



# Are guided internet-based interventions for the indicated prevention of depression in green professions effective in the long run? Longitudinal analysis of the 6- and 12-month follow-up of a pragmatic randomized controlled trial (PROD-A)

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## ABSTRACT

**Objective:** Evidence of long-term stability for positive mental health effects of internet-based interventions (IBIs) for depression prevention is still scarce. We evaluate long-term effectiveness of a depression prevention program in green professions (i.e. agriculture, horticulture, forestry).

**Methods:** This pragmatic RCT ( $n = 360$ ) compares a tailored IBI program to enhanced treatment as usual (TAU+) in green professions with at least subthreshold depression ( $\text{PHQ} \geq 5$ ). Intervention group (IG) received one of six IBIs shown previously to efficaciously reduce depressive symptoms. We report 6- and 12-month follow-up measures for depression, mental health and intervention-related outcomes. Intention-to-treat and per-protocol regression analyses were conducted for each measurement point and complemented by latent growth modeling.

**Results:** After 6 months, depression severity ( $\beta = -0.30$ , 95%-CI:  $-0.52$ ;  $-0.07$ ), insomnia ( $\beta = -0.22$ , 95%-CI:  $-0.41$ ;  $-0.02$ ), pain-associated disability ( $\beta = -0.26$ , 95%-CI:  $-0.48$ ;  $-0.04$ ) and quality of life ( $\beta = 0.29$ , 95%-CI:  $0.13$ ;  $0.45$ ) in IG were superior to TAU+. Onset of possible depression was not reduced. After 12 months, no intervention effects were found. Longitudinal modeling confirmed group effects attenuating over 12 months for most outcomes. After 12 months, 55.56% of IG had completed at least 80% of their IBI.

**Conclusions:** Stability of intervention effects along with intervention adherence was restricted. Measures enhancing long-term effectiveness of IBIs for depression health promotion are indicated in green professions.

**Trial registration:** German Clinical Trial Registration: DRKS00014000. Registered: 09 April 2018.

## 1. Introduction

Internet-based interventions (IBIs) have been shown to be effective for a wide range of mental disorders (Boumparis et al., 2017; Domhardt et al., 2020; Königbauer et al., 2017; Richards et al., 2015; Riper et al., 2018; Sijbrandij et al., 2016). As effectiveness in treatment of mental disorders is well documented, prevention of mental disorders moves increasingly into the focus of researchers. Research evaluating the application of IBIs for prevention purposes across different mental disorders is still scarce and yields inconsistent results (Ebert et al., 2017a;

Sander et al., 2016). Yet, implementation of prevention programs into routine care might be a promising approach to reduce the burden of mental disorders in general population. Preventive IBIs are best evaluated for the prevention of Major Depressive Disorder (MDD) (Ebert et al., 2017a; Sander et al., 2016).

IBIs for depression treatment have been shown to be clinically effective (Königbauer et al., 2017) and cost-effective (Paganini et al., 2018) in reducing depressive symptom severity in adults with a diagnosed depression against different comparators, however, findings for symptom reduction and depression prevention in subthreshold

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depressive syndromes are less conclusive. A recent Individual Patient Data (IPD) meta-analysis reported a pooled effect size of Hedges'  $g = 0.39$  post-treatment for efficacy of IBIs in adults with subthreshold depression (Reins et al., 2021). Previous estimates of subthreshold depression reduction were slightly lower with  $SMD = 0.25$  (Deady et al., 2017) and  $SMD = -0.26$  (Rigabert et al., 2020). While short-term effectiveness for symptom reduction in subthreshold depression seems overall well documented with small to moderate effect sizes (Deady et al., 2017; Reins et al., 2021; Rigabert et al., 2020), fewer studies evaluate effectiveness for longer Follow-Up (FU) periods.

For onset of MDD, a pooled risk reduction ranging between 28% (Reins et al., 2021) and 42% (Deady et al., 2017) was reported after a period of 12 months. In comparison, pooled effect sizes for reduction of subthreshold depressive severity are overall small with  $g = 0.30$  for 3- to 6-month FUs and  $g = 0.27$  for 12-month FU (Reins et al., 2021). In a previous meta-analysis, an  $SMD = 0.21$  was reported for reduction of subthreshold depression symptoms for FUs of at least 6 up to 12 months (Deady et al., 2017). Even though the medium- and long-term effectiveness of IBIs for reduction of depressive symptoms in subthreshold depression seems relatively robust with small effect sizes, the number of available primary studies is still highly limited (Deady et al., 2017; Reins et al., 2021; Rigabert et al., 2020).

Effectiveness of IBIs for subthreshold depressive symptom reduction has already been demonstrated in different contexts and across different target groups, ranging from adolescents (Calear et al., 2009; Topper et al., 2017), students (Cook et al., 2019; Lintvedt et al., 2013), workers (Imamura et al., 2015, 2014), elderly people over 50 years (Spek et al., 2008, 2007) or chronic back pain patients (Sander et al., 2020). However, the effectiveness of IBIs in promoting mental health in subthreshold depression has been little studied in the context of specific occupations. A variety of relevant occupational health risk factors in farmers and farm operators (i.e. farmer, workers and family members) have been reported facilitating the development of mental disorders such as depression and anxiety (Daghagh Yazd et al., 2019; Fraser et al., 2005; Lunner Kolstrup et al., 2013), and even leading up to suicide (Klingelschmidt et al., 2018; Kunde et al., 2017; Milner et al., 2013). The most often identified risk factors across studies encompassed stressors like pesticide exposure, financial worries, weather conditions like drought, poor physical health or past injuries, heavy workload and stress in farming, government policies and paper-work or loneliness and lack of social relationships (Daghagh Yazd et al., 2019), illustrating the high mental strain due to adverse working conditions in this occupational group. Potentially elevated levels of depressive symptoms have been reported specifically for farmers in the United States (Rudolph et al., 2020) and Canada (Jones-Bitton et al., 2020). In United Kingdom, higher level of psychological morbidity was reported in farmers compared to non-farmers (Hounsome et al., 2012). Similarly, higher level of depressive symptoms were found in farmers compared to non-farmers (Sanne et al., 2004) or other occupational groups (Sanne et al., 2003; Torske et al., 2016) in Norway. In contrast, prevalence of depressive episodes was found to be lowest in male farmers and to be in the midfield for female farmers compared to other occupational groups in France (Cohidon et al., 2009), whereas in Greece, prevalence of depressive symptoms was found to be higher in farmers compared to non-farmers in higher age groups, with results being reversed in younger age (Demos et al., 2013). A systematic review comparing depression rates across men-dominated occupational groups across countries found elevated levels of depression specifically for farmers (Roche et al., 2016). Social support (Bjornestad et al., 2019; Furey et al., 2016) and feeling of belongingness (McLaren and Challis, 2009) seem to be protective factors for depressive symptoms and mental distress in farmers, while attitudes such as stoicism and self-reliance (Hull et al., 2017; Judd et al., 2006) have been reported as potential barriers for health care

utilization. Use of health care in farmworkers has been also associated with sociodemographic variables, i.e. health care utilization being higher in women, in higher age, with higher education or when accompanied by family (Georges et al., 2013). In general, research focusing on depression in farmers has been primarily conducted in United States, Australia, United Kingdom and Norway, with only few studies conducted in countries of the European Union (Hagen et al., 2019). As the situation of farmers depend on government policies, regulations and funding, adverse working conditions and associated risk for depression might differ considerably internationally. Overall, adequate preventive measures seem indicated in this occupational group to reduce psychological strain, prevent the development of (subthreshold) depressive syndromes and enhance overall mental health.

Typical workplace-centered interventions for primary prevention are measures to increase employee control and physical activity or to implement workplace health promotion programs (Joyce et al., 2016). Whereas majority of adverse working conditions in green professions seem difficult to modify due to external circumstances (e.g. drought or flooding, governmental regulations, price erosion for products), IBIs as person-centered interventions have already shown promising mental health effects in occupational contexts (Joyce et al., 2016; Lehr et al., 2016; Phillips et al., 2019; Stratton et al., 2017). Also, previous studies have efficaciously demonstrated that depressive symptom severity can be reduced by IBIs directly targeting depression (Buntrock et al., 2016, 2015; Ebert et al., 2017b; Nobis et al., 2015) as well as IBIs targeting risk factors for depression such as stress, insomnia, anxiety or problematic alcohol consumption (Boß et al., 2018; Ebenfeld et al., 2021; Ebert et al., 2015; Heber et al., 2016). Thus, we evaluate long-term effectiveness of a tailored IBI program consisting of six different IBIs targeting either depression or risk factors for the development of depression. Participants received an IBI program tailored to their individual problem area by focusing either on depressive symptoms with (GET.ON Mood Enhancer Diabetes) or without comorbid diabetes (GET.ON Mood Enhancer), stress (GET.ON Stress), insomnia (GET.ON Regeneration), panic and agoraphobia (GET.ON Panic) or problematic alcohol consumption (GET.ON Be clever - drink less).

We evaluate effectiveness of this tailored IBI program for depression health promotion in subthreshold (to clinical) depression as part of a nationwide initiative from the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) aiming to prevent depression in green professions (i.e., agriculturists, foresters and horticulturists) in Germany. Overall, the depression prevention initiative from SVLFG entails a portfolio of internet- and tele-based interventions being evaluated regarding their short- and long-term effectiveness and cost-effectiveness in several randomized controlled trials (Braun et al., 2019; Terhorst et al., 2020; Thielecke et al., 2020). In addition, the internet- and tele-based interventions are implemented into routine care and evaluated regarding implementation success (Bührmann et al., 2020; Freund et al., 2020).

The IBI program for depression health promotion in subthreshold (to clinical) depression was already shown to be effective for reduction of depressive symptoms severity at 9-week post-randomization in the occupational group of green professions compared to enhanced Treatment As Usual (TAU+) (Braun et al., 2021). Moreover, the IBI program had an overall health-promoting effect as sleep quality, pain-associated disability and quality of life were also enhanced 9-week post-randomization (Braun et al., 2021). Participants were classified as adherent to intervention protocol and thus, as a completer if they completed at least 80% of their IBI until 9-week post-randomization. As completer rate was low at 9-week post-randomization with 22.2% of IG (Braun et al., 2021), the continuing usage of the IBI program was monitored over the FU period of 12 months and program adherence was particularly taken into account in the assessment of program

effectiveness.

The aim of this article is to evaluate if intervention effects of the IBI program reported 9-week post-randomization are stable over a 6- and 12-month follow-up (FU) period, thus, if the IBI program is continuously effective (1) in reducing subthreshold depressive symptoms, (2) in improving other mental health outcomes (e.g. sleep quality, pain-associated disability or quality of life), and if (3) reliable change in depression symptoms, (4) reduction of depression onset or improvement in depression remission in the respective subgroups with or without potential depression at baseline and (5) long-term negative side effects or reliable deterioration occur compared to TAU+.

## 2. Material and methods

### 2.1. Study design

This is a two-armed pragmatic randomized controlled trial aiming to evaluate effectiveness and cost-effectiveness of a tailored IBI program in comparison to TAU+, i.e. having unrestricted access to TAU rather than receiving TAU by default. The primary outcome was depressive symptom severity at 9-week post-randomization (T1). Secondary outcomes are measured 9-week (T1), 6- (T2), 12- (T3), 24- (T4), and 36 months (T5) post-randomization. A detailed overview can be found in the corresponding study protocol (Braun et al., 2019). This article focuses on the 6- and 12-month FU results, while effectiveness results at T1 were already reported (Braun et al., 2021). This research has been conducted in accordance with the Declaration of Helsinki. This trial has been approved by the Ethics Committee of University of Ulm (No. 454/17) and registered in the German Clinical Trials Registry (DRKS0014000).

### 2.2. Inclusion and exclusion criteria

Participants had to be policyholders from a social health care insurance for agriculturists, foresters and horticulturists (SVLFG) in Germany. Policyholders were included if a) they were entrepreneurially active or a contributing spouse, family member or pensioner, b) had at least a subthreshold depressive symptomology (Perceived Health Questionnaire-9 (PHQ-9)  $\geq 5$ ) and c) age  $\geq 18$ . Participants were excluded in case of a) current psychotherapeutic treatment, b) indication for suicidal risk and inability to distance from suicidal ideation, and c) preference for participation in the parallel trial PACT-A (Terhorst et al., 2020) if a parallel chronic pain symptomology was present.

### 2.3. Recruitment and participants

Participants were recruited via different recruitment channels commonly used by the cooperating health insurance company. This included 80,000 postal invitation letters, several articles in the members journal as well as study information made available on different websites. All recruiting channels referred to an online-screening for evaluation of inclusion and exclusion criteria. Eligible participants received a study invitation after completing the online-screening. Participants who gave informed consent were invited to the baseline assessment (T0). After completion of the baseline assessment participants were included into the study by randomization. A permuted block randomization was conducted with randomly arranged blocks sizes (8, 10, 12) with a ratio of 1:1 by a person not otherwise involved in the study processes. As data collectors were blinded, only the persons administering the different interventions knew the group membership. Blinding of study participants was not possible. Based on a power analysis (Braun et al., 2019), 360 participants were included in the study.

### 2.4. Intervention

In both intervention conditions participants had unrestricted access to Treatment As Usual (TAU). The actual use of TAU has been registered

with the Trimbo Institute and Institute of Medical Technology Questionnaire for Costs Associated with Psychiatric Illness (TiC-P) (Bouwman et al., 2013). A detailed overview is given in Table 3.

#### 2.4.1. Control group

The Control Group (CG) received additionally an online-document with psycho-educative information a) summarizing risk factors for mental disorders (e.g. depression) and for sequelae (e.g. chronic pain) and the role of stress, b) differentiating between prevention, treatment and relapse prevention, c) offering self-help services for policyholders of SVLFG and general tips for health promotion and stress reduction, d) differentiating ways into inpatient and outpatient psychiatric and psychotherapeutic treatment as well as contact information for further support services (e.g. debt counseling, farmers meetings, self-help groups) and e) information about coping with crisis situations and how to get immediate help for acute crises situations e.g. in case of suicidality. Each topic was summarized on one page. We developed this material specifically for the use in this study. Thus, the CG had access to TAU+.

#### 2.4.2. Intervention group

The Intervention Group (IG) received access to an IBI program for depression health promotion in subthreshold (to clinical) depression tailored to participant needs by selection of one guided IBI out of a portfolio of six IBI aiming at different symptom areas. The training GET.ON Mood Enhancer focused on depressive symptoms (Buntrock et al., 2014), GET.ON Mood Enhancer Diabetes on depressive symptoms in diabetes patients (Nobis et al., 2013), GET.ON Recovery on insomnia (Thiart et al., 2013), GET.ON Stress on chronic stress burden (Ebert et al., 2014), GET.ON Panic on panic and agoraphobic symptoms (Ebenfeld et al., 2014), and GET.ON Be smart - drink less on harmful alcohol consumption (Boß et al., 2015). The trainings entailed 6–8 standard modules (6 standard modules: GET.ON Mood Enhancer, GET.ON Mood Enhancer Diabetes, GET.ON Recovery, GET.ON Panic; 7 standard modules: GET.ON Stress; 8 standard modules: GET.ON Be smart - drink less) with a duration of 30–60 min. The intended training duration was 6–8 weeks based on the recommendation to complete one training module weekly. The training GET.ON Mood Enhancer Diabetes encompassed in addition two add-on modules and one refresh module. All trainings have already been evaluated across different samples and have been shown to effectively reduce depressive symptom severity either post-treatment and/or at 6-month FU (Boß et al., 2018; Buntrock et al., 2015; Ebenfeld et al., 2021; Ebert et al., 2017b, 2015; Heber et al., 2016). For GET.ON Mood Enhancer additionally, a reduced onset of MDD as well as reduction of depressive symptoms was reported at 12-month FU (Buntrock et al., 2016, 2015). The content of the IBIs has been customized to the specific target group of green professions by adapting testimonials and stories of exemplary personas to the situation in green professions, e.g. targeting typical conflicts or problems of people living and working in green professions. Further, picture and video material included was adapted to green professions.

The IBI program consisted of three steps: (I.) Based on a *psycho-diagnostic assessment* consisting of several self-report questionnaires of the baseline assessment, the assigned eCoach derived a recommendation which training was indicated. (II.) During the *initial contact* between participants and eCoach the training recommendation was discussed as part of a shared decision-making process. Based on the psycho-diagnostic assessment and the initial contact a suitable IBI was selected and unlocked, and (III.) during the *training phase*, the participants were advised to complete one training module per week. After each completed module the participant received feedback by the eCoach. The feedback was given based on participant preference either by telephone or the internal messaging function of the intervention platform. Time spent per feedback both via telephone or internal message was indicated with 20 min by GET.ON institute.

After completion of the training a *consolidating phase* followed for the

duration of 12 months. The consolidating phase entailed monthly contact to the eCoach via telephone or internal messaging function of the intervention platform based on participant preference. This prolonged eCoach contact beyond the duration of the training aimed to promote the transfer of the learned and to integrate and consolidate the training content into everyday life.

As this is a pragmatic trial, main focus in the intervention condition was to always provide adequate intervention for individual participants needs. Participants were able to switch to another training before completion of the first module, if they reported the assigned training as unsuitable. Further, participants could request access to a second guided training directly after completion of the first. Both the assigned eCoach and supervisor had to approve these requests. As a second training, all six IBIs were admissible. Additionally, the training GET.ON Chronic Pain focusing on psychological distress due to chronic pain symptomology could be assigned. This training was separately evaluated in a parallel randomized controlled trial PACT-A and is described in detail in the corresponding study protocol (Terhorst et al., 2020). If another training was assigned, the consolidating phase followed after completion of the second training.

The training program was conducted by the external service provider GET.ON Institute. ECoaches were trained psychologists (M.Sc. or diploma), psychotherapists in training or licensed psychotherapists working as freelancers for the GET.ON Institute. ECoaches were supervised by a licensed psychotherapist. A detailed description of the intervention condition is given in the corresponding study protocol (Braun et al., 2019).

## 2.5. Outcome measures

All outcome measures were conducted as online-assessments via the survey tool Unipark. Reliability of outcome measurements were reported using Revelle's omega total from R package "psych" (McNeish, 2017), which poses a superior alternative to Cronbach's alpha (Dunn et al., 2014).

### 2.5.1. 6- and 12-month FU measures

The 6- and 12-month FU measures include the Quick Inventory of Depressive Symptomology 16 (QIDS-SR16) for measuring depressive symptom severity as well as onset and remission of potential MDD at FU (Rush et al., 2003). Reliability of this depression inventory was good (T2:  $\omega = 0.83$ , T3:  $\omega = 0.82$ ). A self-report version of the Composite International Diagnosis Interview (CIDI) as applied in the WHO World Mental Health Surveys International College Student Project (Auerbach et al., 2018) was included to assess onset and remission of potential MDD and bipolar disorder (BPD). Sensitivity of CIDI screening scales (CIDI-SC) was reported with 80.2% for Major Depressive Episode (MDE) and 74.0% for BPD at the optimal threshold for classification of DSM-IV/SCID cases. Specificity was reported with 90.1% for MDE and 98.8% for BPD for classification of non-cases at the optimal threshold based on DSM-IV/SCID non-cases (Kessler et al., 2013a). The Perceived Stress Scale (PSS) was applied to assess subjective level of stress (Cohen et al., 1983). The scale reached high reliability (T2:  $\omega = 0.91$ , T3:  $\omega = 0.93$ ). The Insomnia Severity Index (ISI) was applied to assess insomnia symptoms (Gerber et al., 2016). The reliability of the scale was high (T2:  $\omega = 0.92$ , T3:  $\omega = 0.91$ ). Inventories to assess anxiety symptomology included the General Anxiety Disorder Screener 7 (GAD-7) for general anxiety (Spitzer et al., 2006) as well as the Panic and Agoraphobia Scale (PAS) for panic and agoraphobia symptoms (Bandelow, 1995; Bandelow et al., 1995). Both inventories were very reliable (GAD: T2:  $\omega = 0.89$ , T3:  $\omega = 0.89$ ; PAS: T2:  $\omega = 0.93$ , T3:  $\omega = 0.93$ ). For evaluation of pain symptomology, the Multidimensional Pain Interference Scale (MPI) assessing pain-associated impairment (Flor et al., 1990; Kerns et al., 1985) as well as a Numeric Rating Scale (NRS) assessing pain intensity were included. Reliability of the MPI was very good (T2:  $\omega = 0.99$ , T3:  $\omega = 0.98$ ). The Alcohol Use Disorders Identification Test (AUDIT) was

applied to assess problematic alcohol consumption (Babor et al., 2001; Saunders et al., 1993a, 1993b). This scale was reliable (T2:  $\omega = 0.82$ , T3:  $\omega = 0.86$ ). Emotional exhaustion was evaluated with a subscale of the Maslach Burnout Inventory (MBI-GS) at 12-month FU (Maslach et al., 1997). Reliability was excellent (T3:  $\omega = 0.96$ ). Additionally, the Assessment of Quality of Life (AQoL-8D) Inventory was included (Richardson et al., 2014). The AQoL-8D had excellent reliability (T2:  $\omega = 0.94$ , T3:  $\omega = 0.95$ ). Finally, the Subjective Prognostic Employment Scale (SPE) was included to assess subjective perception of work capacity in the future. The SPE is characterized by very good reliability ( $\text{rep} = 0.99$ ) as reported by the authors (Mittag and Raspe, 2003). Additionally, health care service use was recorded based on the TiC-P (Bouwman et al., 2013).

### 2.5.2. Intervention-related 6- and 12-month FU measures

Working alliance between participant and therapist was rated at 12-month FU both by IG participants and assigned eCoaches with the corresponding version of the Working Alliance Inventory (Wilmers et al., 2008). Both, the patient (WAI-SR) and the therapist version (WAI-SRT) showed very high reliability (WAI-SR: T3:  $\omega = 0.97$ , WAI-SRT: T3:  $\omega = 0.94$ ). Analogous to this, technological alliance assessing the extent to which the program supports the person in achieving therapeutic goals was included at T2. The Technological Alliance Inventory for Online Therapy (TAI-OT) developed by Labpsitec (<http://www.labpsitec.uji.es/esp/index.php>) had excellent reliability (T2:  $\omega = 0.97$ ). Further, a series of items formulated by the authors of the present study were included to evaluate quality of intervention and eCoach support during intervention conduct and consolidating phase (i.e. modality of eCoach contact, overall satisfaction with eCoach, relevance of the IBI content for the personal situation, usability of the IBI and the intervention platform, problems during training conduct). Also, a battery of possible reasons for intervention dropout was formulated. Further, possible negative effects of the IBI program were assessed with the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP) (Ladwig et al., 2014), based on a version specifically adapted to the IBI context.

## 2.6. Data analysis

Data analysis was conducted in R (R Core Team, 2020). Data analysis is reported conform to the Consolidated Standards of Reporting Trials (CONSORT) statement and extension for pragmatic trials (Moher et al., 2010; Schulz et al., 2010; Zwarenstein et al., 2008). Significance level was in all analyses reported two-sided and defined as  $p < .05$ . The study was powered to detect an effect of  $d = 0.35$  (Cuijpers et al., 2014a) with a one-sided  $t$ -test ( $\alpha = 0.05$ ;  $1 - \beta = 0.90$ ) at 9-week post-randomization (T1) for the primary outcome. As we took into account an attrition of 28% (Richards and Richardson, 2012), overall 360 participants were included in the study. Effectiveness results for T2 and T3 were analyzed as cross-sectional measurement points analogue to previously reported effectiveness results for T1 (Braun et al., 2021). In a second step, Second order latent Growth curve Models (SGMs) were modeled to analyze longitudinal growth. This approach allowed us to a) analyze the intervention effects over time compared to cross-sectional analysis investigating intervention effects at a specific time point, b) to model linear and quadratic growth models to determine the most appropriate model and to pinpoint possible change points, and c) to conduct an analysis based on latent factors derived from item-level compared to linear regression models based on measures of a single observed variable (i.e. the sum score of the outcome) (Geiser et al., 2013).

### 2.6.1. Cross-sectional analysis

Missing data was imputed based on the Multiple Imputation by Chained Equations (MICE) procedure (van Buuren and Groothuis-Oudshoorn, 2011) including all variables as a predictor, which were used in the analysis (i.e. group as a predictor for 6- and 12-month outcomes, since we predict 6- and 12-month outcomes by group).



Furthermore, we included variables as predictors based on the bivariate correlation in the observed data as well as based on correlations with non-response (van Buuren and Groothuis-Oudshoorn, 2011). Hence, we based our assumption of missingness at random on this rigorous selection process of predictors in the imputation model taking also variables into account on which the missingness is depending. 20 data sets were imputed. Data analyses were performed with each data set and pooled according to Rubin's Rule (Rubin, 1996, 1987). Imputation of missing data was based on the previously applied procedure for analysis of T1 (Braun et al., 2021) and based on observed data T0–T3. Analyses were always conducted as Intention-to-Treat (ITT) analyses based on imputed data unless otherwise indicated.

Separate linear regression models were defined for ITT-analysis of continuous z-standardized measurements for both T2 and T3 and corrected for the baseline level. Means, standard deviations and standardized regression coefficients were reported along with 95%-CI. Additionally, effect size Cohen's *d* (Cohen, 1988) along with 95%-CI based on means and SDs was reported.

Generalized linear models were applied for analysis of dummy coded categorical variables. Logistic regression models were applied for calculation of Reliable Change Index (RCI) for depressive symptomology (Jacobson and Truax, 1991). RCI calculation for  $z = 1.96$  as standard deviation unit of change (Rozenental et al., 2019) was based on reliability of  $\alpha = 0.77$  for QIDS-SR16 (Roniger et al., 2015). This resulted in a threshold level of at least 5.88 points difference between pre and post-test means of QIDS-SR16 to qualify as significant change at the 95% level. Odds Ratios (OR) were reported along with 95%-CI for analysis of reliable improvement and deterioration.

Poisson regression models were conducted for analysis of onset and remission of MDD and BPD. Incidence Rate Ratios (IRR) were reported along with 95%-CI. Onset and remission of MDD was based on categorical analysis of QIDS-SR16. QIDS-SR16  $\geq 13$  was defined as cut-off score for categorization as MDD case at baseline and 6- and 12-month FU (Lamoureux et al., 2010). Additionally, onset and remission of MDD and BPD were analyzed based on a self-report version of CIDI (Auerbach et al., 2018). Number Needed To Benefit (NNTB) and Number Needed To Harm (NNTH) were reported along with 95%-CI (Altman, 1998; Bender, 2001) for significant effects.

In addition to ITT-analysis, sensitivity analyses were conducted to test robustness of the results. A complete-case analysis was conducted to validate the assumption that data was missing at random (Thabane et al., 2013). Additionally, per-protocol analyses for T2 were performed based on the subsample, who completed at least 80% of the intervention until 6-month FU (T2). For T3, per-protocol analyses were conducted based on the subsample who completed at least 80% of the intervention until 12-month FU (T3).

### 2.6.2. Longitudinal analysis

Latent growth curve modeling was applied to model longitudinal effects for T0–T3 data. Data analysis was conducted with "growth" function of R package "lavaan" (Rosseel, 2012). We used full information maximum likelihood as an estimator to handle missing values and applied robust (Huber-White) standard errors and a scaled chi-square test asymptotically equal to the Yuan-Bentler test (Yuan and Bentler, 2000) to obtain robust results.

For all continuous outcomes SGMs were conducted. SGMs are based on multiple repeated measures of observed variables and offer several advantages over First order latent Growth curve Models (FGMs), which are based on a single repeated measure e.g. the sum score of a depression inventory (Geiser et al., 2013). Latent factors of the LGMs were derived based on item-level of the continuous outcomes. For modeling quality of

life, due to the high number of items the eight dimensions of AQoL-8D (Richardson et al., 2014) were used as latent factors.

For specification of the SGMs, the following routine was applied (Gana and Broc, 2019): The intercepts of the reference indicators and the means of the first-order latent variables were fixed at zero. The intercepts of the other indicators were constrained to time equivalence. Measurement autocorrelations were calculated. The second-order factors of the model were defined by fixing the loading of the intercepts at 1.00. The latent slope factor was loaded by setting each repeated measure to a linear time coding. Baseline level was defined as time zero. T1 to T3 were loaded with weights 1 to 3. We modeled linear and quadratic growth curves.

Group membership was included as a time-invariant predictor. For each outcome measure we report growth models with a) group as a predictor for linear change (Model 1), b) group as a predictor for the intercept and linear change (Model 2), c) group as a predictor for linear and quadratic change (Model 3), and d) group as a predictor for the intercept as well as linear and quadratic change (Model 4). For details, see Appendix B, Fig. B.1. Model comparisons per outcome were made by 1) model convergence and 2) model fit to select the most appropriate model.

We reported full standardized estimates and robust standard errors along with significance level. Additionally, we investigated potential concavity inflection points (e.g. decline in depression to incline in depression) based on non-standardized estimates (Gana and Broc, 2019). For each model, we report the model fit indices chi<sup>2</sup> difference tests (Bentler and Bonett, 1980), Root-Mean Square Error of Approximation (RMSEA) (Browne and Cudeck, 1992), Comparative Fit Index (CFI) (Bentler, 1990) and Standardized Root Mean Square Residual (SRMR) (Hu and Bentler, 1999) along with the Akaike Information Criterion (AIC) (Akaike, 1974) and the Sample-Sized Adjusted Bayesian Criterion (SSABIC) (Schwarz, 1978). In case fit indices were ambivalent (e.g., some favoring model a and some favoring model b), we based the model decision on SRMR and RMSEA (Moshagen and Auerswald, 2018).

## 3. Results

### 3.1. Participants

The study flow is presented in Fig. 1. The 6-month FU was completed by 120 IG participants and 133 CG participants. At 12-month FU, 108 IG participants and 120 CG participants followed through with the online-assessment. Thus, in the IG a dropout rate of 33.33% at T2 and 40.0% at T3 occurred. In the CG, the dropout rate amounts to 26.11% at T2 and 33.33% at T3. Participants either dropped out by giving no response to the assessment invitation (IG: 28.33% at T2, 35.0% at T3; CG: 20.0% at T2, 27.22% at T3) or by withdrawing their consent for the study participation and data processing (IG: 5.0% at T2/T3, CG: 6.11% at T2/T3). In the latter case participant data were excluded from the ITT-analysis. Baseline characteristics of the study sample are reported in Table 1.

### 3.2. Use of the IBI program

The distribution of the trainings at T2 was identical to the distribution at T1 (Braun et al., 2021): Predominantly the trainings GET.ON Stress ( $n = 102$ , 59.65%), GET.ON Mood Enhancer ( $n = 42$ , 24.56%) and GET.ON Recovery ( $n = 15$ , 8.77%) were allocated. GET.ON Panic ( $n = 5$ , 2.92%), GET.ON Be clever - drink less ( $n = 2$ , 1.17%) and GET.ON Mood Enhancer Diabetes ( $n = 2$ , 1.17%) were only seldom assigned. 3 participants (1.75%) did not receive a training as they did not log-in to the

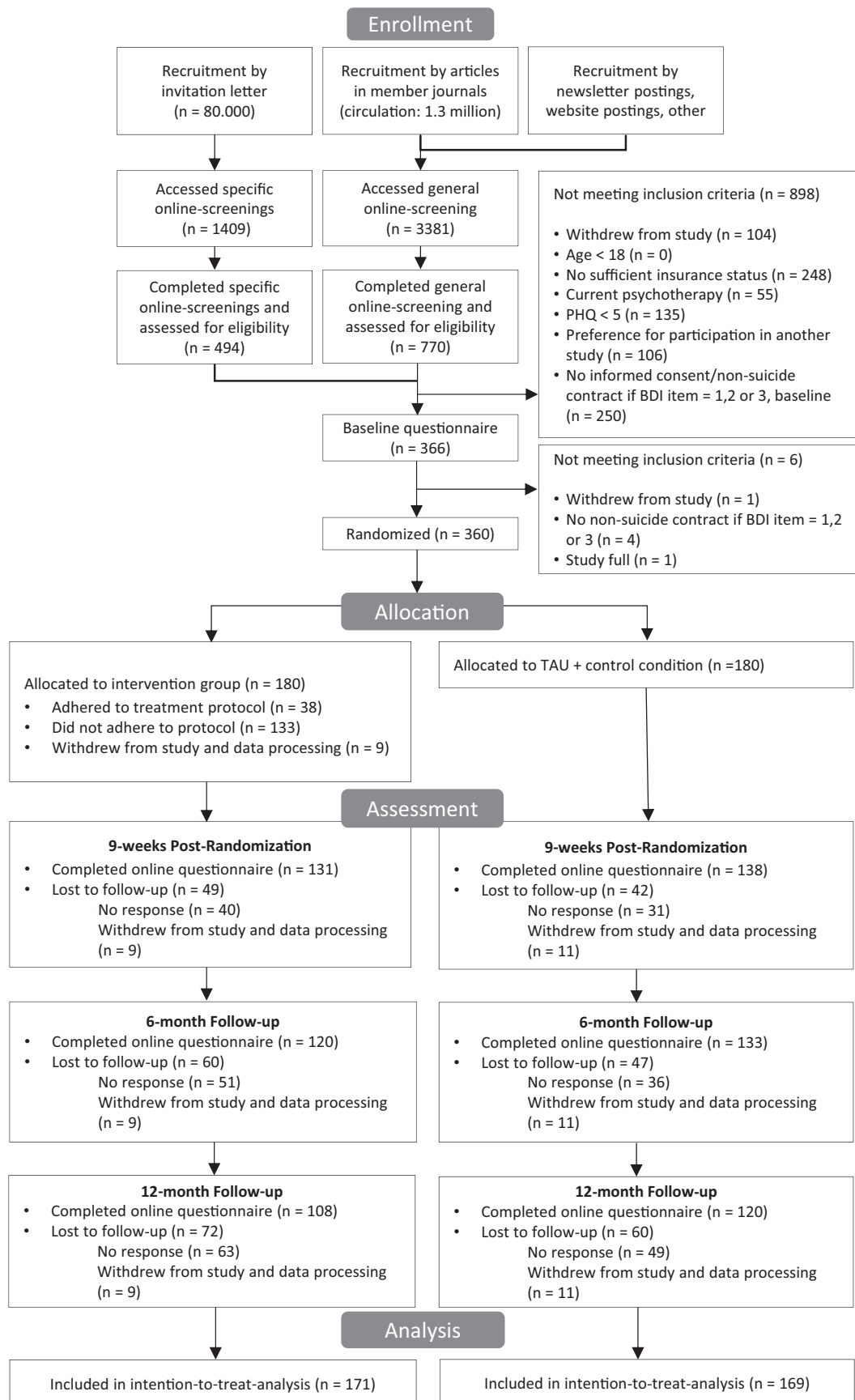
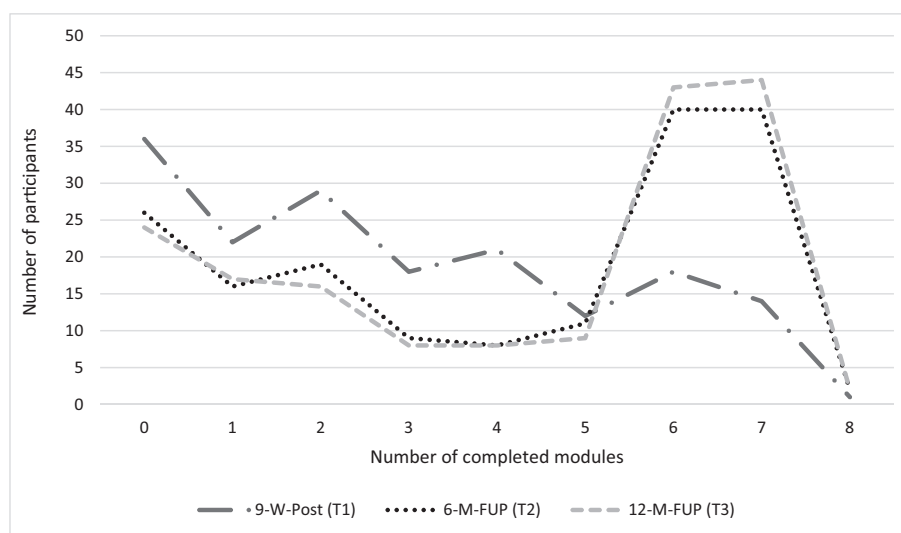


Fig. 1. Study flow.

**Table 1**  
Characteristics of the study sample at baseline (T0).

Variable	IG (N = 171)	CG (N = 169)	Total (N = 340)
<b>Sociodemographic characteristics</b>			
Age, mean (SD)	50.02 (9.58)	51.11 (10.78)	50.56 (10.19)
Female sex, n (%)	102 (59.6)	94 (55.6)	196 (57.6)
Ethnicity white, n (%)	171 (100.0)	168 (99.4)	339 (99.7)
Married or in a relationship, n (%)	154 (90.1)	149 (88.2)	303 (89.1)
<b>Educational level</b>			
Low, n (%)	73 (42.7)	90 (53.3)	163 (47.9)
Middle, n (%)	49 (28.7)	33 (19.5)	82 (24.1)
High, n (%)	49 (28.7)	46 (27.2)	95 (27.9)
<b>Occupational role</b>			
Entrepreneur, n (%)	91 (53.2)	95 (56.2)	186 (54.7)
Contributing spouse or family member, n (%)	65 (38.0)	57 (33.7)	122 (35.9)
Pensioner or spouse of pensioner, n (%)	11 (6.4)	16 (9.5)	27 (7.9)
Inability to work, n (%)	4 (2.3)	1 (0.6)	5 (1.5)
<b>Depression symptom severity (QIDS-SR16)</b>			
Normal (0–5), n (%)	34 (19.9)	21 (12.4)	55 (16.2)
Mild (6–10), n (%)	66 (38.6)	73 (43.2)	139 (40.9)
Moderate (11–15), n (%)	47 (27.5)	58 (34.3)	105 (30.9)
Severe (16–20), n (%)	22 (12.9)	16 (9.5)	38 (11.2)
Very severe (≥21), n (%)	2 (1.2)	1 (0.6)	3 (0.9)
<b>Insomnia (ISI)</b>			
Not clinically relevant (0–7), n (%)	57 (33.3)	44 (26.0)	101 (29.7)
Subthreshold (8–14), n (%)	82 (48.0)	76 (45.0)	158 (46.5)
Moderate (15–21), n (%)	31 (18.1)	45 (26.6)	76 (22.4)
Severe (22–28), n (%)	1 (0.6)	4 (2.4)	5 (1.5)
<b>Generalized Anxiety (GAD-7)</b>			
Minimal (0–4), n (%)	42 (24.6)	25 (14.8)	67 (19.7)
Mild (5–9), n (%)	78 (45.6)	92 (54.4)	170 (50.0)
Moderate (10–14), n (%)	33 (19.3)	46 (27.2)	79 (23.2)
Severe (15–21), n (%)	18 (10.5)	6 (3.6)	24 (7.1)
<b>Panic and agoraphobia (PAS)</b>			
Subthreshold (0–8), n (%)	115 (67.3)	108 (63.9)	223 (65.6)
Mild (9–18), n (%)	41 (24.0)	45 (26.6)	86 (25.3)
Moderate (19–28), n (%)	9 (5.3)	15 (8.9)	24 (7.1)
Severe (29–39), n (%)	6 (3.5)	1 (0.6)	7 (2.1)
Very severe (≥40), n (%)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Alcohol consumption (AUDIT-10)</b>			
Low risk drinking or abstinence (0–7), n (%)	156 (91.2)	150 (88.8)	306 (90.0)
Medium level of alcohol problems (8–15), n (%)	14 (8.2)	16 (9.5)	30 (8.8)
High level of alcohol problems (16–19), n (%)	1 (0.6)	2 (1.2)	3 (0.9)
Possible alcohol dependence (20–40), n (%)	0 (0.0)	1 (0.6)	1 (0.3)

We report means (SD) or n (%) per group at baseline.



**Fig. 2.** Number of completed standard modules during the first training for T1–T3.  
 Note. Each curve depicts number of completed standard modules for the main training participants absolved of the IBI program until 9-week post-randomization (T1), 6-month FU (T2), and 12-month FU (T3).

**Table 2**  
ITT-Analysis of secondary outcomes at 6-month (T2) and 12-month FU (T3).

Variable	IG (N = 171)	CG (N = 169)	ITT <sup>a</sup> (95% CI)	P	Cohen's d (95% CI)
<b>Depression</b>					
QIDS-SR16					
Baseline	9.76 ± 4.79	10.27 ± 4.02			
6 months	5.70 ± 4.06	7.14 ± 4.12	-0.30 [-0.52; -0.07]	<b>.012</b>	-0.35 [-0.57; -0.14]
12 months	6.06 ± 4.41	6.88 ± 4.41	-0.12 [-0.37; 0.13]	.337	-0.19 [-0.40; 0.03]
Reliable improvement					
6 months	41 (24.0)	32 (18.9)	1.35 [0.80; 2.27]	.259	-
12 months	30 (17.5)	35 (20.7)	0.81 [0.47; 1.40]	.459	-
Reliable deterioration					
6 months	2 (1.2)	3 (1.8)	0.65 [0.11; 3.97]	.645	-
12 months	0 (0.0)	1 (0.6)	0.00 [0.00; ∞]	.996	-
Onset of MDD					
6 months	3 of 118 (2.5)	8 of 123 (6.5)	0.97 [0.93; 1.01]	.121	-
12 months	1 of 118 (0.8)	6 of 123 (4.9)	0.97 [0.94; 1.00]	.054	-
Remission of MDD					
6 months	31 of 53 (58.5)	24 of 46 (52.2)	1.04 [0.96; 1.12]	.327	-
12 months	24 of 53 (45.3)	24 of 46 (52.2)	1.00 [0.93; 1.08]	.965	-
<b>Perceived stress</b>					
PSS-10					
Baseline	20.61 ± 6.80	22.21 ± 5.93			
6 months	16.81 ± 7.49	18.32 ± 6.86	-0.08 [-0.29; 0.13]	.438	-0.21 [-0.42; 0.003]
12 months	17.55 ± 8.16	18.80 ± 7.84	-0.04 [-0.31; 0.23]	.760	-0.16 [-0.37; 0.06]
<b>Insomnia</b>					
ISI					
Baseline	9.96 ± 5.19	11.22 ± 5.21			
6 months	6.51 ± 5.13	8.45 ± 5.27	-0.22 [-0.41; -0.02]	<b>.028</b>	-0.37 [-0.59; -0.16]
12 months	7.32 ± 5.61	8.71 ± 5.70	-0.11 [-0.32; 0.10]	.313	-0.25 [-0.46; -0.03]
<b>Anxiety</b>					
Generalized anxiety (GAD-7)					
Baseline	7.84 ± 4.39	8.09 ± 3.47			
6 months	4.88 ± 3.86	5.69 ± 3.62	-0.18 [-0.40; 0.04]	.110	-0.22 [-0.43; -0.002]
12 months	5.11 ± 4.34	6.04 ± 3.91	-0.19 [-0.45; 0.06]	.138	-0.23 [-0.44; -0.01]
Panic and agoraphobia (PAS)					
Baseline	7.05 ± 8.04	7.28 ± 7.28			
6 months	3.02 ± 4.91	3.73 ± 5.80	-0.12 [-0.35; 0.11]	.311	-0.13 [-0.34; 0.08]
12 months	3.12 ± 5.36	4.19 ± 5.96	-0.17 [-0.41; 0.06]	.147	-0.19 [-0.40; 0.02]
<b>Pain</b>					
Pain-associated disability (MPI)					
Baseline	14.51 ± 14.26	15.33 ± 14.77			
6 months	9.68 ± 11.95	13.62 ± 14.33	-0.26 [-0.48; -0.04]	<b>.020</b>	-0.30 [-0.51; -0.09]
12 months	11.41 ± 12.84	12.28 ± 13.55	-0.04 [-0.28; 0.21]	.753	-0.07 [-0.28; 0.15]
Pain intensity (NRS)					
Baseline	7.18 ± 6.53	7.75 ± 7.13			
6 months	6.14 ± 6.57	7.12 ± 6.65	-0.10 [-0.31; 0.11]	.352	-0.15 [-0.36; 0.06]
12 months	7.10 ± 7.18	7.11 ± 7.38	0.04 [-0.18; 0.25]	.729	-0.002 [-0.21; 0.21]
<b>Alcohol consumption</b>					
AUDIT-10					
Baseline	3.37 ± 2.89	3.87 ± 3.52			
6 months	2.82 ± 2.33	3.28 ± 2.90	-0.05 [-0.19; 0.09]	.494	-0.17 [-0.39; 0.04]
12 months	2.07 ± 2.40	2.25 ± 2.67	0.04 [-0.15; 0.23]	.694	-0.07 [-0.28; 0.14]
<b>Emotional exhaustion</b>					
MBI-GS (subscale EE)					
Baseline	15.87 ± 7.97	16.64 ± 7.50			
12 months	13.28 ± 8.90	14.56 ± 9.10	-0.08 [-0.27; 0.11]	.421	-0.14 [-0.35; 0.07]
<b>Quality of life</b>					
AQoL-8D					
Baseline	68.49 ± 10.34	66.94 ± 9.21			
6 months	75.52 ± 10.16	71.32 ± 10.31	0.29 [0.13; 0.45]	<b>&lt;.001</b>	0.41 [0.20; 0.63]
12 months	74.34 ± 11.39	71.65 ± 11.51	0.13 [-0.08; 0.34]	.222	0.23 [0.02; 0.45]
<b>Subjective prognosis of employment</b>					
SPE					
Baseline	0.78 ± 0.96	0.77 ± 0.94			
6 months	0.64 ± 0.94	0.64 ± 0.89	-0.01 [-0.21; 0.19]	.940	-0.002 [-0.21; 0.21]
12 months	0.71 ± 1.01	0.81 ± 0.97	-0.11 [-0.31; 0.10]	.297	-0.10 [-0.31; 0.11]

ITT-analyses are based on imputed data. We report means ± SD or n (%) per group for baseline, 6- and 12-month FU. We report OR for reliable change and deterioration as well as IRR for onset and remission of MDD along with 95%-CI based on robust standard errors. Significant changes ( $p < .05$ ) are printed in bold letters.

AQoL-8D = Assessment of Quality of Life; AUDIT-10 = Alcohol Use Disorder Identification Test; CG = Control group; CI = Confidence Intervals; EE = Emotional Exhaustion; GAD-7 = Generalized Anxiety Disorder; IG = Intervention group; IRR = Incidence Rate Ratio; ISI = Insomnia Severity Index; MBI-GS = Maslach-Burnout-Inventory General Survey; MDD = Major Depressive Disorder, MPI = Multidimensional Pain Inventory; NRS = Numeric Rating Scale (Pain Intensity); OR = Odds Ratio; PAS = Panic and Agoraphobia Scale; PSS-10 = Perceived Stress Scale; QIDS = Quick Inventory of Depressive Symptomatology; SPE = Subjective Prognosis of Employment.

<sup>a</sup> Between-group difference as standardized regression estimates ( $\beta$ ) adjusted for baseline with 95%-CI based on robust standard errors.



intervention platform until T2. One of these participants could be assigned to GET.ON Stress before T3.

At T2, 88 participants (51.46%) and at T3 95 participants (55.56%) completed at least 80% of the IBI. 26 participants (15.20%) at T2 and 24 participants (14.04%) at T3 did not complete the first module. In Fig. 2, number of participants per number of completed standard modules and time of measurement is shown.

A change of training before completion of the first module was requested by 3 participants before T2. Use of an additional guided IBI after completion of the main IBI increased from 3 (1.75%) participants at T2 to 7 (4.09%) at T3. GET.ON Chronic Pain was never assigned until T3. Fig. A.1 (Appendix A) depicts the number of participants per total number of completed modules and time of measurement.

### 3.3. Depressive symptom severity

In ITT-analysis, a small effect of reduction of depressive symptomatology at T2 was found in IG compared to CG ( $\beta = -0.30$ , 95%-CI:  $-0.52$  to  $-0.07$ ,  $p = .012$ ). For T3, no significant group difference in depressive symptom severity was found ( $\beta = -0.12$ , 95%-CI:  $-0.37$  to  $0.13$ ,  $p = .337$ ). These results are consistent with results of complete-case and per-protocol analyses. When we added a term in ITT-analysis to investigate a possible interaction effect between baseline depressive symptom severity and group we found no interaction between these variables neither at T2 (interaction coefficient  $\beta = -0.04$ , 95%-CI:  $-0.24$  to  $0.17$ ,  $p = .723$ ) nor at T3 (interaction coefficient  $\beta = -0.07$ , 95%-CI:  $-0.29$  to  $0.14$ ,  $p = .495$ ), while group effect remained significant at T2 ( $\beta = -0.30$ , 95%-CI:  $-0.52$  to  $-0.07$ ;  $p = .012$ ) and non-existent at T3 ( $\beta = -0.12$ , 95%-CI:  $-0.37$  to  $0.13$ ,  $p = .340$ ). Further details are summarized in Table 2 and Appendix A (Tables A.1, A.2). The course of depressive symptom severity over time per group based on ITT-analysis is displayed in Fig. 3.

### 3.4. Depression response

ITT-analysis revealed that odds for reliable improvement in depressive symptomatology (QIDS-SR16) were neither significantly increased in favor of IG for T2 ( $OR = 1.35$ , 95%-CI:  $0.80$  to  $2.27$ ,  $p = .259$ ) nor for T3 ( $OR = 0.81$ , 95%-CI:  $0.47$  to  $1.40$ ,  $p = .459$ ). Similar results were found in complete-case and per-protocol analyses. Further details are summarized in Table 2 and Appendix A (Tables A.1, A.2).

### 3.5. Onset and remission of potential MDD and BPD

In ITT-analysis, no significant group differences were found for onset of MDD based on categorical analysis of QIDS-SR16 at T2 ( $IRR = 0.97$ , 95%-CI:  $0.93$  to  $1.01$ ,  $p = .121$ ) and T3 ( $IRR = 0.97$ , 95%-CI:  $0.94$  to  $1.00$ ,  $p = .054$ ) in the subgroup of participants who were not categorized as a potential MDD case at baseline (IG:  $n = 118$ , CG:  $n = 123$ ). Similarly, no group differences were found for remission of MDD based on categorical analysis of QIDS-SR16 at T2 ( $IRR = 1.04$ , 95%-CI:  $0.96$  to  $1.12$ ,  $p = .327$ ) and T3 ( $IRR = 1.00$ , 95%-CI:  $0.93$  to  $1.08$ ,  $p = .965$ ) in the subgroups of participants who were categorized as a potential MDD case at baseline (IG:  $n = 53$ , CG:  $n = 46$ ) (Table 2). Complete-case and per-protocol analyses yielded similar results (Appendix A, Tables A.1, A.2). Due to multicollinearity, imputation models for CIDI did not converge. Thus, onset and remission of MDD and BPD based on CIDI was analyzed solely for observed data. In complete-case analysis, only chances for remission of BPD were significantly enhanced at T3 ( $IRR = 0.12$ , 95%-CI:  $0.01$  to  $0.66$ ,  $p = .047$ ) with  $NNTB = 15.21$  ( $NNTB$  7.84 to  $NNTB$  86.57), however in favor of CG (Appendix A, Table A.1).

### 3.6. Mental-health related outcomes

In ITT-analysis, a significant reduction of insomnia severity ( $\beta = -0.22$ , 95%-CI:  $-0.41$  to  $-0.02$ ,  $p = .028$ ) and of pain-associated disability ( $\beta = -0.26$ , 95%-CI:  $-0.48$  to  $-0.04$ ,  $p = .020$ ) along with increased quality of life ( $\beta = 0.29$ , 95%-CI:  $0.13$  to  $0.45$ ,  $p < .001$ ) in IG compared to CG were observed at T2. Similarly, these effects were found in complete-case and per-protocol analysis (Appendix A, Tables A.1, A.2). An additional effect for reduction of generalized anxiety was found in both, complete-case ( $\beta = -0.24$ , 95%-CI:  $-0.45$  to  $-0.03$ ,  $p = .024$ ) and per-protocol analyses ( $\beta = -0.23$ , 95%-CI:  $-0.45$  to  $-0.003$ ,  $p = .047$ ) at T2. Additionally, panic and agoraphobic symptoms ( $\beta = -0.22$ , 95%-CI:  $-0.43$  to  $-0.01$ ,  $p = .037$ ) were reduced in complete-case analysis at T2, whereas in per-protocol analysis perceived stress ( $\beta = -0.26$ , 95%-CI:  $-0.49$  to  $-0.03$ ,  $p = .026$ ) was reduced at T2 compared to TAU+.

For T3, ITT-analysis revealed for no group effects at all (Table 2). In complete-case analysis for T3 additional effects regarding generalized anxiety ( $\beta = -0.25$ , 95%-CI:  $-0.48$  to  $-0.03$ ,  $p = .026$ ) and panic- and agoraphobic symptoms ( $\beta = -0.22$ , 95%-CI:  $-0.43$  to  $-0.004$ ,  $p = .046$ ) were found. In per-protocol analysis, several improvement regarding mental health outcomes were found for T3 (perceived stress:  $\beta = -0.25$ ,

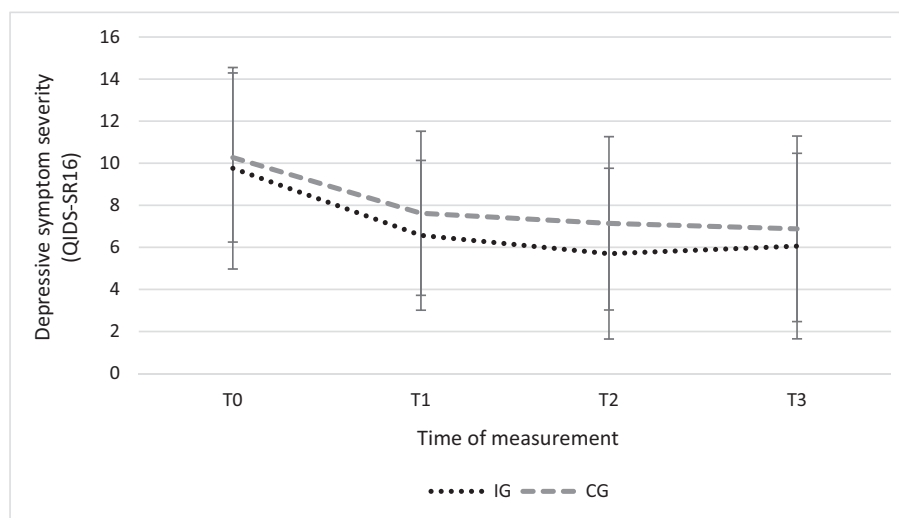


Fig. 3. Depressive symptom severity over time (T0–T3) per group.

Note. Means (SD) were derived from ITT-analyses based on imputed data. Depressive symptom severity is displayed per group from baseline (T0) to 12-month FU (T3).

**Table 3**  
Health care service use at 6-month (T2) and 12-month FU (T3).

	IG		CG		Difference between groups, % (95%-CI) <sup>a</sup>			
	Baseline <sup>b</sup> (n = 171)	6-Month FU <sup>c</sup> (n = 120)	12-Month FU <sup>d</sup> (n = 108)	Baseline <sup>b</sup> (n = 169)	6-Month FU <sup>c</sup> (n = 133)	12-Month FU <sup>d</sup> (n = 120)	6-Month FU <sup>c</sup>	12-Month FU <sup>d</sup>
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Primary care clinician	137 (80.12)	87 (72.5)	75 (69.44)	124 (73.37)	102 (76.69)	83 (69.17)	-4.19 [-14.89; 6.47]	-0.28 [-11.65; 12.06]
Psychotherapist	4 (2.34)	5 (4.17)	2 (1.85)	3 (1.78)	7 (5.26)	3 (2.50)	-1.10 [-6.81; 4.77]	-0.65 [-5.43; 4.28]
Psychiatrist, neurologist, psychosomatic medicine specialist	11 (6.43)	7 (5.83)	9 (8.33)	11 (6.51)	9 (6.77)	9 (7.50)	-0.93 [-7.27; 5.60]	0.83 [-6.43; 8.44]
Psychiatric institute outpatient clinic	1 (0.58)	1 (0.83)	0 (0)	2 (1.18)	4 (3.01)	4 (3.33)	-2.17 [-6.70; 1.99]	-3.33 [-8.25; 0.66]
Outpatient stay in psychiatric clinic	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.75)	1 (0.83)	-0.75 [-4.14; 2.41]	-0.83 [-4.57; 2.67]
Outpatient stay in psychosomatic clinic	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.75)	1 (0.83)	-0.75 [-4.14; 2.41]	-0.83 [-4.57; 2.67]
Inpatient stay in a psychiatric clinic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.00 [-2.81; 3.10]	0.00 [-3.10; 3.43]
Inpatient stay in a psychosomatic clinic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.00 [-2.81; 3.10]	0.93 [-2.27; 5.06]
Stay in a rehabilitation clinic for mental and psychosomatic disorders	1 (0.58)	0 (0)	1 (0.93)	0 (0)	2 (1.50)	1 (0.83)	0.16 [-3.84; 4.51]	-0.83 [-4.67; 2.67]
Antidepressants (prescription)	15 (8.77)	9 (7.5)	10 (9.26)	16 (9.47)	9 (6.77)	12 (10.00)	0.73 [-5.87; 7.64]	-0.74 [-4.60; 7.37]

CG = Control group, IG = Intervention group, TiC-P = Trimbos Institute and Institute of Medical Technology Questionnaire for Costs Associated with Psychiatric Illness.

<sup>a</sup> See Newcombe, 1998.

<sup>b</sup> Baseline covering the previous 3 months as measured with the TiC-P.

<sup>c</sup> 6-Month follow-up covering the previous 3 months as measured with the TiC-P.

<sup>d</sup> 12-Month follow-up covering the previous 3 months as measured with the TiC-P.

95%-CI: -0.50 to -0.01,  $p = .041$ ; insomnia severity:  $\beta = -0.26$ , 95%-CI: -0.48 to -0.03,  $p = .024$ ; generalized anxiety:  $\beta = -0.29$ , 95%-CI: -0.55 to -0.04,  $p = .026$ ; emotional exhaustion:  $\beta = -0.22$ , 95%-CI: -0.43 to -0.10,  $p = .041$ ; quality of life:  $\beta = 0.21$ , 95%-CI: 0.02 to 0.41,  $p = .030$ ; subjective prognosis of employment:  $\beta = -0.25$ , 95%-CI: -0.47 to -0.03,  $p = .028$ ).

No significant group differences were found for usage of health care services at T2 and T3 (Table 3).

### 3.7. Intervention-related outcomes

Technological alliance was high at T2 with  $M = 60.65$  ( $SD = 14.67$ ). Therapeutic alliance at T3 was rated high both from participant ( $M = 41.77$ ,  $SD = 11.98$ ) and eCoach perspective ( $M = 36.12$ ,  $SD = 8.43$ ). Even though participants could choose every time anew if the eCoach contact should occur via telephone or in written form, 64.6% ( $n = 73/113$ ) of the participants at T2 and 61.3% ( $n = 38/62$ ) at T3 reported that they had solely communicated in written form with their eCoach. Overall, 86.7% ( $n = 98/113$ ) of the participants at T2 and 91.9% ( $n = 57/62$ ) at T3 reported being satisfied or very satisfied with their eCoach. 56.6% rated relevance of the IBI content ( $n = 64/113$ ), 68.1% usability of the intervention platform ( $n = 77/113$ ) and 74.3% usability of the IBI ( $n = 84/113$ ) as high or very high at T2. 30.1% ( $n = 34/113$ ) of IG participants at T2 reported problems such as technical problems ( $n = 16$ ), comprehension difficulties ( $n = 8$ ), appointment arrangement with eCoaches ( $n = 12$ ) or poor internet connection ( $n = 9$ ) during training conduct. For intervention dropout most often the following reasons were reported: not enough time available (T2:  $n = 13/20$ , 65.0%; T3:  $n = 13/22$ , 59.1%), occupational workload too high (T2:  $n = 11/20$ , 55.0%; T3:  $n = 8/22$ , 36.4%), not enough motivation (T2:  $n = 6/20$ , 30.0%; T3:  $n = 8/22$ , 36.4%), symptoms already subjectively improved (T2:  $n = 5/20$ , 25.0%; T3:  $n = 5/22$ , 22.7%), subjective training goal of the participant already achieved (T2:  $n = 5/20$ , 25.0%, T3:  $n = 4/22$ , 18.2%) or technical issues (T2:  $n = 2/20$ , 10.0%; T3:  $n = 3/22$ , 13.6%).

#### 3.7.1. Negative effects and reliable deterioration

Based on the INEP, 76 (44.19%) of overall 172 negative effects were reported associated with the IBI program by a total of 46 participants at T2. At T3, 61 (40.67%) of overall 150 negative effects were reported associated with the IBI program by a total of 41 participants. The most frequently reported negative effects in relation with the intervention were "Neglect of hobbies and social contacts because of online-training" (T2:  $n = 25/76$ , T3:  $n = 23/61$ ) and "Feeling of being forced to do exercises by the online-training/ by eCoach" (T2:  $n = 12/76$ , T3:  $n = 10/61$ ). A detailed overview is included in Tables A.3 and A.4 (Appendix A).

In ITT-analysis, no group difference in odds for reliable deterioration of depressive symptomatology (QIDS-SR16) at T2 ( $OR = 0.65$ , 95%-CI: 0.11 to 3.97,  $p = .645$ ) was observed. At T3, the logistic regression model did not converge due to limited variance. Complete-case and per-protocol analyses yielded similar results (Appendix A, Tables A.1, A.2).

### 3.8. Longitudinal analysis

#### 3.8.1. Depressive symptomatology

The best model fit regarding course of depressive symptoms was attained by model 4 with an overall good model fit. There was no group difference regarding baseline level of depressive symptoms ( $\beta = -0.08$ ,  $SE = 0.03$ ,  $p = .251$ ). No significant longitudinal effect for reduction of depressive symptomatology in IG compared to CG was observed ( $\beta = -0.20$ ,  $SE = 0.03$ ,  $p = .071$ ). After 1.71 time units the change over time turned from a reduction of depressive symptoms to an increase in IG in comparison to CG. The quadratic slope

indicating a growth rate of  $\beta = 0.21$  ( $SE = 0.01, p = .092$ ) in IG compared CG was not significant either. An overview of model estimates (Table B.1) and model fit (Table B.2) of the calculated models can be found in Appendix B.

### 3.8.2. Mental-health related outcomes

For insomnia severity we found model 3 superior with very good model fit. We observed a significant greater reduction of insomnia severity over time with a linear growth rate of  $\beta = -0.44$  ( $SE = 0.06, p = .004$ ) in favor of IG. After approximately 1.73 time units, the change over time turned from a reduction of insomnia severity to a significant increase in IG compared to CG ( $\beta = 0.40, SE = 0.02, p = .013$ ). The best model fit for pain-associated disability yielded model 4. Still, model fit was not very good as indicated by  $SRMR = 0.100$  and  $RMSEA = 0.100$  (90%-CI: 0.096; 0.104). The model indicated no group difference regarding baseline level ( $\beta = -0.03, SE = 0.20, p = .622$ ). We observed a significantly greater reduction of pain disability over time with  $\beta = -0.25$  ( $SE = 0.17, p = .011$ ) in favor of IG. 1.60 time units later, the change over time turned to a significant increase of pain disability with a growth rate of  $\beta = 0.25$  ( $SE = 0.06, p = .013$ ) in IG compared to CG. For quality of life model 1 was superior with good model fit and revealed a longitudinal difference in effect for enhancement of quality of life. Based on this model, we observed a linear growth rate of  $\beta = 0.30$  ( $SE = 0.21, p = .008$ ) in favor of IG over the course of 12 months. The best-fitting model for panic and agoraphobia symptoms was linear and demonstrated a greater decrease of symptoms in favor of the IBI program with a negative linear growth of  $\beta = -0.31$  ( $SE = 0.03, p = .037$ ). The model fit was restricted as indicated by  $SRMR = 0.140$ .

No longitudinal effects favoring IG were observed for the selected models of the remaining outcomes. Details of model estimates and model fits are in Tables B.1 and B.2 in Appendix B.

## 4. Discussion

In this study we examined maintenance effects of a tailored IBI program compared to TAU+ over the course of 12 months in the target group of green professions. This is the first study to our knowledge investigating not only short-term, but also long-term effectiveness of an elaborate IBI program for depression health promotion in subthreshold to clinical depression in green professions. We found a small significant effect of depression reduction in favor of IG at 6-month FU with  $d = -0.35$ , whereas at 12-month FU the difference was not significant ( $d = -0.19$ ). The 6-month effect was comparable to the effect of depression reduction of  $d = -0.28$  observed 9-week post-randomization (Braun et al., 2021). As an  $SMD = 0.24$  was argued to represent a minimal important difference for a clinically relevant effect (Cuijpers et al., 2014b), results of the present trial indicate a clinically relevant maintenance effect at 6-month FU in this pragmatic study on a tailored IBI program for green professions. Moreover, baseline depressive symptom severity was found not to moderate intervention outcome. Thus, this tailored IBI program was effective at 6-month FU independent from initial symptom severity and can be helpful for people across a wide range of (clinical) depressive symptomology. Latent growth curve modeling revealed no significant longitudinal effect for reduction of depressive symptom severity favoring IG over the course of 12 months. We also did not find any effect for reliable improvement of depressive symptomology. Also, no significant difference in onset or remission of MDD was observed at either time of measurement based on the ITT-analysis. Only the effect for reduction of onset of MDD was close to significance ( $p = .054$ ).

Whereas the effect size of the IBI program at 6-month FU regarding reduction of subthreshold to clinical depression is overall consistent with previously reported meta-analyses for effectiveness of IBIs for subthreshold depression reduction (Deady et al., 2017; Reins et al., 2021), the attenuation of the effect until 12-month FU stands in contrast with previous meta-analyses reporting small effect sizes at 12-month FU

(Deady et al., 2017; Reins et al., 2021). Still, the existing meta-analyses are limited by the small number of studies evaluating long-term effectiveness in reduction of subthreshold (to clinical) depression symptomology (Deady et al., 2017; Reins et al., 2021; Rigabert et al., 2020). Onset of MDD was only non-significantly reduced compared to CG. This stands in contrast to previous studies reporting distinct effects for risk reduction of MDD onset (Deady et al., 2017; Reins et al., 2021). Yet, statistical power was highly limited in this study, as the respective analyses were not based on the total sample but on the subsample of participants not fulfilling criteria for possible MDD at baseline.

The previously found health-promoting effects of the IBI program 9-week post-randomization regarding insomnia severity, pain-associated disability and quality of life (Braun et al., 2021) based on ITT-analysis were maintained until the 6-month FU, but attenuated until 12-month FU. No further group effects were found either at 6- or 12-month FU. Fittingly, longitudinal modeling in the total sample based on ITT-principle revealed that both insomnia severity and pain-associated disability first decreased and then again started to increase in favor of IG shortly before T2. Thus, both models confirmed that the intervention effects started to attenuate between T2 and T3. The best-fitting model for quality of life indicated a continual increase with a growth rate of  $\beta = 0.30$  in the IG over the course of 12 months. In contrast to cross-sectional analysis at 6- and 12-month FU, we found that panic and agoraphobia symptoms decreased with a constant growth rate of  $\beta = -0.31$  in favor of the IBI program over the course of 12 months. Model fit both for pain-associated disability and panic and agoraphobia symptoms was restricted. Overall, latent growth modeling of outcomes confirmed results of cross-sectional analysis, thereby supporting the results of the conducted cross-sectional analysis at 6- and 12-month FU.

Interestingly, no overall effect of stress reduction was observed in exploratory ITT-analysis contrary to previous studies evaluating effectiveness of this intervention for stress reduction (Heber et al., 2016), even though the IBI GET.ON Stress was the most utilized intervention in this study, demonstrating the important role of work-related stress for mental well-being in green professions. This might be due to restricted power as only a subgroup of participants received this training and adherence was overall restricted. However, it is also conceivable, that adverse working condition have a crucial role for work-related stress in this occupational group. Hence, person-centered interventions alone might not be sufficient to reduce perceived stress effectively. Instead, combination with a workplace-centered intervention might be indicated to effectively reduce work-related stress. Persisting adverse working conditions counteracting the intervention effects might be even a possible explanation for the small effect size regarding depression reduction at 6-month FU or even the attenuation of the intervention effect until 12-month FU. The possible influence and impact of specific occupation-related stressors is beyond the scope of this article, but should definitely be investigated in future studies, possibly in an RCT study focusing solely on the primary outcome of work-related stress investigating the specific impact of GET.ON Stress as intervention.

The effect of reduction of pain-associated disability in the exploratory ITT-analysis can be seen as surprising as GET.ON Chronic pain was not assigned once until 12-month FU. This effect might be due to the fact that some of the study participants screened positive for chronic pain symptomology prior to study inclusion chose to participate in the present trial instead of an alternative study focusing on chronic pain symptomology (Terhorst et al., 2020). Hence, the reduction of pain-associated impairment might be an unspecific, generic intervention effect.

Only per-protocol analysis yielded further health-promoting effects including improvements in perceived stress, sleep quality, generalized anxiety and quality of life for both 6- and 12-month FU. Further, improvement of pain-associated disability at 6-month FU and emotional exhaustion as well as subjective prognosis of employment at 12-month FU were enhanced in favor of the IBI program in the per-protocol analysis. This is comparable to results 9-week post-randomization,

where broader health-promoting effects were found in per-protocol analysis compared to ITT-analysis (Braun et al., 2021). Thus, a number of maintenance mental-health promoting effects of this depression promotion program can be found in participants completing at least 80% of the intervention modules until 6-month FU, respective 12-month FU.

Even though between-group maintenance effects in ITT-analysis were limited to 6-month FU, substantial within-group symptom reduction for most outcomes at 6- and 12-month FU was evident in the IG. As there was also a pronounced within-group symptom reduction in the CG, it seems that TAU+ already resulted in relevant symptom reduction, leaving only limited room for further symptom reduction by the IBI program to go beyond that. Use of TAU instead of waitlist group as comparator has already been shown to diminish treatment effects in internet-based depression treatment (Richards and Richardson, 2012). In addition, psychoeducational programs for depression prevention and treatment have been shown to be similarly effective to other psychotherapies in reducing both onset of depression and depressive symptoms severity across different populations (Cuijpers et al., 2009). This raises the question if any preventive intervention aiming to reduce sub-threshold to clinical depression in this target group would be able to exceed the effect of the TAU comparator enhanced with the psycho-educational information material in the long-term.

However, there are also a number of explanations conceivable for the overall limited maintenance group effects in favor of IG in ITT-analysis. First, adherence was highly restricted until 9-week post-randomization. As this was a pragmatic trial in routine care setting, intervention use could continue after post-randomization assessment at 9 weeks. Indeed, intervention use increased substantially from 9-week post-randomization (22.2% of IG completing at least 80% of their IBI (Braun et al., 2021)) to 51.46% of IG at 6-month FU and 55.56% at 12-month FU completing at least 80% of their IBI revealing pragmatic intervention use over time. As a conclusion, distribution of intervention dose extended over a longer time period than usual for this specific target group, which holds implication for intervention and study design and should be taken into consideration for future studies.

Second, even though adherence increased over time, the overall adherence is still notably below average. Intervention dropout rates of guided IBIs for treatment of depression were previously estimated as 28% on average, i.e. this corresponds to an average completion rate of 72% (for total intervention) (Richards and Richardson, 2012). Another meta-analysis reports on average a completion rate of 67.5% (for at least 80% of the intervention), respective 65.1% (for total intervention) of IBIs based on guided cognitive-behavioral therapy for depression treatment (Van Ballegooijen et al., 2014). Therefore, measures to increase adherence in this target group are highly indicated. Participants reported predominantly little available time, high occupational workload, low motivation as well as a subjective improvement of symptoms as dropout reasons. Even though some problems such as technical issues during training conduct were reported, they mostly were not reported as pivotal for dropout. Yet, participants experiencing severe technical issues might have stopped participating in the study altogether. Even though automatic reminders were sent if the participant did not continue with the next module, a more intensive and probably also more personal reminding strategy might be indicated to overcome time-management and motivational problems. Elaborate strategies like sending of reminder e-mails based on participant-behavior as well as on course timeline (Titov et al., 2013), regular telephone coaching focused on adherence (Mohr et al., 2013) or implementation of an SMS coach (Eckert et al., 2018) have already been shown to substantially increase intervention adherence. Indeed, previous studies evaluating effectiveness of GET.ON Mood Enhancer, Mood Enhancer Diabetes and GET.ON Stress observing high rates of intervention adherence and effectiveness already implemented a SMS coach (Buntrock et al., 2016, 2015; Ebert et al., 2017b; Heber et al., 2016; Nobis et al., 2015).

Further, in studies previously evaluating effectiveness of the applied IBIs (Boß et al., 2018; Buntrock et al., 2016, 2015; Ebenfeld et al., 2021;

Ebert et al., 2017b; Heber et al., 2016; Nobis et al., 2015) study samples were characterized by predominantly high educational level in contrast to the study sample at hand. Education among other sociodemographic factors like age is positively associated with the access to internet (Estacio et al., 2019) and higher eHealth literacy (Neter and Brainin, 2012). Higher eHealth literacy seems to be also associated with more intensive processing and use of health information (Neter and Brainin, 2012). EHealth literacy is restricted especially in rural compared to urban populations (Wuyou and Facca, 2020). Content and design of IBIs should be adapted to presumed eHealth literacy of the target sample to bridge this digital divide (Estacio et al., 2019; Neter and Brainin, 2012). Possibly, complexity reduction of content and design of the IBIs might be indicated to accommodate for lower educational level and presumed lower eHealth literacy in this occupational group and to enhance the actual use of and adherence to the IBIs.

Third, previous subgroup analyses revealed that only the training GET.ON Mood Enhancer led to significant reduction of depressive symptomatology at 9-week post-randomization (Braun et al., 2021). This subgroup analysis for different trainings was highly restricted by limited power (Braun et al., 2021). Perhaps, long-term effectiveness of the IBI program was restricted as possibly not all trainings in the IBI program were equally effective in reduction of depressive symptom severity. Reduction of depressive symptoms has so far only been demonstrated for most trainings of the IBI program across heterogenous target groups after a duration of 6 months (Boß et al., 2018; Buntrock et al., 2015; Ebenfeld et al., 2021; Ebert et al., 2017b, 2015; Heber et al., 2016) but solely for GET.ON Mood Enhancer after one full year (Buntrock et al., 2016, 2015).

Fourth, external critical factors might have affected the entire target population and might have weakened the intervention effect over time. As harvest and thus, income and financial security in agriculture is highly depending on external factors like weather conditions, major periods of drought (e.g. summers 2018/2019 in Germany) pose a serious stress factor in this target group. This has already been exemplary shown for Australia (Berry et al., 2011; Edwards et al., 2015).

Apart from positive intervention effects, we also monitored reliable deterioration and negative effects over the 12-month FU period. There was no indication for reliable deterioration due to the IBI program. As reported at 9-week post-randomization (Braun et al., 2021) the negative effects "Neglect of hobbies and social contacts because of online-training" and "Feeling of being forced to do exercises by the online-training/by eCoach" were most often reported at 6- and 12-month FU. As a potential side effect of the IBI program participants seemingly felt pressured because of limited time constraints and subjectively perceived high requirements regarding training exercises. This reflects the limited time resources and high occupational workload in the target group and thus, the previously reported dropout reasons. As therapeutic and technological alliance were both high, and participants reported mostly high or very high satisfaction with their eCoach, the IBI program seems overall well accepted in the target group.

Further, we monitored use of routine care in the target group over the 12-month FU phase. We did not see a group difference in use of routine care (i.e. hospitalizations, psychotherapy etc.), as would be expected in a study evaluating a depression promotion program in predominantly subthreshold (to clinical) depression. Further, we did not observe any noticeable differences in health care service use between study groups during the 12-month FU phase. As international research suggests, that farmers experience more barriers in help-seeking for mental disorders than non-farmers (Hull et al., 2017) and stigma against depression being in rural contexts more prominent than in urban contexts (Jones et al., 2011), we presumed that participation in this low-threshold IBI program might even contribute to de-stigmatization of mental health issues and enhance willingness to take up further help offers. Yet, participation in this IBI program did not lead to an increased use of the health care system during the first year. This might be due to the ongoing participation in the depression promotion program. In some



cases, participants received access to a second training with a different thematic focus. Subsequently to the training phase, IG participants were in monthly contact with their eCoach for the duration of one year during the consolidating phase.

The study results are also restricted by several limitations. First, results for long-term effectiveness are restricted by substantial study dropout in the course of the FU period, which is why we conducted a sensitivity analysis based on complete cases only. Parameter estimates of ITT-analysis and complete-case analysis were comparable for most outcomes. This supports the assumption that data was missing at random and that the results of the ITT-analysis are robust (Thabane et al., 2013). Second, the study was powered to detect an effect size of  $d = 0.35$  for the primary outcome at 9-week post-randomization. As effect sizes are presumably lower for 12-month FU (Deady et al., 2017; Reins et al., 2021), the study was probably underpowered to detect a significant reduction of depressive symptom severity after 12 months. Further, the power analysis for the primary outcome was based on one-sided testing. Yet, assumption of a one-sided effect based on previous effectiveness studies can be seen as not sufficient to conduct one-sided testing (Bland and Altman, 1994). If two-sided testing is assumed, the target sample size would have amounted to a total of 442 participants and thus, analysis of the primary outcome would have been underpowered against the background of  $1 - \beta = 0.9$  in the present trial. For the interpretation of the results, it should be noted that the analyses reported in this article are based on secondary outcomes and thus, are of exploratory nature. This is a general restriction of the results reported. *P*-values are only reported for orientation and should not be misinterpreted as confirmatory testing. Third, heterogeneity in the intervention conduct may have reduced internal validity, but was essential to ensure a high external validity in this pragmatic effectiveness trial evaluating a depression promotion program to be implemented into routine care. Fourth, we did not exclude participants with depressive symptomology above subthreshold depression level. A substantial proportion ( $n = 146/340$ , 42.94%) of the study sample suffered from a moderate or more severe level of depressive symptomology at the beginning of the study (Braun et al., 2021). Level of impairment by depressive symptoms was very heterogeneous. Thereby this study results are only to a limited extent comparable to depression prevention studies carefully selecting participants with subthreshold depression only. Yet, the study's aim was to pragmatically examine low-threshold online prevention offers as they already take place. In this context, a strict differentiation along the somewhat arbitrary threshold of categorically defined mental disorders, where only those below clinical depression status receive the prevention offer seems not to be the rule (Bland and Streiner, 2013; Pignone et al., 2002; Thombs et al., 2012). This approach is supported by this study's results, as we were able to show, that the IBI program was effective at 6-month FU independent from depressive symptom severity at baseline and therefore, is suitable for both people with subthreshold and with clinical depressive symptomatology, the latter being (among others) indicative for a possible major depression episode. This is in line with previous research showing low-intensity interventions to be at least as effective for more severe depressed patients as for patients with subthreshold depressive symptoms, hence being suitable as initial intervention in a stepped care model for even of more severe depression (Bower et al., 2013). Fifth, the study sample was reduced from 4790 potentially interested persons accessing the screening link to 360 actually eligible persons participating in the study. Therefore, the study sample is influenced by processes of self-selection. Presumably only participants with a given intervention and research motivation succeed to return the required documents and be included in the study. As the study sample is selective, this restricts generalizability of the study results to the whole target group. Sixth, the evaluated IBI program for depression health promotion entailed six different IBIs aiming at various risk factors for development of depression and IBIs were assigned consistent with the individual symptom profile of the participant. Thus, motivation for study participation was only in a part

of the study sample focused on depressive symptoms. Indeed, the distribution of the particular IBIs suggests, that predominantly perceived stress (GET.ON Stress: 59.65%) was reported as the main issue in the study sample besides depressive symptoms (GET.ON Mood Enhancer, 24.56%). Therefore, this study is only to a limited extent comparable to studies evaluating IBI programs with the solely focus on depressive symptoms. Seventh, as a methodical limitation we did not apply standardized diagnostic interviews for MDD and BPD categorization, but categorized participants at baseline and FU measurement points according to a cut-off scores of QIDS-SR16 and additionally self-report versions of the CIDI. Screening scales cannot ensure perfect classification of MDD and BPD when compared with structured clinical interviews (Kessler et al., 2013b, 2013a; Lamoureux et al., 2010). Further, analyses for onset and remission of MDD or BPD are exploratory in nature and substantially underpowered as we were only able to analyze the corresponding reduced subsamples of participants fulfilling or not fulfilling cut-off scores. Thus, methodological quality regarding the evaluation of onset and remission of potential MDD and BPD in the respective subgroups is highly restricted. Eight, as situation of farmers in Germany largely depends on funding and regulation in the European Union, generalizability of the results is likely given for countries that are part of the European Union but is presumably restricted in international comparison. Moreover, design of and access to the healthcare and health insurance systems, ways how IBIs are provided and related costs in the occupational group of green professions might differ in international comparison and restrict generalizability further.

## 5. Conclusions

In conclusion, this IBI program for depression health promotion in subthreshold (to clinical) depression reduces depressive symptom severity medium-term after 6 months. Thus, results indicate a clinically relevant maintenance effect (Cuijpers et al., 2014b) at 6-month FU for the use of this IBI program in a pragmatic study setting. We also found this clinically relevant maintenance effect to be independent from initial baseline symptom severity, which is why this tailored IBI program can be indeed recommended for subthreshold as well as clinical depressive symptomatology. We were not able to show that participants, compared to the CG, benefit in terms of depression severity reduction from participating in the IBI program after one year. These results were obtained from cross-sectional analysis and confirmed by longitudinal modeling of latent variables further supporting the results. In this context the overall low adherence rate in the IBI program in this target group is to be emphasized. As effectiveness results are limited by low adherence, measures to enhance the completion of a substantial amount of intervention modules are highly indicated. To derive specific recommendations on how to increase intervention adherence and long-term maintenance effects further research is needed to identify relevant predictors of uptake and adherence to IBIs in green professions. This should also include sufficiently powered subgroup analysis of specific green professions such as farmers, horticulturalists or forestry workers as we cannot yet conclude that IBIs like the one examined in the present trial do work the same across all green profession workers. The consideration and integration of further innovative advancements for digital interventions like persuasive design (Baumeister et al., 2019), artificial intelligence (Ebert et al., 2019), automated chatbots (Bendig et al., 2019) or just-in-time interventions (Nahum-Shani et al., 2018) might be viable options to improve intervention adherence along with long-term stability of intervention effects. Further, the emerging evidence regarding mediators and mechanisms of change for IBIs in depression (Domhardt et al., 2021) should be considered for future investigations. This research contributes to the growing but still very limited research body evaluating long-term effectiveness of online measures for depression health promotion in the general population as well as in specific target groups.



## Published protocol paper

Braun, L., Titzler, I., Ebert, D. D., Buntrock, C., Terhorst, Y., Freund, J., Thielecke, J., & Baumeister, H. (2019). Clinical and cost-effectiveness of guided internet-based interventions in the indicated prevention of depression in green professions (PROD-A): Study protocol of a 36-months follow-up pragmatic randomized controlled trial. *BMC Psychiatry*, 19, 278. <https://doi.org/10.1186/s12888-019-2244-y>.

## CRedit authorship contribution statement

DDE and HB obtained funding for this study. HB, DDE, IT, LB and YT contributed to the study design. HB, DDE, IT are supervising the recruitment and trial management as (operational) project lead. LB is responsible for recruitment, project administration and coordination of the trial. JT and JF support the recruitment. LB performed the data analysis including data curation, formal analysis and visualization and wrote the original draft of the manuscript. All authors provided critical revision of the article and approved the final manuscript.

## Role of the funding source

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## Declaration of competing interest

Prof. Dr. Harald Baumeister (HB) reports to have received consultancy fees and fees for lectures/workshops from chambers of psychotherapists and training institutes for psychotherapists in the e-mental-health context. Prof. Dr. David Daniel Ebert (DDE) reports to have received consultancy fees/served in the scientific advisory board from several companies such as Minddistrict, Lantern, Novartis, Sanofi, Schoen Kliniken, Ideamed, German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is stakeholder of the Institute for health training online (GET.ON), which aims to implement scientific findings related to digital health interventions into routine care. Ingrid Titzler (IT) reports to have received fees for lectures/workshops in the e-mental-health context from training institutes for psychotherapists. She was research and implementation project lead of the trial site Institute for health training online (GET.ON) for the European implementation research project ImpleMentAll (11/2017-03/2021) funded by the European Commission. All authors linked to GET.ON institute (DDE, IT) had no influence over analysis and interpretation of study results. The remaining authors report no conflicts of interest.

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## Appendices. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.invent.2021.100455>.

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