are summarized by the CFIR domain. Each CFIR domain is divided into qualitative and quantitative results. Qualitative findings on barriers ($n = 20$) and facilitating factors ($n = 10$) from the perspective of staff involved in the referral process are illustrated in Figure 2 and as Supplementary Table, including a definition and quotation of the identified theme. Barriers ($n = 13$) and facilitating factors ($n = 14$) from focus groups with the implementation team are shown in Figure 3. Quantitative results on CFIR items among the implementation team are displayed in Table 4, for employees involved in the referral process in Table 5. Descriptive differences between the two interventions as well as between the different types of employees are pointed out.

3.2.1. Intervention characteristics

3.2.1.1. Qualitative findings

Staff involved in the referral process described five facilitating factors regarding intervention characteristics. Namely, they reported that advantages lie in the "flexible usage" (5/71, 7.0%), the "offer of a crisis hotline" (5/71, 7.0%), "location independence" (4/71, 5.6%), "anonymity" (4/71, 5.6%) of the digital interventions, and the "variety of health offers" (3/71, 5.6%). Then, the implementation team described the "high quality and effectiveness of digital health offers" (5/7, 71.4%) and "benefits of digital offerings during the COVID-19 pandemic" (2/7, 28.6%) as facilitating factors and "technical problems with access codes/online-platform" (1/7, 14.3%) as a barrier to implementation.

3.2.1.2. Quantitative findings

Overall, the average ratings among all employees can be described as high, indicating that intervention characteristics facilitate the implementation. The ratings among the implementation team revealed strong research evidence and the benefit of a pilot implementation phase with both mean ratings above 4.20. Costs for the implementation were rated as rather high ($M = 3.40$), and the implementation was described as a rather complex process across all items ($M \geq 3.60$). Among the implementation team and call center agents, the relative advantage of the tele-based coaching ($4.20 \leq M \geq 4.73$) was rated as high and that of the IBI program as neutral ($3.47 \leq M \geq 3.67$) in these occupational groups, while field workers rated both digital interventions on an equal level ($M = 3.77$).

3.2.2. Outer setting

3.2.2.1. Qualitative findings

Five facilitating factors and eight barriers emerged with regard to the outer setting from the perspective of staff involved in the referral process. Employees perceived an "acceptance of mental health services" (16/71, 23.0%) as well as an "interest in digital interventions" (10/71, 14.0%) among the insured. They saw the "easy access to digital health services" (2/71, 2.8%), "quick contact with the insured" (6/71, 8.4%) and "prior knowledge about health offers among the insured" (3/71, 4.2%) as helpful. At the same time, they described "inhibitions about using the internet/PC" (16/71, 23.0%), a "lack of time among the insured" (21/71, 21.0%), "skepticism about offers for mental strain" (12/71, 17.0%), and "prioritization of other tasks/topics" (9/71, 13.0%) among the insured. Further barriers were a "poor internet connection/missing PC" (7/71, 9.9%), a "lack of problem comprehension" (7/71, 9.9%), a "lack of access authorization/insured status" (5/71, 7.0%),

TABLE 3 Sociodemographic data of the employees participating in the implementation study, presented by occupational group and the overall sample (N = 93).

Characteristics	Implementation team (n = 7)	Field worker and in-house staff (n = 75)	Call centre agents (n = 11)	Overall sample (N = 93)
Age M (SD)	41.29 (10.1)	49.88 (8.2)	50.55 (8.7)	49.29 (8.6)
Gender n (%)				
Female	4 (57.1)	17 (22.7)	9 (81.8)	30 (32.3)
Male	3 (42.9)	58 (77.3)	2 (18.2)	63 (67.7)
Years worked at the company				
Less than 1 year	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
1–2 years	0 (0.0)	2 (2.7)	0 (0.0)	2 (2.2)
2–3 years	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
3–5 years	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.1)
5–10 years	2 (28.6)	8 (10.7)	1 (9.1)	11 (12.0)
10–20 years	2 (28.6)	25 (33.3)	1 (9.1)	28 (30.1)
20–30 years	2 (28.6)	24 (32.0)	4 (36.4)	30 (32.6)
30–40 years	1 (14.3)	15 (20.0)	5 (45.5)	21 (22.8)
More than 40 years	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Role at company				
Field worker	–	65 (86.7)	–	–
In-house staff	–	4 (5.3)	–	–
Consultant in a similar field	–	6 (8.0)	–	–
Consultation on health offers in the past (n = 78)				
Yes	–	50 (72.3)	7 (77.8)	57 (73.1)
No	–	19 (27.5)	2 (22.2)	21 (26.9)
Consultation on mental health services in the past (n = 50)				
Yes	–	29 (58.0)	–	–
No	–	21 (42.0)	–	–

"inhibitions during registration" (4/71, 5.6%), and "forgetting about health offers" (1/71, 1.0%) among the insured. In focus groups with the implementation team, "positive feedback from participating insured persons" (3/7, 42.9%) was described as a facilitating factor for the implementation. At the same time, three barriers were identified: "incertainty and stigma regarding mental health issues among the insured" (3/7, 42.9%), "inhibitions about using the internet/phone" (4/7, 57.1%), and "difficulty reaching/calling the insured" (1/7, 14.3%).

3.2.2.2. Quantitative findings

The mean ratings of items assessing the outer setting from the perspective of the implementation team were above 4.25, indicating that this domain facilitates service implementation. The ratings of the implementation team indicate that the needs and preferences of the insured were taken into account in the decision to implement internet- and tele-based health services and that employees involved in the referral process were aware of these needs and preferences.

3.2.3. Inner setting

3.2.3.1. Qualitative findings

Two facilitating factors and seven barriers regarding the inner setting were identified among employees involved in the referral process. The participants emphasized the availability of "appropriate materials for consultation" (12/71, 17.0%), and the "good teamwork within the SVLFG" (9/71, 13.0%). However, a "need for (adaptation of) educational materials" (14/71, 20.0%), "need for training/information" (13/71, 18.0%), a "lack of support from supervisors" (3/71, 4.2%), and "lack of involvement in current developments of the project" (12/71, 17.0%) were reported. Other identified barriers were "lack of time during consultations" (12/71, 17.0%), "bureaucratic burden" (5/71, 7.0%), "problems during the referral process" (3/71, 4.2%), and "technical problems during consultation" (1/71, 1.0%). Four facilitating and five hindering factors were reported in the focus groups with the implementation team. They described "good cooperation, exchange and communication within the SVLFG" (5/7, 57.1%), "simplification of referral process" (2/7, 28.6%), "less time pressure due to the

FIGURE 2
Barriers and facilitating factors from the perspective of staff involved in the referral process (field workers and in-house staff $n = 62$; call center agents $n = 9$), on implementation determinants based on CFIR. MHS, mental health services.

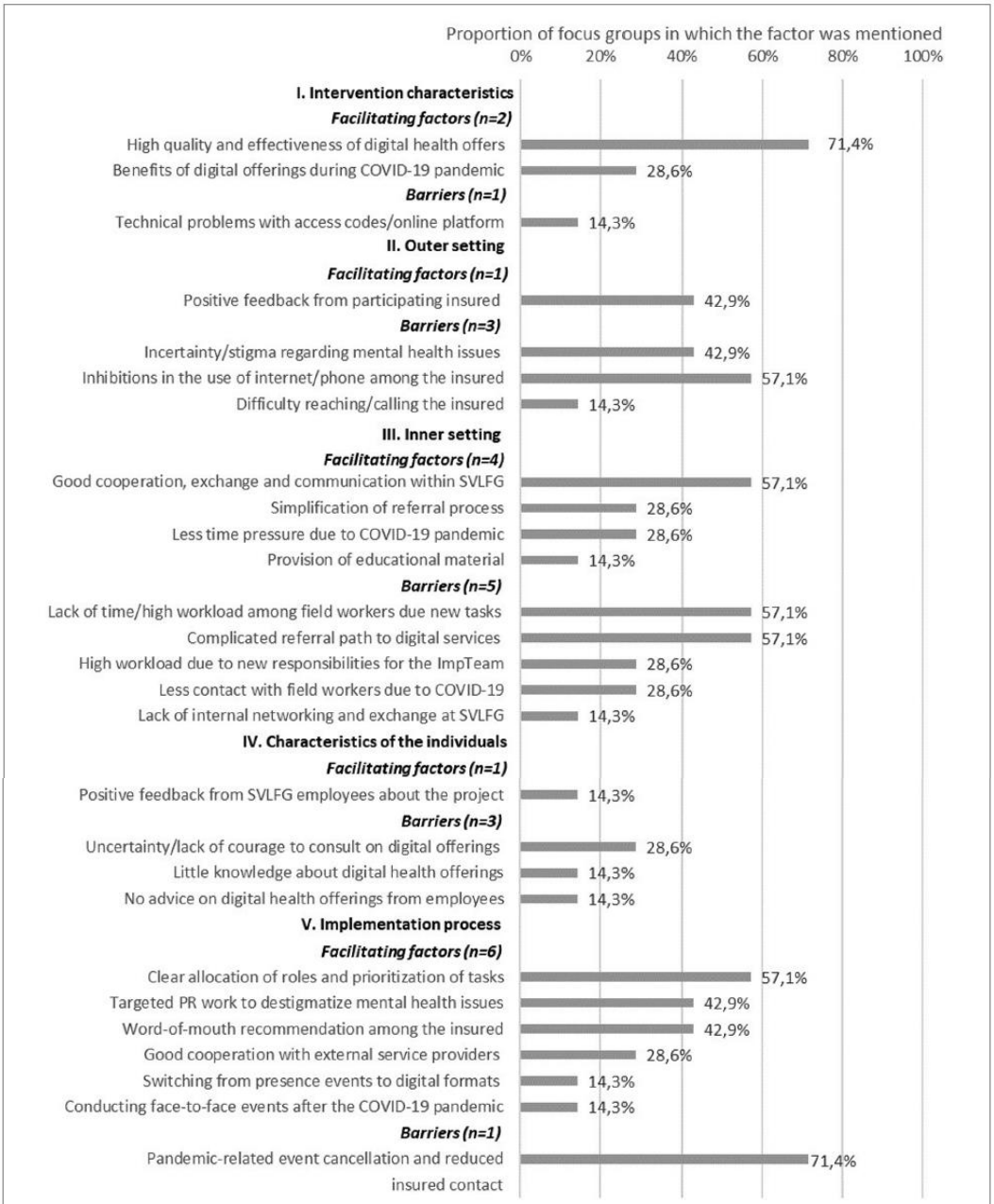

FIGURE 3
Barriers and facilitating factors from the perspective of the implementation team ($n = 7$) on implementation determinants based on five CFIR dimensions.

COVID-19 pandemic" (2/7, 28.6%) as many events had to be cancelled due to the pandemic, and the "provision of education material" (1/7, 14.3%) as helpful. Barriers pointed out by the implementation team were a "lack of time and high workload among field workers due to news tasks" (5/7, 57.1%), "complicated referral path to digital services" (5/7, 57.1%), "high workload due

TABLE 4 Descriptive data of the implementation team on implementation determinants based on CFIR dimensions ($n = 6$).

Items per CFIR construct	Implementation team ($n = 6$) *M* (SD)
I. INTERVENTION CHARACTERISTICS	
Evidence Strength & quality (per intervention)	
The research evidence on effectiveness supports my belief that the *online health trainings* are effective.	4.67 (0.52)
The research evidence on effectiveness supports my belief that the *personalized tele-based coaching* is effective.	5.00 (0.0)
I assume that influential stakeholders (i.e., key groups of people or stakeholders involved in the implementation) are convinced of the effectiveness of the *online health trainings*.	4.00 (1.10)
I assume that influential stakeholders (i.e., key groups of people or stakeholders involved in the implementation) are convinced of the effectiveness of the *personalized tele-based coaching*.	4.50 (0.84)
Trialability	
It was advantageous that the internet- and tele-based health services were implemented in selected pilot regions in Bavaria and Schleswig-Holstein before the nationwide rollout.	4.20 (0.84)
Complexity	
It is/was difficult to train employees to implement the internet and tele-supported health services.	3.60 (1.14)
Overall, I believe that implementing internet- and tele-based health services is a complex and challenging process.	3.67 (1.03)
Design quality & packaging	
How helpful did you find available tools (e.g., online resources, marketing materials, etc.) to help you implement and use internet- and tele-based health services?	3.11 (1.78)
Cost	
The average cost of the *online trainings* per participant is high.	3.00 (1.22)
The average cost of the *personalized tele-based coaching* per participant is high.	3.20 (1.30)
The costs for the implementation of the internet- and tele-based interventions are high.	3.40 (1.14)
Relative advantage	
When you consider the advantages and disadvantages of the *online health trainings*, how would you rate the situation overall?	3.67 (0.97)
When you consider the advantages and disadvantages of the *personalized tele-based coaching*, how would you rate the situation overall?	4.73 (0.41)
II. OUTER SETTING	
Patient needs & resources	
The needs and preferences of the insured were taken into account in the decision to implement internet- and tele-based health services.	4.6 (0.55)
SVLFG employees are aware of the needs and preferences of the insured persons they counsel as part of their official duties.	4.33 (0.82)
External policy & incentives	
Regional, state or national policies, as well as legal requirements, have significantly influenced the decision to implement internet- and tele-based health services.	4.25 (1.50)
III. INNER SETTING	
Structural characteristics	
In your view, to what extent do the SVLFG infrastructure features hinder or facilitate the implementation of internet- and tele-based health services?	2.0 (1.55)
Networks & communications	
I perceive the working relationship with colleagues in my department as good.	3.83 (0.98)
I perceive the working relationship with colleagues in other departments as good.	4.00 (0.0)
Implementation climate	
Overall readiness for the implementation of internet- and tele-based health services at SVLFG is high.	3.17 (1.17)

(*continued*)

TABLE 4 Continued

Items per CFIR construct	Implementation team ($n = 6$) M (SD)
Tension for change	
There is a high demand for internet- and tele-based health services to counteract mental stress among the insured.	4.50 (0.55)
Internet- and tele-based health care offerings are important to meet the needs of the insured or other organizational goals.	4.67 (0.52)
Compatibility	
The *online health trainings* fit my values and norms.	4.33 (0.52)
The *personalized tele-based coaching* fits my values and norms.	4.67 (0.52)
The *online health trainings* fit the values and standards within SVLFG.	4.00 (1.10)
The *personalized tele-based coaching* fits the values and norms within SVLFG.	4.17 (1.17)
The *online health trainings* fit with existing work processes and practices in my environment.	3.83 (0.41)
The *personalized tele-based coaching* fits with existing work processes and practices in my environment.	4.50 (0.55)
Relative priority	
The implementation of internet and tele-based health services is a high priority compared to other initiatives at SVLFG that take place throughout the implementation period.	4.40 (0.55)
Available resources	
SVLFG has sufficient resources to implement and manage internet- and tele-based health services.	3.67 (1.37)
The implementation team has sufficient staff support needed to implement the internet and tele-based health services.	3.33 (1.37)
Access to knowledge & information	
SVLFG employees received adequate training on internet and tele-based health services.	4.0 (1.10)
IV. CHARACTERISTICS OF INDIVIDUALS	
No items were recorded for this dimension.	
V. PROCESS	
Planning	
We have spent sufficient time planning the implementation of internet- and tele-based health services.	3.60 (1.52)
The plan for implementing internet- and tele-based health services is detailed.	3.60 (1.14)
The plan to implement internet- and tele-based health services is/was realistic and feasible.	2.83 (0.98)
Implementation team members have clearly defined roles and responsibilities.	3.17 (1.33)
Engaging	
SVLFG has ensured that all employees have been informed about internet and tele-based health services, including those who do not offer counselling on them.	2.67 (1.21)
Formally appointed internal implementation leaders	
Does this person [the formally appointed internet implementation leader] have sufficient authority to implement the internet and tele-based health services? (yes/no)	100% (0.0)
Champions	
Some SVLFG employees (e.g., field, office, and call center staff) actively support and promote internet- and tele-based health services beyond what is required.	4.0 (1.10)
External change agents	
How helpful did you find the support outside SVLFG (e.g., external service providers, associations, and other organizations)?	2.08 (0.74)
Executing	
Internet- and tele-based health services were implemented according to the established plan.	3.00 (1.41)

(*continued*)

TABLE 4 Continued

Items per CFIR construct	Implementation team ($n = 6$) M (SD)
Reflecting & evaluating	
There are clear goals within SVLFG or the implementation team for the implementation of internet and tele-supported health services.	3.33 (1.03)
We use data from insured persons to improve care.	3.50 (1.22)
We use data to guide the implementation of internet- and tele-supported health services.	2.83 (1.83)
There is frequent communication within SVLFG about how various change processes are underway as part of the implementation of internet- and tele-supported health services.	3.50 (1.22)

Scores of 4 or above can be interpreted as positive aspects in the implementation process, while scores below 3 were classified as areas for improvement (except for the items regarding to cost and complexity, where higher agreement suggests higher cost or complexity).

to new responsibilities for the implementation team" (2/7, 28.6%), "less contact with field workers due to COVID-19 pandemic" (2/7, 28.6%), and "lack of internal networking and exchange at SVLFG" (1/7, 14.3%).

3.2.3.2. Quantitative findings

In the results on the implementation team perspective, many factors were rated with neutral to high agreement ($3.80 \leq M \geq 4.80$), especially networks and communications, tension for change, compatibility with values and existing working processes, relative priority of the digital interventions, and access to knowledge and information. Structural characteristics were rated as hindering ($M = 2.0$). Among staff involved in the referral process, readiness for implementation was evaluted as neutral with means of 3.48 for field workers and 3.68 for call center agents. Leadership engagement with regard to the direct supervisor ($M = 4.15$) and the implementation team supervisor ($M = 3.90$) was perceived as neutral to high by call center agents. Among field workers, leadership engagement from the direct supervisor ($M = 2.90$) and the implementation team ($M = 3.36$) were rated as "in need of improvement" to "neutral". The same also applies to the ratings of availability of sufficient resources by field workers ($2.84 \leq M \geq 3.75$).

3.2.4. Characteristics of the individuals

3.2.4.1. Qualitative findings

The analysis revealed one facilitating factor and five barriers regarding characteristics of the individuals among employees involved in the referral process. The employees described "personal consultations" (10/71, 14.0%) as beneficial. At the same time, they pointed to barriers such as the "COVID-19 related reduction in onsite contacts with insured persons" (13/71, 18.0%), "lack of consultations" (6/71, 8.5%), "addressing mental health issues" (11/71, 15.0%), "little routine in advising on health care services" (9/71, 13.0%), "difficulties in recognizing the relevance of mental health issues" (8/71, 11.0%), and "no time for self-experience through employee participation" (1/71, 1.0%). The implementation team mentioned one facilitator and three barriers in relation to this dimension. Specifically, they described the benefit of "positive feedback from SVLFG employees about the project" (1/7, 14.3%) and the hindrances of "uncertainty and lack of courage to consult on digital health offerings among employees" (2/7, 28.6%), "little knowledge about digital health offerings" (1/7, 14.3%), and "no advice on digital health offerings from employees" (1/7, 14.3%).

3.2.4.2. Quantitative findings

Reportings on "knowledge and beliefs about the intervention", "other personal attributes", and "individual stage of change" were neutral to high among employees involved in the referral process ($3.03 \leq M \geq 4.93$). While ratings on "self-efficacy" revealed neutral to high agreement rates among call center agents ($3.91 \leq M \geq 4.88$), most of the answers (4/6) were below 3.0 ($2.72 \leq M \geq 2.91$) among field workers, indicating room for improvement. Overall, the credibility of the interventions was rated as high ($M > 4.44$) by employees involved in the referral process. The employees indicated that they expected the interventions to improve symptoms by at least 49.5%.

3.2.5. Implementation process

3.2.5.1. Qualitative findings

The analysis revealed the facilitating factor "increased advertising of the digital health service in the media" (3/71, 4.2%) and a barrier regarding "confusing website of the SVLFG" (5/71, 7.0%) among staff involved in the referral process. In addition, the implementation team described six facilitating factors and one hindering: "clear allocation of roles and prioritization of tasks" (4/7, 57.1%), "targeted public relations work to destigmatize mental health issues" (3/7, 42.9%), "word-of-mouth recommendation among the insured" (3/7, 42.9%), "good cooperation with external service providers" (2/7, 28.6%), "switching from onsite events to digital formats" (1/7, 14.3%), and "conducting face-to-face events after the COVID-19 pandemic" (1/7, 14.3%) were perceived as facilitating factors, while the "pandemic-related cancellation of events and reduced insured contact" (5/7, 71.4%) was a barrier.

3.2.5.2. Quantitative findings

Concerning the implementation process, the average values resulted in a wide range between 2.08 and 4.0 across all constructs. Agreement among the implementation team was highest for "champions" (e.g., individuals who dedicate themselves to supporting the implementation; $M = 4.0$) and lowest for "external change agents" (e.g., individuals outside the SVLFG; $M = 2.08$), and "engaging" ($M = 2.67$) indicating room for improvement.

3.2.5.3. Reporting data

As the data showed (see Figure 4), most of the 510 dissemination activities conducted within 3.5 years were classified as strategies in the field of educational meetings ($n = 277$ activities), followed by local opinion leaders ($n = 48$ activities), and marketing ($n = 47$ activities).

10.3389/fdgth.2022.1083143

TABLE 5 Descriptive data of employees involved in the referral process on implementation determinants based on CFIR dimensions ($n = 89$).

Item	Call center agents *M* (SD)	*N*	Field worker *M* (SD)	*N*	Total *M* (SD)	*N*
I. INTERVENTION CHARACTERISTICS						
Relative advantage						
When you consider the advantages and disadvantages of the *online health trainings*, how would you rate the situation overall?	3.47 (0.76)	11	3.77 (0.70)	77	3.73 (0.71)	87
When you consider the advantages and disadvantages of the *personalized tele-based coaching*, how would you rate the situation overall?	4.2 (0.62)	11	3.77 (0.65)	77	3.83 (0.66)	87
II. OUTER SETTING						
No items were recorded for this dimension.						
III. INNER SETTING						
Compatibility						
Providing advice on *online health trainings* during company visits or by telephone is compatible with my job as a call center employee or field or office employee.	4.21 (0.93)	11	3.64 (1.07)	67	3.72 (1.06)	78[a]
Providing advice on the *personalized tele-based coaching* during company visits or to provide advice by telephone is compatible with my job as a call center employee or field or office employee.	4.21 (0.93)	11	3.48 (1.08)	67	3.57 (1.06)	78[a]
Readiness for implementation						
Organisational Readiness for Implementing Change: Efficacy[b]	3.71 (0.46)	11	3.43 (0.68)	78	3.57 (0.63)	89
Organisational Readiness for Implementing Change: Commitment[b]	3.80 (0.55)	11	3.55 (0.65)	78	3.71 (0.60)	89
Organisational Readiness for Implementing Change (total score)[b]	3.68 (0.45)	11	3.48 (0.64)	78	3.63 (0.58)	89
Leadership engagement						
Implementation Leadership (direct supervisor)[b]	4.15 (0.53)	10	2.90 (0.76)	53	3.09 (0.86)	63
Implementation Leadership (implementation team)[b]	3.93 (0.50)	10	3.36 (0.50)	53	3.51 (0.69)	63
IV. CHARACTERISTICS OF INDIVIDUALS						
Knowledge & beliefs about the intervention						
I am aware of the content and goals of the *online health trainings*.	4.39 (0.63)	11	3.62 (0.86)	67	3.73 (0.87)	78[a]
I am aware of the content and goals of *personalized tele-based coaching*.	4.39 (0.70)	11	3.31 (0.89)	67	3.46 (0.94)	78[a]
I know the content and goals of the *online health trainings*.	4.27 (0.70)	11	3.51 (0.84)	67	3.62 (0.86)	78[a]
I know the content and objectives of *personalized tele-based coaching*.	4.27 (0.66)	11	3.20 (0.95)	67	3.36 (1.00)	78[a]
I am familiar with the content and goals of the *online health trainings*.	4.15 (0.85)	11	3.32 (0.89)	67	3.44 (0.93)	78[a]
I am familiar with the content and goals of *personalized tele-based coaching*.	4.27 (0.76)	11	3.06 (1.00)	67	3.23 (1.06)	78[a]
Credibility Expectancy Questionnaire (items 1–3, 5): *online health trainings*[b]	4.48 (1.15)	10	4.44 (0.91)	62	4.44 (0.94)	72
Credibility Expectancy Questionnaire (items 1–3, 5): *personalized tele-based coaching*[b]	4.93 (1.17)	10	4.54 (0.90)	62	4.59 (0.94)	72
Credibility Expectancy Questionnaire (item 4): By the end of the *online health trainings*, how much improvement of mental well-being of the insured do you think will occur?	49.5% (26.5)	10	50.60% (20.3)	62	50.44% (21.1)	72
Credibility Expectancy Questionnaire (item 4): By the end of the *personalized tele-based coaching*, how much improvement of mental well-being of the insured do you think will occur?	60.7% (27.6)	10	55.27% (17.3)	62	56.03% (18.9)	72
Credibility Expectancy Questionnaire (item 6): By the end of the *online health trainings*, how much improvement of mental well-being of the insured do you really feel will occur?	47.4% (26.6)	10	50.08% (21.6)	62	49.71% (22.2)	72
Credibility Expectancy Questionnaire (item 6): By the end of the *personalized tele-based coaching*, how much improvement of mental well-being of the insured do you really feel will occur?	59.9% (28.6)	10	54.97% (19.4)	62	55.65% (20.7)	72

(*continued*)

TABLE 5 Continued

Item	Call center agents *M* (SD)	*N*	Field worker *M* (SD)	*N*	Total *M* (SD)	*N*
Self-efficacy						
I am confident that I can advise insureds about *online health trainings* during site visits or by phone, even if insureds are not motivated.	3.97 (1.05)	11	2.91 (1.12)	67	3.06 (1.16)	78[a]
I am confident in my ability to counsel insureds during facility visits or by telephone for *personalized tele-based coaching*, even if insureds are not motivated.	4.09 (1.09)	11	2.73 (1.02)	67	2.92 (1.13)	78[a]
I am confident that I can advise insureds on *online health trainings* during site visits, even if there is little time.	3.91 (0.91)	11	2.78 (1.14)	67	2.94 (1.17)	78[a]
I am confident in my ability to advise insureds on *personalized tele-based coaching* during facility visits, even when there is little time.	4.15 (0.90)	11	2.72 (1.03)	67	2.92 (1.12)	78[a]
I am confident that I could advise insureds on *online health trainings* during site visits or by phone if I wanted to.	4.88 (0.93)	11	3.40 (1.10)	67	3.51 (1.11)	78[a]
I am confident that I could advise insureds during facility visits or by telephone for *personalized tele-based coaching* if I wanted to.	4.21 (0.83)	11	3.17 (1.04)	67	3.32 (1.07)	78[a]
Individual stage of change						
I can easily integrate the internet- and tele-based interventions into my existing work.	3.13 (1.13)	10	3.38 (0.96)	61	3.36 (0.98)	71
Work is assigned to those with skills appropriate to the the internet- and tele-based interventions.	3.50 (0.93)	10	3.97 (0.87)	61	3.91 (0.90)	71
Sufficient training is provided to enable staff to implement the internet- and tele-based interventions.	4.13 (0.35)	10	3.16 (1.01)	61	3.27 (1.01)	71
Other personal attributes						
I am skilled at advising insureds on online health trainings during site visits or by telephone.	4.15 (0.79)	11	3.37 (0.97)	77	3.48 (0.98)	78[a]
I am skilled at advising insureds on personalized tele-based coaching during facility visits or by telephone.	4.21 (0.83)	11	3.24 (1.01)	77	3.38 (1.04)	78[a]
In the next 4 weeks, I will in any case advise the insured persons about the online health trainings courses during the company visits or by telephone.	3.79 (1.02)	11	3.39 (1.78)	77	3.44 (1.78)	78[a]
In the next 4 weeks, I will advise the insured in every case during the company visits or by telephone for personalized tele-based coaching.	3.91 (0.80)	11	3.52 (1.63)	77	3.78 (1.70)	78[a]
How strong is your intention to advise insureds about online health trainings during site visits or by telephone?	3.73 (1.17)	11	3.47 (0.97)	77	3.50 (1.00)	78[a]
How strong is your intention to advise insureds during site visits or by telephone on personalized tele-based coaching?	4.03 (0.91)	11	3.03 (1.11)	77	3.17 (1.13)	78[a]
V. PROCESS						
No items were recorded for this dimension.						

[a]Due to an error in the programming of the online survey, not all employees received the item.
[b]Instead of a single item, several items or a complete measurement were used to assess the respective construct.

4. Discussion

Despite the availability of evidence-based digital interventions for the prevention of depression, few interventions find their way into practice. To our knowledge, this is the first study examining the nationwide implementation of internet- and tele-based interventions to prevent depression in a high-risk population (e.g., farmers, forest owners, and gardeners) based on the CFIR (43). The research focus is on facilitating factors and barriers in the implementation of digital interventions from the perspective of health care workers of a social insurance, which helps to elucidate the implementation and to derive recommendations for future adoption and uptake.

4.1. Summary

Intervention characteristics seem to have the highest positive impact on the implementation of digital interventions from the perspective of both the implementation team and referral staff. The relative advantage of digital interventions, quality of the interventions, and strength of evidence appeared to be facilitating factors in the implementation of the internet- and tele-based interventions in the agricultural setting.

In comparison, the outer setting, inner setting, individual characteristics, and implementation process were less consistently regarded by all staff groups as having facilitated the implementation of digital prevention services. Most of the qualitatively revealed

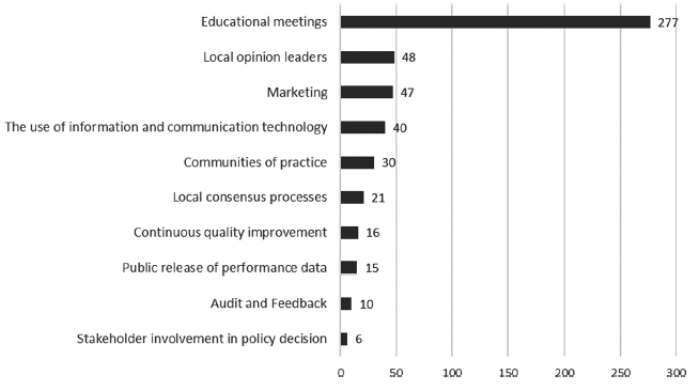

FIGURE 4
Dissemination activities from April 2019 to September 2022 (n = 510), categorized according to the EPOC taxonomy (65). An activity can be assigned to several categories.

barriers were related to the outer setting, in particular to "patient needs and resources". The employees reported to have perceived from the insured, among others, inhibitions about using digital interventions and skepticism about offers for mental strain. At the same time, facilitating factors reflecting the acceptance of mental health services and the general interest of the insured were noted by staff involved in the referral process. Likewise, as indicated by the quantitative ratings for "patient needs and resources" as well as "external policy and incentives", predominantly beneficial aspects for implementation could be achieved (e.g., consideration of needs and preferences of the insured during implementation; facilitating influence of regional, state or national policies, as well as legal requirements on the implementation).

With regard to the inner setting, many barriers referred to "available resources", and "access to knowledge and information", including a need for training and information on the interventions and further educational materials. Although several educational meetings were reported as dissemination activities and kickoff events and training sessions were conducted, there seems to be a need for further information and ongoing training for employees. However, many quantitatively assessed constructs of the inner setting ("tension for change", "compatibility", "relative priority") also served to facilitate the service implementation from the perspective of health care workers.

Further barriers to implementation were identified in relation to the characteristics of individuals. Employees involved in the referral process mentioned having little routine in advising on health care services as well as difficulties in recognizing and addressing mental health issues. The results showed a difference in the agreement rates of the occupational groups. While call center agents evaluated most constructs with high agreements ($M > 4.0$), agreement rates in the group of field workers can be characterized as neutral for "knowledge and beliefs about the intervention" and "other personal attributes", and as rather hindering for "self-efficacy".

With regard to the implementation process, facilitating factors were identified in the focus groups with the implementation team, including a clear allocation of tasks and targeted PR activities to destigmatize mental health issues. In the quantitative ratings, facilitating factors related to active implementation support by champions and formally appointed internal implementation leaders and barriers regarding engaging and informing of employees about digital health offerings could be determined by the implementation team. 510 dissemination activities have been carried out so far, most of them in the field of educational meetings, local opinion leaders, and marketing, while others such as strategies like audit and feedback have hardly been used so far.

As there might be differences between the IBI program and TC, some constructs were recorded separately for each intervention. The results for both interventions are generally comparable with neutral to high agreement rates, with slightly higher agreement ratings in favor of the personalized tele-based coaching with regard to "evidence strength and quality", "relative advantage" and "knowledge and beliefs" about the intervention, particularly evident in the perception of the implementation team and call center agents. However, the current power of the study as well as the unequal number in the groups did not allow for a significance test. As the results of the accompanying randomized controlled trials show (28–30, 34), both interventions effectively reduce depressive symptoms posttreatment.

When interpreting the results, it is important to note that, the COVID-19 pandemic occurred as an unforeseen and uncontrollable event, and the effects are reflected in several constructs. On one hand, kickoff events, exhibition stands, and educational meetings had to be cancelled due to the pandemic, which led to reduced onsite contact with the insured as well as less contact between field workers and the implementation team. On the other hand, digital interventions proved beneficial and important, and these continued to be offered during the pandemic, compared to onsite services. The implementation team indicated that the cancellation of events also eased time pressure, which in turn had a beneficial effect on the planning of new implementation activities. Furthermore, implementation activities could be adapted

and planned onsite events were transferred in a digital format. However, the conduction of onsite events from 2022 was also experienced as beneficial by the implementation team.

In the study, different professional groups were interviewed and surveyed. It is particularly evident that there is often an overlap in experiences between professional groups, e.g., both the implementation team and the staff involved in the referral process reported many barriers in relation to the outer and inner setting. In many areas, the results between the professional groups complement each other well (e.g., referral staff who are in daily contact with the insured mentioned even more facilitating factors and barriers regarding "patient needs and resources"). Since the working areas of the employees and therefore the focus, experiences, and tasks in the implementation are different, this contributes to a comprehensive analysis of the implementation process.

4.2. Comparison to literature

Although CFIR is one of the most frequently used frameworks to examine implementation in diverse health settings (68), literature in the area of digital interventions to prevent depression is scarce. Hadjistavropoulos et al. (44) conducted a process evaluation based on the CFIR to understand facilitating factors and barriers impacting the implementation of iCBT within community mental health clinics. In line with their study, intervention characteristics were perceived as mostly facilitating the implementation. Similar to our study, the inner setting was identified as the most significant barrier to implementation due to limited resources for internet-based Cognitive Behavioral Therapy (iCBT) (44). In addition, a greater priority given to face-to-face psychotherapy was reported as a barrier to implementation (44), which was not found in our study. Another reported barrier in the implementation of iCBT was the need for even greater engagement of stakeholders in iCBT (44), which also applies for the prevention setting in this study.

Two studies about the implementation of IBIs for depression prevention in adolescents (37) or for depression treatment in adults (69) showed that primary care physicians or nurses perceive the preventive approach of internet interventions as valuable (37). The pilot study (37) reported that it is challenging to train the individuals to achieve a sufficient level of counseling competence, whereas the qualitative study (69) reported a lack of habit and routine and little knowledge about IBIs that could have hindered the referral process and led to low referral rates in primary care physicians. This is consistent with some of the barriers identified in our study related to staff involved in the referral process (e.g., need for training, difficulties in addressing mental health issues, little routine in advising on health care services).

In line with systematic reviews examining factors influencing the implementation of digital interventions (70, 71), our findings indicate that the implementation of digital interventions for depression prevention are influenced by diverse constructs instead of a single construct explaining implementation. Access to knowledge and information seems to be important for the implementation of e-health interventions (70), which was identified as a hindering factor in our study. While access to ongoing system support had a positive impact on implementation, Ross et al. (70) identified it as a barrier to implementation when it was lacking, which is consistent with identified aspects related to training and educational materials in this study.

Most of the identified hindering themes in our study are related to "patient needs and resources". These barriers are in accordance with previous studies indicating that help-seeking behavior is lower and stigmatization of mental disorders is higher among farmers compared to other occupational groups (25). Furthermore, many of our identified barriers and facilitating factors are in line with findings of qualitative results of another substudy of ImplementIT (31) from the perspective of users (farmers who participated in digital services to prevent depression), including "location independence" and "anonymity" as positive drivers and a "lack of time" and "inhibitions about using the internet" as negative drivers for the acceptance of and satisfaction with the IMI program (17, 32, 33).

4.3. Implications

Because of the multifaceted aspects considered in the CFIR, it was a useful framework to explore and map the various contextual factors in the implementation of digital interventions. With the help of the CFIR, adaptations of the digital interventions as well as recommendations for the further implementation and scale-up can be derived. However, we have found an overlap between constructs of the inner setting and individual characteristics as individuals could also be considered part of the inner setting.

Additionally, previous implementation studies on digital interventions for depression identified a lack of methodological rigor and a need for validated questionnaires in the implementation of e-mental health interventions (72). Since no questionnaire exists in which all CFIR constructs are captured, this study provides considerations and initial starting points for data collection and analysis within a mixed-methods approach for other researchers who plan to evaluate the implementation of digital interventions.

Several measures for the further implementation of digital offerings among farmers can be derived from the results. Special attention should be given to addressing barriers regarding "patient needs and resources". Counteracting the stigmatization of mental stress is a constant and ongoing process, which was also described as beneficial by the implementation team. When implementing technology in the area of prevention, it is often necessary to create an awareness that targeted interventions can increase well-being and significantly reduce the subsequent occurrence of depression. This could be strengthened through targeted press and PR activities, which also refer to the reported positive experiences of participated farmers, and the involvement of local stakeholders. At the level of the inner setting, it could be crucial to conduct (follow-up) trainings for employees in order to provide information about the interventions and current developments and to strengthen the exchange of experiences among each other. In addition to training, other ways of reaching employees at regular intervals should be considered to enhance access to knowledge and information (e.g., newsletter, regular online or onsite meetings). An extension of educational materials (e.g., videos) tailored to the needs of the respective occupational group could be useful to support the consultations. A further strategy according to the

CFIR-ERIC Matching Tool (73), which matches barriers to implementation strategies, might be to "involve executive boards" (e.g., supervisors) in the implementation effort to enhance leadership engagement. In order to address barriers with regard to characteristics of the individuals, the trainings should also pay attention to how mental health topics could be addressed or which health offer is useful with the respective insured. Additionally, implementation strategies such as to "conduct ongoing training" for both digital interventions as well as to "make training dynamic" (e.g., by varying the methods of information delivery and making the training interactive to accommodate different learning styles) might strengthen "self-efficacy" as reported in the CFIR-ERIC Matching Tool (73). To enhance "reflecting and evaluating" implementation strategies such as to "develop and implement tools for qualtiy monitoring" as well as to "develop and organize quality monitoring systems" seem to be suitable (73).

For the field of depression prevention, the findings indicate that there are synergies when IBIs and tele-based coachings are implemented as technology-based interventions to complement on-site services. We could identify and address different and common barriers and facilitating factors, while also addressing different preferences and conditions in implementation. Offering different services (individual, group, on-site, tele-based, internet-based) centrally managed by a call center that coordinates inventions from different service providers allows the end-user a lower access threshold with maximum consideration of their needs and could solve the scaling problems observed in research (e.g., low uptakes) (74), where so far usually only one intervention has been implemented and considered. In addition, the findings indicate that it is critical to include, besides end-users, key gatekeepers such as health care workers and their experiences in providing consultations on digital health services as well as implementers at the social insurance company. Further stakeholders in the health care system (e.g., employees/psychologists of the external service providers, political representatives, decision makers of the social insurance) should also be considered, which is partly done in another study by ImplementIT (31) and will be published elsewhere.

4.4. Limitations

Our results should be considered in light of the following limitations. First, a smaller sample size among employees than expected could be reached for participation. While 365 employees involved in the consultation process were trained, only 93 of them chose to participate in the study. Furthermore, selection bias may have occurred in that the participants were likely to be more open and motivated to the implementation of digital interventions (selection bias), and positive responses to satisfy the study team (response bias) may occurred as well, which could have resulted in a more positive assessment of service implementation than would have been the case with a representative sample of employees. Second, as no questionnaire exists that covers all CFIR constructs, a mixture of different questionnaires/items with various scales has been used in the study. Therefore, some of the scales had to be transformed during the evaluation in order to be able to present the results uniformly. Third, barriers and facilitating factors were captured generally and not formulated specifically with respect to each CFIR construct, which would have resulted in a larger output for all CFIR dimensions. However, this can also lead to participants responding more openly and less constrained by predetermined deductive-formulated questions. This can be an advantage because more facets outside fixed constructs are raised. Forth, it is unclear what impact the different assessment time points in the respective rollout areas with different characteristics (e.g., regional conditions, team structures, stage of implementation) might have. Fifth, the qualitative results refer to individual responses from employees and cannot be generalized due to the explorative approach.

4.5. Conclusion

Our findings contribute to an understanding of the facilitating and hindering factors in the implementation of digital interventions for depression prevention among farmers from the perspective of health care workers and are part of a complex implementation study design (ImplementIT) (31). The study presents that the use of various mixed-methods for data collection including surveys, open-ended questions, focus groups, and reporting data contribute a comprehensive understanding of the implementation process. While both offerings (guided IBIs, personalized tele-based coaching) are widely accepted by health care workers, the results also point to some barriers and contribute to deriving recommendations for further implementation. For example, to improve access to knowledge and information, as well as beliefs about digital prevention services, implementation strategies focusing on educational meetings for employees and distribution of educational materials tailored to the occupational group within the SVLFG might be helpful.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Ethics Committee of the Friedrich-Alexander-Universität Erlangen-Nürnberg. The participants provided their written informed consent to participate in this study.

Author contributions

DE, HB, and MB obtained funding for the SVLFG evaluation project. JF and IT developed the study design, interview/focus group guide, surveys and were responsible for the selection of theoretical frameworks and measurements as well as evaluation methods. JF was responsible for recruitment of participants, coordination and collection of data as well as for the analyses and development of code system. IT managed and supervised the

study, recruitment, data collection and data analyses as operational lead of the project and provided feedback on the code system. IT, JT, and LB contributed to recruitment. JF wrote the manuscript. IT contributed to and supervised the further writing of the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

DE has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. DE is stakeholder of the GET.ON Institute/HelloBetter, which aims to implement scientific findings related to digital health interventions into routine care. HB has received consultancy fees, fees for lectures/workshops from chambers of psychotherapists and training institutes for psychotherapists in the e-mental-health context and license fees for an internet intervention. MB is scientific advisor of mentalis GmbH and GET.ON Institute/HelloBetter, both providers of digital mental health care products and services. MB is also co-founder and stakeholder of mentalis GmbH. IT reports to have received fees for lectures/workshops in the e-mental-health context from training institutes and congresses for psychotherapists. She was the project lead for the research project ImpleMentAll (funded by the European Commission) at GET.ON, which aimed to investigate the effectiveness of tailored implementation strategies compared to implementation as usual (11/2017-03/2021). JF, JT, LB declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2022.1083143/full#supplementary-material.

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5. General Discussion

5.1 Summary

This dissertation aimed to provide insights on current challenges in digital health interventions to prevent mental disorders, with a particular focus on the following aspects: a) limited evidence on the cost-effectiveness of DHIs, b) a lack of validated measures in implementation science, and c) limited evidence on the implementation of DHIs into routine care. To address the first challenge, the limited evidence on the cost-effectiveness of DHIs to prevent mental disorders, economic evaluations of two DHIs targeting different risk factors for developing mental disorders were performed in Studies 1 and 2. Study 1 examined the potential for the cost-effectiveness of a universal digital stress management intervention for employees with a 6-months timeframe. The results suggested that this intervention is cost-effective and offers a favorable benefit-to-cost ratio. Study 2 focused on the cost-effectiveness of guided and unguided DHIs for problematic alcohol drinking among employees compared to a WLC with a 6-months timeframe within an indicated prevention approach. The guided intervention appeared to be both cost-beneficial and cost-effective and was superior to the unguided intervention and a WLC. The second challenge, the need for validated measures in implementation science, was addressed in Study 3. Overall, predominantly good psychometric characteristics were observed for the G-NoMAD, supporting its further usage to assess the degree of normalization of an intervention in German implementation settings. The third challenge, limited evidence on implementing DHIs to prevent mental disorders in routine care, was addressed in Studies 4 - 6. In Study 4, the design of a national implementation study was developed to evaluate the implementation of two digital health interventions, a tailored guided internet-based intervention program and

personalized tele-based coaching, to prevent depression among farmers, foresters, and gardeners. Study 5 assessed participants' experiences (N = 22) regarding the acceptance of and satisfaction with the guided IBI program in this agricultural setting. In Study 6, determinants influencing the implementation of two digital interventions to prevent depression among farmers and individuals in related occupations were examined based on the CFIR from the perspective of healthcare workers (N = 93) at the social insurance company SVLFG. Studies 5 and 6 showed that the insured individuals and the employees primarily accept digital prevention interventions. In addition, the results from both studies help to understand the implementation process and derive tailored implementation strategies for further use of DHIs for depression prevention in an agricultural setting.

5.2 Comparison to Previous Literature

5.2.1 Studies 1 - 2

Evidence for economic evaluations of digital prevention of mental disorders is scarce. Studies 1 and 2 are presumably the first economic evaluations of a universal digital stress management intervention and (un-)guided interventions to reduce problematic drinking in employees from both a societal and an employer's perspective. From a societal perspective, the unguided DHI for stress management in Study 1 had an 80% probability of being cost-effective per QALYs gained at a willingness-to-pay of €20,000, compared to the WLC group. The results of Study 1 are consistent with other economic evaluations of the same DHI with eCoach guidance for stressed employees in the context of indicated prevention (PSS ≥ 22) (60,61). In a study by Kählke et al. (60), a 76% probability of being more cost-effective compared to WLC was shown at a societal WTP of €20,000 per QALY gained. Ebert et al. (61) investigated the cost-benefit of the DHI from the

employer's perspective. They reached a similar benefit-to-cost ratio of 1.6 (95% CI: €-1.2 - 4.5) compared to Study 1, with a ratio of 1.77 (95% CI: €-4.0 - 7.7).

The results of Study 2 align with the economic evaluation of (un-)guided DHIs for harmful alcohol drinking in adults in a substance abuse treatment center from a societal perspective (65). Blankers et al. (65) also revealed that a guided DHI showed a greater monetary value than an unguided DHI. The guided DHI yielded a 60% probability of being cost-effective per QALY gained at a WTP of €20,000. A slightly higher probability of 78% was shown in Study 2. The findings of Study 2 are also consistent with a systematic review of the health-economic benefits of DHIs for alcohol use disorder that demonstrated probabilities of DHIs being cost-effective from a societal and public health perspective between 60% to 84%, respectively (64). In addition, the percentage of profit per Euro invested for the guided DHI (61%) in Study 2, respectively, is comparable to a further study on guided DHIs targeting work-related stress in employees (61%) (170). A slightly higher percentage of profit per Euro invested for an unguided DHI (78%) was found in Study 1.

The results of this dissertation also contribute to novel findings concerning guidance on DHIs from an economic perspective. A recent systematic review (N = 32 studies) on the cost-effectiveness of DHIs for mental health problems (57) revealed that due to a paucity of available studies, the ability to discern meaning concerning unguided preventive DHIs was limited. Study 1 demonstrated the economic merit of an unguided DHI for stress management in a universal prevention approach. However, in the indicated prevention setting in Study 2, the guided DHI was superior to the unguided DHI for problematic alcohol consumption from an economic perspective. The results of Studies 1 and 2 suggest

that depending on the prevention approach or focus of the DHI, different guidance formats might be beneficial from an economic point of view.

The results of Studies 1 and 2 also align with a systematic review, which indicates that mental health interventions in employees improve both their well-being and productivity (171). Furthermore, DHIs seem to compare favorably against face-to-face interventions for health promotion in the workplace. According to a systematic review (*N* = 12 RCTs), a negative ROI was reported, on average, for face-to-face interventions (ROI = –0.22, 95% CI: 0.27 - 0.16) (172). Furthermore, Van Dongen et al. (173) demonstrated a negative ROI of a combined social and physical environmental worksite intervention.

5.2.2 Study 3

The validation of the G-NoMAD in Study 3 is one of the first studies that deals with the psychometric evaluation of a German instrument for measuring implementation outcomes. Similar to the results of the G-NoMAD validation, the original English NoMAD validation study (79) showed a clear factor structure and high internal consistency. In the G-NoMAD study, internal consistency and correlations among construct measures were even slightly higher (Cronbach's α = 0.79 - 0.85; construct correlations *r* = 0.64 - 0.76) compared to the validation results of the English version (Cronbach's α = 0.65 - 0.81; construct correlations *r* = 0.49 - 0.68). The current version of the NoMAD also appears comparable with other translations of the instrument into other languages (87–90) in terms of psychometric properties. In the validation study of the Dutch NoMAD (89), the four-factor model showed the best fit to the observed data. In the G-NoMAD validation, the four-factor and the hierarchical model achieved a similar fit. Thus, priority should be given to the practical relevance of the hierarchical model with

an overall score and four subscale scores. Most of the fit indices of the G-NoMAD can be classified as acceptable (SRMR = 0.08) to good (CFI = 0.97; TLI = 0.96). However, the RMSEA value of 0.10 was above the recommended threshold of 0.80 (148). In contrast, good psychometric properties were obtained for all fit indices in the English and Chinese validation studies (79,90). However, in the Dutch validation study (89), all fit indices were outside the desired thresholds (CFI = 0.90, RMSEA = 0.12, SRMR = 0.11, TLI = 0.88), which only applied for the RMSEA value in the G-NoMAD validation. When interpreting fit indices, it should be noted that there are only recommendations for model evaluation and no definitive established guidelines (174). Moreover, it may be the case that a model fits the data even though one or more measures of fit indicate a poor fit. Despite different implementation domains, projects, and settings, it can be considered a strength of the G-NoMAD that essentially favorable psychometric scores were obtained.

While the NoMAD questionnaire has been validated in several languages, including German, this is often not the case for other questionnaires in implementation science. Without well-developed German measures, the validity of the conclusions based on this research is restricted (85). Presently, the EBPAS-36 (175), the ORIC questionnaire (176), and the General Self-Efficacy Scale (GSE) (177), have been validated for use in German-speaking countries and have shown good psychometric properties. There are other measures for the German-speaking contexts, but some lack information on the quality criteria, show only moderate quality, or require further development (85).

5.2.3 Studies 4 - 6

While numerous studies have examined the effects of DHIs on psychological symptoms and disorders, the investigation of implementing DHIs in routine care has often been neglected (91,92). In the national depression prevention project "With Us in Balance" conducted by the German Social Insurance for Agriculture, Forestry, and Horticulture, two digital interventions were investigated within the scope of a broad implementation study. Previous implementation studies focused primarily on DHIs for treating mental disorders, while there is little research on implementing interventions for their prevention. Existing studies have focused on the implementation of DHIs to prevent eating disorders (95) and depression in adolescents (93,94) and adults (96). Study 4 provides an example of a study design evaluating a nationwide implementation of DHIs among a high-risk occupational group, including farmers, forest owners, and gardeners. This study design used various TMFs and integrated different perspectives of implementation (e.g., end-users, implementers, healthcare workers, and coaches from external service providers) within a mixed-methods approach. According to a scoping review on implementing DHIs, many previous studies have inadequate methodological standards (91). Therefore, a solid theoretical foundation, as applied in Study 4, is helpful to advance the understanding of the implementation of DHI for mental disorders in everyday practice.

Studies 5 and 6 refer to several research questions from the study protocol (Study 4) and contribute to evidence on implementing DHIs for preventing depression from users' and healthcare workers' perspectives. From the perspective of end-users (e.g., participating farmers, forest owners, and gardeners), which was the focus of Study 5, the guided DHI program was primarily accepted and perceived as appropriate within a preventive context. This is also in line with the findings of

Study 6, in which healthcare workers reported the perceived acceptance of mental health services and a general interest in DHIs among insured members. Previous studies in the digital treatment of depression yielded equivocal findings regarding the acceptance of DHIs. While DHIs were often described as acceptable (178–180), the acceptance was influenced by individual attitudes, preferences, and needs of patients in other studies (181,182) or considered unsuitable for patients with severe mental disorders (181), which 32% participants (7/22) in Study 5 also mentioned.

The importance of human support in DHIs was reflected in the results of Study 5, in which participants described the eCoach guidance as "positive and trusting" (19/22, 86%), "personal", "professional and competent" (each 18/22, 82%), and "supportive and motivating" (14/22, 64%). This aligns with previous findings on digital depression treatment (182,183). In a qualitative study by Beattie et al. (178), some patients expressed surprise at the quality of the relationships they could develop digitally. However, other participants in Study 5 described eCoach guidance as "lack[ing] of personal contact" (5/22, 23%), "insufficient" (4/22, 18%), or "distant and objective" (3/22, 14%). This is consistent with another qualitative study on a guided DHI for depression treatment, in which some participants mentioned desiring more therapeutic support (184). However, the authors discussed that the extent of therapeutic guidance might differ between patients.

Different needs of the participants were also evident in Study 5. Intervention aspects such as the diary, psycho-educative content, and written contact with the eCoach were identified as positive and negative intervention components. Some participants described the written eCoach contact, for example, as easy to

integrate into daily life, while others reported an unfavorable characterization of the relationship with the eCoach as a result of written contact. Diverse experiences and differing needs among participants within the context of a digital treatment for depression were also reported in a study by Holst et al. (182). Furthermore, despite the tailored approach to individual risk factors and adapting the DHI program to the agricultural setting, the most frequently mentioned negative factor was “lack of individual fit” (12/22, 55%). A desire for more individualization aligns with previous qualitative research on patients’ experiences with digital treatment for depression (180,181). At the same time, participants of Study 5 reported that tailoring the DHI program to the agricultural target group in terms of content and graphics was highly beneficial as such content resonated well with the target population.

Consistent with previous literature on DHIs (31), participating farmers and healthcare workers described in Studies 5 and 6 the easy access, flexible usage, anonymity, and location and time independence as advantages of DHIs and highly relevant for this target group that mostly lives in rural areas. Hadjistavropoulos et al. (161) conducted a process evaluation based on the CFIR to understand facilitating factors and barriers impacting the implementation of internet-based Cognitive Behavioral Therapy (iCBT) within community mental health clinics. In line with the findings in Studies 5 and 6, the CFIR domain “intervention characteristics” was also identified as mainly facilitating the implementation, particularly to the relative advantages of the iCBT program compared to traditional mental health care services.

Interview participants in Study 5 reported technical difficulties concerning the registration process and the online platform, which was also described as a barrier

to the implementation from the perspective of healthcare workers in Study 6. Additionally, both studies identified a lack of computer skills and inhibitions in using the internet or phone for mental health interventions as barriers to intervention use. These findings are in line with previous studies on the uptake and use of digital depression prevention and treatment interventions, in which inadequate computer skills (185), a negative attitude towards computer use (102), functionality challenges, and technical difficulties (102,103,186) were identified as hindering factors. Furthermore, a qualitative study by Zhao et al. (187) on barriers and facilitating factors to integrating DHIs into county mental health services investigated factors for successful implementation of DHIs from different perspectives, including healthcare professionals and project leaders. Digital literacy was identified as one of the key factors influencing the implementation of DHIs at the individual level. A need for education on digital literacy and technical support for DHIs, especially for older adults and individuals with disabilities, was suggested by clinical staff and county leaders in the study by Zhao et al. (187).

In Study 6, healthcare workers reported skepticism, uncertainty, and stigma surrounding mental health issues, which is in line with previous research on mental health in (male) farmers (188–191). Hagen et al. (189) investigated barriers to mental health help-seeking among farmers in Canada, and the qualitative findings showed that help-seeking is influenced by service accessibility, the stigma around mental health in the agricultural community, and anonymity in seeking support. Furthermore, the authors identified farm credibility (e.g., the level of agricultural knowledge among health service providers) as a facilitating aspect in seeking help, which was not described in Studies 5 and 6. In a qualitative study by Eccles et al. (103), some participants believed that depression could not be prevented, which might lead to a reluctance to use DHIs

for depression prevention. The authors concluded that mental health should be prioritized alongside physical health, there should be an increase in mental health awareness, and there is a need to develop effective communication strategies for depression prevention. A shift towards the perception of depression as a preventable disease might be essential for the successful implementation of digital prevention services.

Moreover, Study 6 assessed implementation determinants related to the CFIR domains “inner setting” of the SVLFG and “characteristics of the individuals”. Identified barriers from the perspective of healthcare workers included the need for training, difficulties in addressing mental health issues, and little routine in advising on healthcare services. These barriers are consistent with a systematic review investigating factors influencing the implementation of digital interventions (105). This review described access to knowledge, training, and educational materials as essential aspects for the implementation. A pilot study about the implementation of DHIs for preventing depression in adolescents also reported that training staff for counseling is challenging (93). A lack of routine and limited knowledge about DHIs, which might hinder the referral process and lead to low referral rates, were also reported among primary care physicians in a qualitative study for digital depression treatment (192). Furthermore, time constraints and high workload due to additional tasks were mentioned as barriers to the DHIs implementation among implementers and healthcare workers. These aspects were also factors identified as hindering among professionals implementing e-mental health in inpatient care (186). A systematic review of the success and failure of DHIs identified workflow as the most relevant factor for the outcome of DHIs, which can be influenced by a high workload, workflow disruption, and undefined and changing roles (104). The compatibility of DHIs

with existing work flows was rated as high in Study 6, possibly because the digital offerings were introduced as an extension to existing on-site health offerings, and many processes for DHIs, such as call center counseling, are comparable to processes for on-site services. Additionally, the implementation team described a transparent allocation of roles as a facilitating aspect. Consistent with a further systematic review of e-health interventions (105), Study 6 showed that no single factor is decisive for the success of digital psychological interventions, but rather a complex interplay of various factors influences implementation.

5.3 Strengths

Collectively, the studies included in this dissertation provide new insights into the use of digital health interventions to prevent mental disorders. The economic evaluation in Study 1 was, to the best of the author's knowledge, the first study that investigated the cost-effectiveness of a universal digital stress management intervention for employees. Additionally, the second economic evaluation (Study 2) was the first study that examined the economic merit of (un-)guided DHIs for problematic alcohol use in employees. In order to transfer knowledge about the (cost-)effectiveness of evidence-based interventions into practice, implementation research is vital. To advance implementation research in German-speaking countries, the NoMAD questionnaire, which is a theory-based measure of implementation outcomes, was translated into German, piloted, and validated (Study 3). The other studies (Studies 4 - 6) are part of the German-wide project "With Us in Balance" aimed at preventing depression using digital interventions and working to contribute knowledge on the implementation of DHIs in high-risk occupational groups such as farmers, forest owners, and gardeners. A strength of the study protocol (Study 4) on the national implementation of digital interventions is the combination of different TMFs in a mixed-methods approach,

as well as the inclusion of perspectives from various interest groups. A qualitative interview study (Study 5) provided insights into participants' experiences with a digital intervention adapted to the agricultural setting. Equally important to understand implementation is surveying involved healthcare professionals about barriers and facilitators, which was done in Study 6 from the perspective of healthcare workers and implementers. The results of Studies 5 and 6 provide numerous starting points for the development of digital interventions to prevent depression, the advancement of implementation of the DHIs in the project "With Us in Balance", and recommendations for future implementation projects.

5.4 Limitations

Although the studies included in this dissertation have several strengths, the following limitations must be considered when interpreting the results. First, the research context may have produced a self-selection of individuals more intrinsically motivated to participate in DHIs than those outside the research context (99). Similarly, participating employees may have been more open and optimistic about implementing DHIs than the remaining employees. Consequently, the results may not be generalizable to the broader target population but presumably represent those willing to use or implement DHIs. Second, both DHIs were compared to WLC conditions in the economic evaluations, which may lead to overestimating effects. The pharmaco-economic guidelines recommend treatment-as-usual (e.g., brief face-to-face interventions) as a comparator (193), which should be applied in future studies. Third, the timeframe of the economic evaluations was restricted to 6 months and focused on short-term costs and effects. Health effects, cost savings, and productivity gains could be maintained or decreased long term. Furthermore, costs for the development and implementation of DHIs were not taken into account. Since

implementation costs, in particular, can often be very high and lead to ongoing expenses, these should be given more significant consideration in future studies. Fourth, larger sample sizes are required in economic studies to enable robust economic evaluations of DHIs (194). Costs have a large variance compared with normally distributed health effects. Moreover, no moderators could be identified in the economic evaluation of the digital stress management intervention, possibly due to a small sample size. The effectiveness study of the same digital stress management intervention identified resilience, agreeableness, psychological strain, and self-regulation as moderators for intervention effects (195). Previous studies on the digital prevention of mental disorders showed that older participants with higher symptom severity at baseline benefited significantly more from DHIs than younger participants with lower initial symptom severity (42,196). Researchers should further investigate moderators in cost-effectiveness analyses, which could help identify specific target groups that particularly benefit from digital prevention. Recruitment and implementation strategies can be tailored more closely to such target groups. Fifth, two slightly different translations of the G-NoMAD were used in the validation study, which might reduce the validity of the findings. However, for this reason, a measurement invariance analysis was conducted to compare the latent scale structures between the participant groups of both questionnaire versions. At the same time, the experiences of both research groups could be taken into account, and the study represents a basis for a uniform G-NoMAD questionnaire. Sixth, the qualitative results in Studies 5 and 6 represent the perspective of a few participants and may not be generalizable for the entire agricultural target group or employees at the SVLFG. However, qualitative studies provide deeper insight into the participants' experience and help to understand complex implementation processes from a user or employee perspective. Additionally, qualitative results in Study 6 were complemented by

quantitative results on the CFIR constructs. Seventh, a mixture of different items and questionnaires were used to evaluate the implementation of DHIs based on the CFIR. This led to methodological difficulties (e.g., regarding scale format or unequal representation of CFIR constructs) and required a transformation of the scales for a consistent presentation of results. To date, no questionnaire exists that covers all CFIR constructs.

5.5 Practical Perspectives

The findings of this dissertation have several practical implications. The results of Studies 1 and 2 suggest that DHIs for stress management and reducing alcohol consumption for employees are cost-effective and cost-saving, and thus, provide a promising measure for the prevention of mental disorders. Taking the employer's perspective, DHIs could be a promising way to deliver prevention services in occupational settings. High probabilities of a positive return on investment have been revealed in both studies, suggesting that DHIs addressing stress management and problematic alcohol consumption in employees are likely to be cost-saving. However, many German-language health interventions and apps are currently available through the Google Play and iTunes stores, which often have qualitative deficiencies, low privacy standards, or lack clinical studies on benefits and risks (197). In addition, although meta-analyses generally show the effectiveness of DHIs delivered via an online platform, there are significant differences between interventions and even individual DHIs with negative effect sizes (198). Similarly, the finding that DHIs for stress reduction based on a cognitive-behavioral approach is effective does not constitute a justification that a new DHI following the same approach will be effective (199). Employers should therefore ensure that there is robust evidence of effectiveness for the specific intervention to be implemented. Preferably, the selected DHI should be integrated

into an occupational health management system that includes individual behavioral prevention, such as DHIs, and environmentally oriented prevention to address structural and organizational factors influencing workplace health. Likewise, DHIs can be a possible measure as a result of a psychological risk assessment in the workplace, which aims to assess work-related mental stress and develop preventive measures and represents a legal obligation for companies in Germany (200).

From a societal perspective, DHIs targeting risk factors for mental disorders such as stress and problematic alcohol consumption have a high probability of being cost-effective. The DHIs evaluated in Studies 1 and 2 have been shown to dominate the control groups by achieving lower costs at better health gains. While a guided intervention was superior to an unguided intervention for problematic alcohol consumption, an unguided DHI was also likely to be cost-effective in a universal digital stress management approach. The results of the ROI analyses could encourage not only employers but also public health decision-makers to offer DHIs to employees because of favorable ROIs, as DHIs led to productivity gains (i.e., less absenteeism and presenteeism). The Federal Statistical Office estimated costs associated with mental disorders in the German healthcare system to be around 44.4 billion euros in 2015 (201). Cost-effective interventions for the prevention of mental disorders, therefore, have enormous potential. In many countries, such as the United Kingdom (134), Canada (202), Australia (203), or Sweden (204), health economic evaluations are used to assess the benefits of new interventions and make recommendations for their introduction and funding. Due to scarce resources in the healthcare system, which will be further constrained by the consequences of the Covid-19 pandemic (205), demographic change (206,207), and climate change (208), the importance of cost-effective

interventions will continue to increase in order to allocate the available resources as efficiently as possible. Aspects of cost-effectiveness should also be given more significant consideration in decision-making processes in the German healthcare system to enable more transparent processes and to achieve the greatest possible health benefits for the population and society.

In Germany, digital prevention was recently included in the prevention guidelines as an extension of the offerings for individual behavioral prevention, health promotion and prevention in living environments, and workplace health promotion (22). By § 20 SGB V, funding is provided for digital prevention and health promotion services with scientifically proven health benefits. The findings based on scientifically accompanied projects investigating innovative approaches, such as “With Us in Balance”, are incorporated into the further development of the Prevention Guide. Based on the findings of “With Us in Balance”, several recommendations for DHIs to prevent mental disorders can be made. Particular attention should be given to tailoring the DHIs to the participant’s needs and preferences and the importance of human guidance concerning participants’ motivation, adherence, and technical support. To improve usability, automatic buffering of unfinished modules, a clear structure of the online platform, and tips regarding the use of the platform might be helpful. Regular reminders and a limited time and effort burden to complete a training module represent further recommendations to facilitate the use of digital interventions. Ideas for the personalization of DHIs include introducing optional training elements and tailoring DHIs to the target group. In general, the current importance of DHIs for preventive healthcare is still considered low (209). Consistent dissemination of the prevention recommendation is necessary to increase the use of preventive IMIs, preferably with an accompanying implementation study.

Results on implementing DHIs for depression prevention in farmers and individuals in related professions contribute to understanding barriers and facilitating factors in implementation and deriving appropriate implementation strategies for end-users and healthcare workers. Based on the findings of Study 5, several adaptations for the guided DHI program can be derived to improve the guided DHI program and strengthen its acceptance and satisfaction among farmers, forest owners, and gardeners. In doing so, the identified positive factors should be strengthened, and negative factors related to intervention use should be reduced. Participants' needs and preferences could be addressed by more personalized DHIs concerning eCoach guidance and optional training elements (e.g., diary). The usability should be increased by eliminating technical difficulties and establishing a clearer online platform. The content of the modules should be shortened and simplified, while digital literacy should be strengthened by providing educational information and expanding technical support. Tips for integrating the training contents into daily life should be added to ensure the sustainability of the effects.

Healthcare workers described stigma around mental health in the agricultural context, representing a critical barrier in this implementation setting. Possible implementation strategies to counteract stigma include campaigns for mental health awareness in farmers and individuals in related occupations. An example is the campaign "It Starts With Me" in Canada (210), which was disseminated mainly on social media. It was developed by individuals with an agricultural background and, thus, was perceived as a trusted source of information by Canadian farmers. This campaign aimed to destigmatize mental health problems and change the language about mental health, as stigma and stereotypes are often reflected in language. Increasing mental health awareness and education is a

constant and ongoing process that may improve societal acceptance of prevention interventions and make improving mental health a universal priority. Many of the conducted implementation activities by the SVLFG have addressed this (e.g., interviews and TV reports with those affected). So far, however, these measures have not been implemented as part of a nationwide mental health campaign by the SVLFG. A participatory approach involving the target groups of farmers, forest owners, and gardeners, as well as other involved parties (e.g., agricultural clubs and associations), could be helpful for this purpose.

Further implementation strategies should focus on enhancing knowledge about DHIs and addressing uncertainties with mental health issues among healthcare workers. Follow-up training for employees should be conducted to provide information about DHIs and current developments of the project “With Us in Balance”. Additionally, a newsletter could be helpful to reach the employees at regular intervals. The referral procedure should be simplified and the bureaucratic burden, including filling out a consultation protocol, reduced. Digital tools could be used during on-site consultations with insured persons to make it easier to fill out consultation protocols and forward them to the call center. Using short image videos and appropriate materials for consultation might also be helpful and save time, which could counteract the reported time constraints during counseling. Greater involvement of supervisors in implementation efforts might enhance leadership engagement and thus, positively influence the implementation of DHIs. Regular quality monitoring should make the implementation process measurable, especially when the scientific evaluation is completed. A database for this has already been created for research purposes. Further implementation and recruitment strategies will be able to be derived based on the RE-AIM evaluation of the implementation, the results of which are currently pending.

5.6 Future Research

This dissertation provides several perspectives for future research on the further development, (cost-)effectiveness, and implementation of digital health interventions to prevent mental disorders. This dissertation examined the effects of DHIs on psychological and behavioral outcomes, such as perceived stress and alcohol drinking. However, the consequences of elevated stress and problematic alcohol drinking are numerous. Besides mental disorders, stress is associated with a higher risk for coronary heart disease (26), stroke (27), immunological aging (211), and chronic pain (25). This is also reflected in findings from (neuro-)bioenergetic stress research, which shows that stress leads to increased oxidative stress, low-threshold inflammation, and a constant allostatic load on the body, which increases the risk for various diseases (212). Similarly, alcohol abuse has a direct impact on numerous diseases, including stroke (30), cardiovascular diseases (28,29), infectious diseases, digestive system diseases, cancer, injuries, and poisonings (28). The consequences of alcohol consumption are substantial, accounting for approximately 3.8% of all global deaths and 4.6% of disability-adjusted life-years (213). Considering these findings, the potential for cost savings and cost-effectiveness of DHIs addressing stress and problematic alcohol consumption could be even higher. Researchers should therefore evaluate outcomes such as the incidence of physical diseases (e.g., cardiovascular diseases, cancer, and stroke). As health effects from prevention and health promotion interventions, and economic benefits, often become apparent after years or decades, this requires studies over a more extended period. Evaluations of services that have long-term effects on various diseases are particularly complex (55). Decision analytic models for assessing cost-effectiveness (e.g., Markov models or microsimulation models) (214), in which the long-term costs and effects are

modeled, seem to be a promising target for further research. In addition to stress management and reducing alcohol consumption, other prevention and health promotion areas include physical activity, nicotine dependence, and nutrition. While digital interventions addressing these areas have been shown to be effective (215–217), evidence on cost-effectiveness of such DHIs is lacking.

For the widespread use of DHIs to prevent mental disorders, it is essential to systematically evaluate the ratio between the benefits of DHIs and the resources expended (e.g., in the form of eCoach guidance) (218). Muñoz (219) proposed that automated, evidence-based DHIs should be available free of charge as Massive Open Online Interventions in an open digital library as a basic service. Based on the findings of this dissertation, an unguided digital stress management intervention was likely to be cost-effective, while guided digital interventions to reduce problematic alcohol use were superior to the unguided intervention from a health-economic perspective. Automated DHIs need to keep support costs low while maximizing positive effects. Further research, possibly within a randomized adaptive trial design (220), is needed to determine the optimal level of human support for digital preventive interventions with regard to different types of mental health symptoms in terms of (cost-)effectiveness.

The findings of this dissertation support that digital interventions should ideally be tailored to the individual needs and characteristics of participants, their motivation and prior knowledge, and the desired level of involvement of eCoach guidance. A recent systematic review on tailored DHIs for mental health at the workplace compared to WLC conditions or usual care revealed promising effects regarding sleep, presenteeism, and stress levels (221). The included studies used various strategies for tailoring the intervention, including an algorithm guiding

the assignment of intervention content or the generation of feedback, participant choice of intervention content, and automated messages. Additionally, some interventions also included in-person support. Except for one study, most studies reported moderate or good uptake and a higher adherence than non-tailored digital programs. While these findings are promising, it is critical to learn more about the conceptualization of tailoring DHIs to individual profiles. Similarly, more knowledge on change mechanisms of psychological interventions is needed to design more effective interventions with optimized outcomes (222). Interventions could then be designed to target specific underlying individual risk or protective factors (e.g., rumination, emotion regulation, social skills). Selecting specific variables and developing decision rules for intervention components is crucial for advancing this research. The technology-based presentation of therapeutic content can also be helpful for examining the influence of specific intervention components while keeping other previously difficult-to-control influences like therapist factors (e.g., skills, personal attitudes, professional experience) constant (222). Systematic testing and evaluating of personalized digital interventions could be accomplished using the Sequential Multiple Assignment Randomized Trial (SMART) (223). A RCT by Asplund et al. (224) demonstrated promising results from work-focused DHIs in stress-related disorders compared to generic DHIs, which may accelerate recovery and reduce short-term sickness absence. Therefore, tailored DHIs at the workplace should also be investigated further from an economic point of view.

Great potential for the further development of DHIs also lies in persuasive design, which enables designing engaging interventions by combining insights from health psychology and media informatics (225). Types of persuasive design approaches include self-monitoring and tracking (e.g., ecological momentary

assessment), collaborative features, adaptive content (e.g., feedback based on artificial intelligence through a chatbot), or social comparison (e.g., leaderboards) (226). Research to date has provided initial, promising insights into possible areas of application of artificial intelligence (AI) techniques and machine learning algorithms in psychotherapy, such as identifying mental disorders at an earlier or prodromal stage where interventions may be more effective and personalizing treatment selection based on the unique patient characteristics (227,228). However, further development and research are needed in the use of AI in mental health. It is also crucial to consider ethical implications of these technological developments, such as data ethics, a lack of guidance on the development of AI applications, the potential for misuse (e.g., the use of technologies to replace traditional services), and the exacerbation of existing health inequalities (229).

The abundance of technological solutions has also led to a multitude of terms for DHIs. As a Delphi consensus study with experts showed (40), there are terminological challenges in psychological interventions with digital components. Different names describe the same techniques, and similar names refer to different formats. According to the authors, a common language for DHIs would facilitate research, teaching and practice and could be supported by the development of a standard glossary for the field.

As the results of this dissertation show, difficulties to the uptake and usage of DHIs for preventing mental disorders in the workplace may be encountered. Recruitment difficulties and low adherence have been reported in previous studies on DHIs aimed at employees (97). These were particularly evident in DHIs for alcohol consumption, which was shown in the data collection for Study 2 and a scoping review by Sundström et al. (230). The authors of this review suggested

that qualitative studies could be conducted to examine how recruitment strategies could be designed to reduce those concerns. Additionally, the reached target groups in Studies 1 and 2 were primarily female (≥ 60%) and highly educated, which represent the typical users of DHIs (231). More effort is needed to reach underrepresented groups, such as males and less educated individuals and, thus, improve health equity (i.e., a fair chance for everyone to be as healthy as possible) (232). According to a qualitative study (233), employees appreciate the ability to do training on the job. However, they were concerned that others would see what they were doing when they looked at the screen and felt that the workplace environment was not conducive to dealing with personal issues. Likewise, time constraints and overwork were described as significant obstacles. Additionally, barriers at both the individual and the organizational level, such as a lack of involvement from upper management, have been reported when implementing DHIs in the workplace (234). More work is needed to better understand how DHIs for employees can be successfully implemented in the workplace. Tsantila et al. (235) recently published the "Theory of Change" framework for evaluating complex interventions for mental health in the workplace that should be applied in future studies.

To accompany the implementation in routine care, validated instruments assessing implementation outcomes are powerful tools facilitating the implementation. The findings of this dissertation support the use of the G-NoMAD as a reliable tool for German implementation settings. The modified translation of the G-NoMAD should be further investigated concerning its psychometric properties. Moreover, the sensitivity of the NoMAD to longitudinal change (236) and the verification of the NoMAD questionnaire with other measures assessing implementation outcomes have yet to be examined. The

results indicate that the G-NoMAD is feasible in large organizations and small settings (e.g., a general practitioner's practice), which should be examined further in future research. The existence of valid questionnaires for implementation science enhances the ability of implementation research in German-speaking countries to further test theories and advance implementation science. Further validated questionnaires, especially for German implementation settings, are urgently needed. Future research work in implementation science should also develop a comprehensive questionnaire assessing all CFIR constructs, which would be helpful for future implementation studies. Moreover, some constructs between the CFIR dimensions "inner setting" and "characteristics of the individuals" seemed to overlap. In the meantime, Damschroder et al. (237) recently published an updated version of the CFIR, which addressed gaps in the use of the CFIR and should be applied in future studies investigating the implementation of DHIs.

In the target group of farmers, forest owners, and gardeners, low digital literacy was reported as a barrier to DHIs for depression prevention in this dissertation. It is critical to understand individuals' current level of digital literacy and to examine sociodemographic differences (e.g., age, income) in digital literacy, which have been poorly measured and researched in the field of DHIs. Neglecting differences in digital literacy may exacerbate inequalities in mental healthcare (238). Solutions to enhance digital literacy may lie in increasing the usability of digital interventions and providing accessible and understandable digital literacy training (both general and DHI-specific) (187). To fully engage with DHIs and bridge the "digital divide", Hoffman et al. (239) developed a hands-on and interactive training program to teach digital literacy. The training is based on self-determination theory, technology use cases, and the therapeutic alliance and could

help increase equity in access to and knowledge of digital technologies. Such training could be included as an optional module in the digital intervention.

The findings of this dissertation point toward the importance of mental health literacy for depression prevention, especially among farmers and related professions. *Mental health literacy* is defined as knowledge and beliefs about mental disorders and consists of the ability to search, evaluate, communicate, and access information on mental health (240). It is increasingly valuable for preventing and identifying mental disorders early, reducing stigma, and improving help-seeking behaviors (241). Future studies could explore the role of health literacy, stigmatization, and health outcomes in the context of digital interventions for depression prevention. A possible approach to enhance acceptance of digital mental health interventions is to develop acceptance facilitating interventions (AFIs), for example, short informational videos about DHIs, to increase participants' acceptance of DHIs (242–244). Research on mental-health-related stigma suggests that social contact is an effective intervention to improve stigma-related knowledge and attitudes in the short term (245). Virtual communities, such as interactive chat forums with or without moderators, could allow participants to support each other, share experiences, and, thus, counteract stigmatization (246). In addition to reducing the stigma of depression, indirect prevention could also be helpful in this target population. Indirect prevention focuses on problems that are associated with depression but less stigmatized (e.g., insomnia) and might prevent the onset of depression in an indirect way (247). Initial results of indirect prevention are promising but need to be investigated in more depth in future research.

Due to various risk factors and a widespread increased prevalence of mental disorders in other countries, there is likely also an increased risk of depression among farmers in Germany. However, there is no current epidemiological study on mental disorders and suicide for German farmers. This would be an essential next step to better assess the need and identify subgroups at higher risk (e.g., dairy farmers who are exposed to a very high workload) (248). Recruitment strategies could then be tailored more closely to these specific sub-groups who may benefit most from prevention services.

Besides occupational settings, the usage of preventive DHIs in other settings should be investigated, including schools, universities, or communities. The integration of DHIs could be a first step within a stepped-care approach (249). DHIs could also be easily integrated into existing prevention programs as a blended prevention format. This is supported by meta-analytic results indicating that traditional face-to-face interventions benefit from additional DHI components (250). Given that 75% of all mental disorders occur before the age of 25 (251), future research should specifically examine the potential of DHIs to prevent mental disorders among children, adolescents, and young adults (249).

As DHIs increasingly become used for the prevention of mental disorders, it is crucial to investigate adverse effects that can occur with any intervention (including face-to-face interventions). While negative effects of DHIs for the treatment of mental disorders have been examined in initial studies (252–254), there is minimal available information in the area of preventive DHIs. Possible risks and negative effects could be that people with a tendency to engage in risky behaviors (e.g., self-injury) could be identified too late (especially in interventions for relapse prevention), there may be reduced health-related self-efficacy if the

intervention is unsuccessful, or the development of negative attitudes may occur following a dropout and thus, a reduced willingness to accept other psychological support may result (249).

Further research is needed to better understand implementation processes for DHIs. Long-term implementation outcomes such as cost (e.g., the financial impact of an intervention implementation), penetration (e.g., the integration of an intervention within a service setting and its subsystems), and sustainability (e.g., the extent to which the program is maintained or institutionalized within a setting) have been rarely assessed in previous e-mental health implementation studies (91). In the project "With Us in Balance", the effectiveness and the implementation of DHIs to prevent depression in farmers and related occupations were evaluated separately in pragmatic randomized controlled trials and an implementation study. From a methodological point of view, there is great potential in using effectiveness-implementation hybrid designs that combine elements from both effectiveness and implementation research (255). For DHIs on substance use, Matson et al. (256) proposed a framework for designing trials that evaluate the effectiveness and implementation of DHIs that should be applied and investigated in future research.

The next steps for future implementation research on DHIs are, in particular, to test different implementation strategies against each other and to examine their influence on the implementation of digital interventions (e.g., using the NoMAD questionnaire or other validated instruments). Graham et al. (257) suggested implementation strategies for DHIs in mental healthcare settings, and these strategies should be applied, particularly for DHIs in prevention settings. Given the complexity of integrating DHIs, a multifaceted approach seems necessary for

DHI implementation (257). The use of a self-guided, integrated, and theory-based toolkit for intervention tailoring strategies in the implementation of iCBT services was examined in several countries in Europe and Australia (236). The study showed small positive effects from the toolkit compared to implementation-as-usual, suggesting that the toolkit helps implementers to develop and use effective tailored implementation strategies. Additionally, economic evaluations are needed not only to assess whether a new intervention offers good value for money but also to determine the cost-effectiveness of implementing or adapting a chosen innovation or strategy (258). A comparative economic evaluation of implementation strategies helps to make informed decisions on whether particular strategies efficiently use scarce resources (259). To assess implementation costs, human resource costs (e.g., clinic staff or staff supporting the intervention), accommodation costs, and equipment costs should be monitored (260). Going forward, researchers should conduct comprehensive economic analyses in implementation science to ensure decision-makers have the evidence they need to make the most of available resources and to provide the highest quality healthcare.

As the public health impact of DHIs for preventing mental disorders is closely linked to their successful implementation in routine care, more attention should be given to implementation science. Implementation science is a relatively young discipline that has still to be anchored in the academic system. In many countries such as the USA, United Kingdom, Switzerland, and northern European countries, many institutions and departments already focus on implementation science. This is not (yet) the case in Germany. In order to advance the implementation of evidence-based interventions, it is essential to anchor implementation science more firmly in teaching and research. In particular, offering training and advice on implementation science is essential to equip researchers and practitioners with

the necessary skills. Initiatives such as the “Global Implementation Society”, the “European Implementation Collaborative”, and the “Implementierungs-Netzwerk für Forschung und Praxis” (Implementation Network for Research and Practice) aim to promote implementation science on a global, European, and German level and should be strengthened in the future.

6. Conclusion

Given the high prevalence and burden of mental disorders, their prevention is of great importance. Digital interventions represent promising ways to improve mental healthcare due to their low-threshold accessibility and high scalability. In light of the results of this dissertation on the cost-effectiveness and the implementation of DHIs for preventing mental disorders in occupational settings, DHIs show great potential in addressing challenges in mental healthcare. Stronger links between (cost-)effectiveness and implementation research are critical to fully realize the potential public health impact of digital health interventions to prevent mental disorders.

7. References

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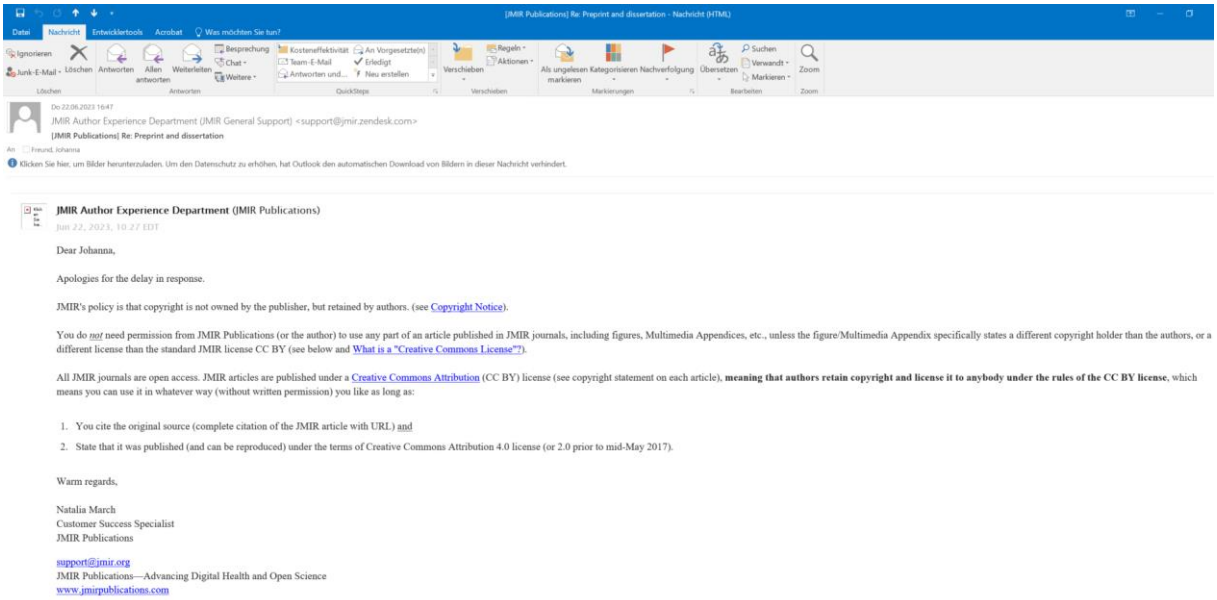

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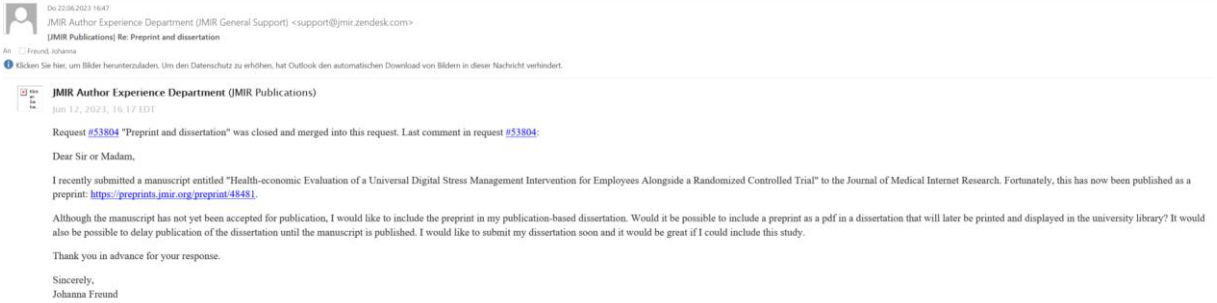

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