

Efficacy of internet-based interventions in the indirect  
reduction of depressive symptoms

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## List of Abbreviations

95% CI	95% Confidence Interval
ANCOVA	Analysis of covariance
CBT	Cognitive behavioral therapy
CES-D	Center for Epidemiological Studies Depression Scale
CSQ-I	Client Satisfaction Questionnaire for internet-based interventions
DSM-5	Diagnostic and statistical manual of mental disorders
GCMO	Get.calm and move.on
ICD-11	International classification of diseases (11th revision)
IG	Intervention Group
IMI	Internet- and mobile based interventions
iSMI	Internet-based stress management intervention
M	Mean
MDD	Major depressive disorder
MHA-W	Mental health advice waiting group
NNT	Number needed to treat
PHQ	Patient Health Questionnaire
PSS	Perceived Stress Scale
PSWQ	Penn State Worry Questionnaire
PTQ	Perseverative Thinking Questionnaire
RCT	Randomized controlled trial
RNT	Repetitive negative thinking
SD	Standard deviation
SMI	Stress management intervention
T1	Baseline
T2	Post-intervention
WLG	Waitlist control group
x-MFU	x-month follow-up

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## Abstract

Depressive disorders are highly prevalent mental disorders associated with an enormous individual and societal burden. The efficacy of both; treatment and prevention of depression have been meta-analytically demonstrated. Over the past two decades, an increasing number of internet-based interventions for depression has been developed and their efficacy was also meta-analytically shown. However, the uptake of such interventions – despite all the suggested advantages of internet-based interventions – is still rather low. The stigma still associated with “depression” may be one major barrier also to internet-based interventions. To overcome this barrier and potentially increase uptake, the paradigm of indirect interventions has been proposed recently. Indirect interventions primarily address common mental health problems, which are presumed to be less stigmatizing, and are suggested to reduce depressive symptoms indirectly. Targeting common mental health problems that are transdiagnostic risk factors for depression and other mental disorders – such as stress or repetitive negative thinking – seems especially promising.

This dissertation evaluated the efficacy of three different internet-based interventions that can be regarded as indirect interventions to reduce depression since they primarily targeted risk factors for depression. For this purpose three registered randomized controlled trials were conducted. In addition to assessing the efficacy of the interventions regarding the primary outcomes, the efficacy to reduce depression and further secondary outcomes was studied.

In Study I ( $N = 200$ ) the efficacy of an internet-based stress management intervention (iSMI), which was adapted and tailored to career starting teachers, was compared to a waitlist control group (WLG). The participants of the intervention group (IG) reported significant reductions on the primary outcome perceived stress at post-intervention (T2),  $\Delta_{\text{WLG-IG}} = 3.5$ ,  $d = 0.52$ , 95% CI [0.24, 0.80], and three-month follow-up (3-MFU),  $d = 0.49$ , 95% CI [0.21, 0.77]. Furthermore, it was shown that the intervention indirectly also reduced depression at T2,  $d = 0.66$ , 95% CI [0.38, 0.94], and 3-MFU,  $d = 0.47$ , 95% CI [0.19, 0.75], and produced significant clinically meaningful reductions of depression with a number needed to treat (NNT) of 3.9 at T2. The effects were sustained at an extended 6-MFU. Besides efficacy, the feasibility to complement the iSMI with a newly developed internet-based classroom management training was shown. Moreover, mediation analyses corroborated the role of problem- and emotion-focused coping skills in the intervention’s effect on stress and the indirect effect of the intervention on depression through stress.

Study II ( $N = 262$ ) demonstrated the efficacy of an internet- and app-based gratitude intervention on the reduction of primary assessed repetitive negative thoughts at T2,  $\Delta_{\text{WLG-IG}} = 6.6$ ,  $d = 0.61$ , 95% CI [0.36, 0.86], and 3-MFU,  $d = 0.75$ , 95% CI [0.50, 1.00], as compared to a WLG. The participants of the IG also reported significantly reduced depressive symptoms at T2,  $d = 0.38$ , 95% CI [0.13, 0.62], and 3-MFU,  $d = 0.40$ , 95% CI [0.15, 0.64], with significant clinically meaningful effects with an NNT of 4.3 at T2. The effects were sustained at an extended 6-MFU. Besides efficacy, mediation analyses showed that repetitive negative thinking mediated the gratitude intervention’s effect on depression.



Finally, Study III ( $N = 351$ ) showed that an internet-based intervention, tackling worries at the beginning of the COVID-19 pandemic, was effective as compared to an active mental health advice group. At T2, two weeks after randomization, the IG reported significantly reduced levels on the primary outcome worry as compared to controls,  $\Delta_{\text{WLG-IG}} = 5.0$ ,  $d = 0.38$ , 95% CI [0.17, 0.59]. Participants of the IG also reported significantly reduced levels of depression at T2,  $d = 0.47$ , 95% CI [0.26, 0.68], with significant clinically meaningful reductions with an NNT of 3.6. The extended follow-ups in the IG indicated that the improvements from baseline were sustained until the 2-MFU and the 6-MFU. In a mediation analysis, worry was shown to mediate the intervention's effect on depression.

Across all three studies a reliable deterioration of depression was occasionally observed ranging from 3% to 5% in the IGs and from 5% to 12% in the control groups at T2.

In summary, the studies in this dissertation demonstrated the efficacy of various indirect interventions focusing on rather common psychological problems to indirectly reduce depressive symptoms. The extent to which depression severity could be reduced is comparable to reductions found within participants with comparable baseline depression severity, in internet-based interventions directly addressing depressive symptoms. Indirect interventions are suggested to increase the uptake of interventions that reduce depressive symptoms, since they might be perceived as less stigmatizing and might broaden the range of interventions to choose from. Future research needs to compare indirect interventions for depression with direct interventions in head-to-head studies regarding uptake, efficacy and potential harmful effects. The indirect interventions examined in this dissertation could then complement the existing range of care for depression and thereby contribute to a reduction of the treatment gap and the burden of disease associated with depression.

## Zusammenfassung

Depressive Störungen sind weit verbreitete psychische Erkrankungen, die mit einer enormen individuellen und gesellschaftlichen Krankheitslast einhergehen. Die Wirksamkeit sowohl der Behandlung als auch der Prävention von Depressionen wurde meta-analytisch nachgewiesen. In den letzten zwei Jahrzehnten wurde eine zunehmende Zahl internetbasierter Interventionen zur Reduktion von Depressionen entwickelt, deren Wirksamkeit ebenfalls meta-analytisch nachgewiesen wurde. Die Akzeptanz solcher Maßnahmen ist jedoch – trotz aller vermuteten Vorteile internetbasierter Interventionen – immer noch recht gering. Das Stigma, das immer noch mit dem Begriff "Depression" verbunden ist, könnte auch bei internetbasierten Interventionen ein wesentliches Hindernis darstellen. Um dieses Hindernis zu überwinden und die Akzeptanz solcher Interventionen zu erhöhen, wurde kürzlich das Paradigma der indirekten Interventionen vorgeschlagen. Dabei werden in erster Linie allgemeine psychische Gesundheitsprobleme fokussiert, von denen angenommen wird, dass sie weniger stigmatisierend sind, um so indirekt depressive Symptome zu verringern (z.B. Stress oder repetitives negatives Denken). Die gezielte Behandlung allgemeiner psychischer Gesundheitsprobleme, die transdiagnostische Risikofaktoren für Depressionen und andere psychische Störungen darstellen, scheint besonders vielversprechend zu sein.

In dieser Dissertation wurde die Wirksamkeit von drei verschiedenen internetbasierten Interventionen untersucht, die als indirekte Interventionen zur Verringerung von Depressionen angesehen werden können, da sie in erster Linie auf Risikofaktoren für Depressionen abzielen. Zu diesem Zweck wurden drei registrierte randomisiert-kontrollierte Studien durchgeführt. Neben der Wirksamkeit der Interventionen hinsichtlich der primären Endpunkte wurde auch die Wirksamkeit zur Reduktion von Depressionen und weiteren sekundären Endpunkten untersucht.

In Studie I ( $N = 200$ ) wurde die Wirksamkeit einer internetbasierten Intervention zur Stressbewältigung (iSMI), die auf Berufseinsteiger in den Lehrerberuf zugeschnitten war, im Vergleich zu einer Wartelisten-Kontrollgruppe (WLG) untersucht. Die Teilnehmer der Interventionsgruppe (IG) berichteten über eine signifikante Verringerung des primären Endpunktes wahrgenommener Stress direkt nach der Intervention (T2),  $\Delta_{WLG-IG} = 3.5$ ,  $d = 0.52$ , 95% CI [0.24, 0.80], und zum 3-Monats-Follow-up (3-MFU),  $d = 0.49$ , 95% CI [0.21, 0.77]. Darüber hinaus konnte gezeigt werden, dass die Intervention indirekt auch Depressionen zu T2,  $d = 0.66$ , 95% CI [0.38, 0.94], und zum 3-MFU reduzierte,  $d = 0.47$ , 95% CI [0.19, 0.75]. Weiterhin zeigte sich eine signifikante, klinisch bedeutsame Reduktion der Depression mit einer Anzahl der notwendigen Behandlungen (number needed to treat, NNT) von 3.9 zu T2. Die Reduktionen blieben auch bis zu einem verlängerten 6-MFU erhalten. Neben der Wirksamkeit wurde auch die Machbarkeit einer Ergänzung des iSMIs durch ein neu entwickeltes Klassenführungs-Training gezeigt. Darüber hinaus zeigten Mediationsanalysen die Rolle der problem- und emotionsorientierten Bewältigungsstrategien bei der Wirkung der Intervention auf Stress und die indirekte Wirkung der Intervention auf Depression durch Stress.

Studie II ( $N = 262$ ) zeigte die Wirksamkeit einer internet- und app-basierten Dankbarkeitsintervention auf die Verringerung primär untersuchter repetitiver negativer Gedanken zu T2,  $\Delta_{\text{WLG-IG}} = 6.6$ ,  $d = 0.61$ , 95% CI [0.36, 0.86], und zum 3-MFU,  $d = 0.75$ , 95% CI [0.50, 1.00], im Vergleich zu einer WLG. Die Teilnehmer der IG berichteten auch über signifikant reduzierte depressive Symptome zu T2,  $d = 0.38$ , 95% CI [0.13, 0.62], und zum 3-MFU,  $d = 0.40$ , 95% CI [0.15, 0.64], mit signifikant klinisch bedeutsamen Effekten mit einer NNT von 4.3 zu T2. Die Effekte hielten auch bis zu einem verlängerten 6-MFU an. Neben der Wirksamkeit zeigten Mediationsanalysen, dass repetitive negative Gedanken die Wirkung der Dankbarkeitsintervention auf Depressionen vermittelte.

Studie III ( $N = 351$ ) zeigte schließlich, dass eine internetbasierte Intervention, die sich mit den Sorgen zu Beginn der COVID-19 Pandemie befasste, im Vergleich zu einer Gruppe, die Tipps zur psychischen Gesundheit in der COVID-19 Pandemie bekommen hatte, wirksam war. Zu T2, zwei Wochen nach der Randomisierung, berichteten die Teilnehmer der IG im Vergleich zu der Kontrollgruppe signifikant geringere Werte für den primären Endpunkt Sorgen,  $\Delta_{\text{WLG-IG}} = 5.0$ ,  $d = 0.38$ , 95% CI [0.17, 0.59]. Die Teilnehmer der IG berichteten zu T2 auch über signifikant geringere Depressionswerte,  $d = 0.47$ , 95% CI [0.26, 0.68], mit einer signifikanten, klinisch bedeutsamen Verringerung mit einer NNT von 3.6. Die verlängerten Follow-up Messungen in der IG deuteten darauf hin, dass die Verbesserungen gegenüber dem Ausgangswert bis zu einem 2-MFU und 6-MFU aufrechterhalten wurden. Eine Mediationsanalyse zeigte auf, dass Sorgen die Wirkung der Intervention auf Depression vermittelten.

In allen drei Studien wurde vereinzelt eine reliable Verschlechterung der Depression beobachtet. Diese lag zwischen 3 % und 5 % in den IGs und zwischen 5 % und 12 % in den Kontrollgruppen zu T2.

Zusammenfassend lässt sich sagen, dass die Studien in dieser Dissertation die Wirksamkeit verschiedener indirekter Interventionen, die sich auf gewöhnliche psychologische Probleme konzentrieren, zur indirekten Verringerung depressiver Symptome zeigen. Die Größenordnungen der Reduktionen sind vergleichbar mit denen, die in Studien mit Teilnehmern mit vergleichbarem Depressionsschweregrad in internetbasierten Interventionen zur direkten Reduktion von Depressionen gefunden wurden. Indirekte Interventionen könnten die Inanspruchnahme von Interventionen zur Verringerung depressiver Symptome erhöhen, da sie als weniger stigmatisierend empfunden und die Auswahl an Interventionen erweitern könnten. In künftigen Forschungsarbeiten sollten die in dieser Arbeit untersuchten indirekten Interventionen zur Reduktion von Depressionen, mit direkten Interventionen zur Reduktion von Depressionen, in direkten Vergleichsstudien untersucht werden. Dabei könnten die Inanspruchnahme, die Wirksamkeit und mögliche unerwünschte Nebenwirkungen verglichen werden. Die in dieser Dissertation untersuchten indirekten Interventionen könnten dann das bisherige Versorgungsangebot für die Reduktion von Depressionen ergänzen und dadurch zu einer Reduktion der Versorgungslücke und der Krankheitslast durch Depressionen beitragen.



**Chapter 1 – General introduction**

This introductory chapter consists of three major sections: The first section summarizes up-to-date epidemiological data and background information on depression. The second section focuses on the evidence of traditional and internet-based approaches for the treatment and prevention of depression. The third section then identifies current challenges in the treatment and prevention of depression and derives the overarching and study-specific goals of this dissertation.

## **Background**

### **Nosology and definition of depression**

Depression is a mental disorder characterized by a variety of heterogeneous symptoms. In addition to impairment in the affective domain (depressed mood, loss of interest and joylessness), there may be symptoms in other domains such as the cognitive (e.g., concentration problems, lowered self-esteem, recurrent thoughts about death), motivational and behavioral (e.g., lack of motivation/energy), or neuro-vegetative domain (e.g., sleep problems, significantly decreased or increased appetite). According to the ICD-11 (World Health Organization, 2019) and the DSM-5 (American Psychiatric Association, 2013) at least one symptom has to be either depressed mood or loss of interest and joylessness in order to diagnose a “depressive disorder episode” (ICD-11) or a “major depressive disorder” (MDD; DSM-5), but further symptoms from other domains have to be present so that at least five symptoms are present for at least two weeks on almost every day (also see: Stein et al., 2020). Depressive symptoms occur on a continuum of varying intensity, number, and duration (e.g. Cuijpers, 2004; Kessler et al., 1997).

Besides depressive symptoms as part of MDD, they can occur in a range of other depressive disorders such as dysthymia, premenstrual dysphoric disorder or within “minor depression” (American Psychiatric Association, 2013; Cuijpers, 2004). The various depressive disorders differ amongst others by severity, course, and duration of symptoms. MDD is often considered as the prototype of the depressive disorder group (American Psychiatric Association, 2013). MDD can vary by severity (ranging from mild to severe) and course (either as a single episode with full or partial remission or with recurrent episodes).

Two further important depressive disorders are chronic depression and dysthymic disorder. While the DSM-5 summarizes these two disorders as the diagnosis of a “persistent depressive disorder”, the ICD-11 distinguishes between a “dysthymic disorder” and a “persistent depressive episode” diagnosis. Persistent depressive disorder according to the DSM-5 requires the depressed mood and at least two further depressive symptoms to be present most of the day for a period of at least two years (dysthymic syndrome); but symptoms may be as severe that the criteria of MDD are fulfilled continuously for two years (persistent episode of MDD) (American Psychiatric Association, 2013; also see: Schramm et al., 2020).

In addition, MDD is often distinguished from so-called “minor depression”, which is a term no longer used in the DSM-5, but still can be diagnosed within the category “Other Specified Depressive Disorders”, e.g. as a depressive episode with subthreshold symptoms. Minor depression is often also

named “subthreshold” or “subclinical depression” and requires between two and four of the Criterion A depressive symptoms to be present for at least two weeks (e.g. Cuijpers, 2004; Kessler et al., 1997). In the following, “depression” or “depressive symptoms” are used in more general statements, MDD is used to refer to the formal diagnosis, and subthreshold symptoms or “minor” depression for depressive symptoms explicitly not fulfilling the MDD criteria.

### **Prevalence of depression**

Depression is a highly prevalent disorder worldwide (e.g. Arias-de la Torre et al., 2021; GBD 2019 Mental Disorders Collaborators, 2022) with prevalence rates suggested to be rising globally (Moreno-Agostino et al., 2021).

In Germany, the 2-week point prevalence of clinically relevant depressive symptoms, regardless of a specific diagnosis, as measured by a score of at least 10 points on the Patient Health Questionnaire (PHQ-8: Kroenke et al., 2009) is estimated to be 10.1% (from a nationwide representative random sample: Bretschneider et al., 2017) in the average adult general population. Extrapolating this estimate, this would correspond to currently seven million adults in Germany with above threshold depressive symptoms in the past two weeks, which is equivalent to about one in 10 adults. Prevalence rates for women (11.6%) are estimated slightly higher than those for men (8.6%) (Bretschneider et al., 2017), corresponding to a gender-ratio of 1.3 : 1. The higher prevalence of depression in women is a most frequently replicated finding with an average gender-ratio across countries slightly above 1.5 : 1 for women and men, respectively (also see: Arias-de la Torre et al., 2021; GBD 2019 Mental Disorders Collaborators, 2022). Currently in Germany, prevalence rates of above threshold depressive symptoms are estimated to be highest in young, low educated women (Bretschneider et al., 2017; also see: Busch et al., 2013; Maske et al., 2016; Streit et al., 2022).

When measuring MDD with a diagnostic clinical interview – thus also considering diagnostic exclusion criteria for MDD – a 12-month Prevalence for Germany around 7.0% has been reported (Bretschneider et al., 2018; Jacobi et al., 2015; Maske et al., 2016). Lifetime prevalence of MDD in Germany is estimated to be 14.5% (Nübel et al., 2020).

Regarding persistent depressive disorder, evidence on prevalence rates for Germany is scarce. First evidence suggests that the lifetime prevalence of chronic MDD and dysthymic disorder is 2.6% and 2.2%, respectively (Nübel et al., 2020). In the United States, 12-month and lifetime prevalence for chronic MDD is estimated to be 1.5% and 3.1%, respectively, and the 12-month and lifetime prevalence for dysthymic disorder is estimated 0.5% and 0.9%, respectively (Blanco et al., 2010).

Besides so-called “clinically relevant” or above threshold depressive symptoms, subthreshold depressive symptoms are suggested to be also highly prevalent (Cuijpers, 2004; Cuijpers et al., 2007; Kessler et al., 1997; Rodríguez et al., 2012) and associated with considerable risk to develop a full-blown MDD (Cuijpers, 2004; Cuijpers & Smit, 2004), although up-to-date prevalence estimates for subthreshold depressive symptoms from well-conducted studies have yet to be conducted.

### **Etiology and risk factors for depression**

Depression is assumed to have a multifactorial causality. According to the diathesis-stress model, depression develops in the interaction of vulnerability factors with current stress or a maladaptive environment (e.g. Gotlib & Hammen, 2015).

In addition to biological (e.g. genetic, physical or hormonal factors), certain sociodemographic (e.g. female gender, belonging to a low socioeconomic or minority group or being unemployed) and lifestyle factors (e.g. smoking, diet, sedentary behavior), psychosocial (e.g. chronic stress) and psychological factors (e.g. repetitive negative thinking) have been found to be associated with an increased risk of depression (for a review: Köhler et al., 2018).

For this dissertation, chronic stress and repetitive negative thinking (RNT) will be of particular importance. Chronic stress can occur within work-related stress, but also due to stressful life events such as starting a career, bereavement, financial problems, divorce or experiencing a pandemic. Both, work-related stress (Madsen et al., 2017) and stress due to stressful life events (McLaughlin et al., 2010; for a meta-analysis: Risch et al., 2009) have been shown to be associated with an increased risk for depression. Another important risk factor for depression is RNT. RNT is a form of recurrent thinking that comprises cognitive processes such as worry and rumination and has also been shown to be a risk factor for the development and maintenance of depression (for a review: A. G. Harvey et al., 2004; Watkins, 2008).

### **Development and course of depression**

Meta-analytic data of epidemiological studies suggest that depression mostly develops early in life. The peak age of onset for depressive disorders is estimated to be around 20 years, and 50% of individuals suffering from depression are estimated to have their first episode at or before the age of 30 (Solmi et al., 2022).

Remission rates for untreated MDD after three months differ widely, depending on the setting of recruitment, ranging from 12.5% (meta-analysis of participants within waitlist-controlled trials: Mekonen et al., 2022) to 23% (meta-analysis of untreated individuals from primary care: Whiteford et al., 2013), to 50% (in individuals without care in a large prospective epidemiological survey: Spijker et al., 2002), with significantly lower remission rates in samples from waitlist control groups (WLG) as compared to primary care patients (Whiteford et al., 2013).

More consistently, the percentage of individuals with MDD that report enduring depressive (Spijker et al., 2002) or enduring full-blown MDD symptoms (Rubio et al., 2011) for 24 months ranges between 20% (Spijker et al., 2002) and 25% (Rubio et al., 2011) in the general population and chronicity rates among clinical samples with comorbid mental disorders are estimated to be even higher (Penninx et al., 2011). Believing these estimates, this means that about one in four to one in five individuals with MDD suffers from enduring depressive symptoms for 24 months or longer.

Despite non-comorbid MDD does not become chronic for the majority, it is estimated that around half of the individuals of the general population that experience an episode of MDD will experience



recurrences thereof (e.g. Eaton et al., 2008; Hardeveld et al., 2013). Recurrence rates among clinical samples, however, are much higher (for a review and critical discussion see: Monroe & Harkness, 2022). In these, the vast majority are expected to experience recurrences (e.g. Hardeveld et al., 2009; Mueller et al., 1999; Solomon, 2000) with about 40% reporting to have experienced four or more and nearly 20% to have experienced more than 10 episodes (Hollon et al., 2006).

Moreover, a considerable number of patients despite successful treatment (being antidepressant medication or psychotherapy) experience residual symptoms after remission of MDD (e.g. Carney et al., 2007; Nierenberg et al., 2010; Nil et al., 2016; D. J. Taylor et al., 2010).

### **Comorbidity of depression**

Depressive disorders are highly comorbid disorders, either occurring prior, parallel, or following other disorders. They show a high comorbidity with other mental disorders (Plana-Ripoll et al., 2019) with comorbid anxiety disorders suggested to be among the most common with a prevalence rate of nearly 70% (Kessler et al., 2015; ter Meulen et al., 2021).

Besides high comorbidity of mental disorders, prevalence rates of poor physical health are also higher than what could be expected by chance alone in individuals with depressive disorders. For example, high comorbidity was found for cardiovascular (e.g., heart failure, peripheral artery disease), metabolic (e.g., diabetes, polycystic ovary syndrome), inflammatory (e.g., psoriasis, arthritis, inflammatory bowel disease) or neurological (e.g., post-stroke) diseases (for a review: Gold et al., 2020; also see: Momen et al., 2020).

### **Factors associated with prognosis**

Several factors have been identified as risk factors for a poorer prognosis of depression in terms of chronicity or recurrences. In addition to personality and socioemotional factors (e.g. high levels of negative emotionality/neuroticism, low self-esteem, low level of social support), a range of clinical and biographical variables have repeatedly been suggested as risk factors. These variables include childhood adversity, family history of mood and/or personality disorders, younger age at onset, longer duration of (untreated) depressive episodes, and comorbidities. Notably, chronic stress and RNT have also been found to be associated with a poorer prognosis (for reviews: Burcusa & Iacono, 2007; Hölzel et al., 2011; D. N. Klein & Santiago, 2003; Kraus et al., 2019; Struijs et al., 2021).

Importantly, the prognosis for depression also differs across socioeconomic groups and was meta-analytically found to be poorer for socioeconomically disadvantaged individuals (i.e. being unemployed, struggling financially, not homeowners or without formal education qualifications; Buckman, Saunders, Stott, et al., 2022).

### **Burden associated with depression**

Depressive disorders are associated with a high disease burden, of which the chronic and recurrent depressive disorder forms are suggested to account for the largest burden as compared to single depressive episodes (GBD 2019 Mental Disorders Collaborators, 2022; Monroe & Harkness, 2022; Nübel et al., 2020). In 2019, depressive disorders were ranked as the second leading cause for years

lived with disability (YLDs) globally (GBD 2019 Mental Disorders Collaborators, 2022). Depressive disorders are associated with enormous individual, economic and societal costs (Greenberg et al., 2021; Kessler, 2012; for a meta-analysis: König et al., 2020) and evidence suggests that not only above threshold, but also subthreshold levels are associated with increased economic and societal costs (Müller et al., 2021).

Beyond the high burden of depression due to years lived with disability, depression is also associated with increased mortality and thus years of lost life (YLLs) – although the percentage of depression on YLL can be regarded as rather small compared to other diseases and has not been assessed in the GBD studies (Cuijpers et al., 2014; Cuijpers & Smit, 2002; GBD 2019 Mental Disorders Collaborators, 2022; Machado et al., 2018). Although depression is an established risk factor for suicide (Plana-Ripoll et al., 2020; Ribeiro et al., 2018), most premature mortality associated with depression is not attributed to suicide but to causes of death related to general medical conditions (Plana-Ripoll et al., 2020).

To conclude, depression is a highly prevalent, often recurrent and sometimes chronic disorder that is highly impairing, associated with high morbidity and mortality and a substantial individual, economic, and societal burden. This highlights the need for effective interventions to reduce this burden. The next chapter summarizes evidence on the treatment of depression.

## **Treatment of depression**

### ***Traditional formats of treatment for depression***

Traditionally, face-to-face psychotherapy and pharmacotherapy are used to treat depression (AWMF et al., 2022; NICE, 2022). Meta-analytical evidence shows that antidepressants are effective for the acute treatment of moderate-to-severe MDD, with an overall standardized mean difference of 0.30 at a median duration of eight-weeks post randomization against placebo (Cipriani et al., 2018), but not or only to a minimal extent for mild depression (Fournier et al., 2010; Kirsch et al., 2008).

Regarding psychotherapy, meta-analytical evidence shows the efficacy of different psychotherapeutic interventions – including cognitive-behavioral therapy (CBT), interpersonal therapy and psychodynamic therapy – with strongest evidence for CBT (Barth et al., 2013; Cuijpers et al., 2019). For CBT as compared to WLGs moderate to large effect sizes ( $g = 0.78$ ) are reported at post-intervention and moderate effect sizes ( $g = 0.45$ ) against usual care and (psychological or pill) placebo in a network meta-analysis (Barth et al., 2013). However, effect sizes drop to small ( $g = 0.36$ ) when considering only low risk of bias studies (Cuijpers et al., 2019).

The comparison of psychotherapy and pharmacotherapy in a network meta-analysis showed no difference regarding efficacy in the short-term, but greater acceptability of psychotherapy over pharmacotherapy (Cuijpers et al., 2020) and psychotherapy was shown to be more effective than pharmacotherapy over the longer term (Cuijpers et al., 2013, 2020). For individuals with at least moderate depression, a combined treatment with psychotherapy and pharmacotherapy was shown to be more effective than psychotherapy or pharmacotherapy alone (Cuijpers et al., 2020).

National health guidelines for depression treatment largely reflect this and further evidence in their recommendations (AWMF et al., 2022; NICE, 2022), although the German S3 guideline has been criticized for not adequately reflecting the state of the evidence, especially regarding evidence for different psychotherapeutic treatment approaches (Rief et al., 2022).

To conclude, with psychotherapy and pharmacotherapy, effective treatments for depression are available. However, although effective interventions are available for depression, a substantial number of individuals with depression does not seek or receive help (Chisholm et al., 2016; for a meta-analysis: Mekonen et al., 2021; Thornicroft et al., 2017). The barriers to mental health treatment will be described in the following chapter.

### ***Unmet need and barriers to mental health treatment***

The unmet need for mental health care for depression is high around the globe, with higher treatment gaps in countries with lower gross national product (Chisholm et al., 2016; for a meta-analysis: Mekonen et al., 2021; Thornicroft et al., 2017). Even in high-income countries it is estimated that less than every fourth individual with depression receives minimally adequate treatment (Chisholm et al., 2016; Mekonen et al., 2021; Thornicroft et al., 2017).

More specifically, for Germany it is estimated that about 32% of those with depression receive minimally adequate treatment (Thornicroft et al., 2017) and the median duration of delay in treatment seeking after first onset of depression in Germany was estimated to be two years more than a decade ago (Wang et al., 2007), with waiting times for outpatient psychotherapeutic treatment upon request of about five months (German Federal Chamber of Psychotherapists, 2018).

Reluctance to seek help was shown to be higher in specific socioeconomic groups. For example being younger or elderly, being male as well as being lower educated or belonging to certain ethnic groups was shown to be associated with decreased help-seeking behavior for depression (for a review: Magaard et al., 2017).

Several factors are suggested as causes explaining the large numbers of unmet need. A considerable number of those meeting criteria for MDD seem not to perceive a need themselves to seek help (Thornicroft et al., 2017). Many also remain undetected in primary care settings (Mitchell et al., 2009) with general practitioners in the majority of the cases being the first health professionals contacted (Thompson et al., 2004).

Even to those who perceive a need for mental health care, structural barriers such as financial issues (e.g. costs of the service), availability and accessibility issues (e.g. long waiting times or the inability to get an appointment) or location and transportation issues to access mental health services (e.g. when living in rural areas) are common barriers to treatment; varying between countries with different health care systems (Andrade et al., 2014; Gulliver et al., 2010).

Although structural barriers must not be neglected, attitudinal barriers seem to play an even greater role than structural barriers in explaining unmet need in Germany (Andrade et al., 2014). Attitudinal barriers comprise attitudes such as the preference to handle problems on one's own, believing that

treatment is not effective, perceived stigma and embarrassment associated with mental health treatment or fear of discrimination (Clement et al., 2012; Gulliver et al., 2010). In fact, fear of stigmatization has repeatedly been suggested as a major factor explaining reluctance to seek professional mental health care for depression (Barney et al., 2006; Boerema et al., 2016; Clement et al., 2015; Fox et al., 2018) and suffering from current depression even seems to increase the perceived magnitude of this barrier (Mohr et al., 2010; Pyne et al., 2004).

Unfortunately, up until today, the fear of stigmatization due to depression seems justified. Stigmatization of people with depression – despite effective intervention campaigns to reduce mental health stigma (for review: Mehta et al., 2015; Thornicroft et al., 2016) – seems still a major problem even in high-income countries. Although evidence suggests that seeking professional help for depression is becoming more accepted in the general population, there seems to be little positive change – and partially even change to the worse – in the general population’s attitudes towards people with depression (for Germany: Angermeyer et al., 2013; for USA: Pescosolido et al., 2010; for Australia: Reavley & Jorm, 2012; for a review and meta-analysis: Schomerus et al., 2012) and evidence suggests structural discrimination in several areas of life (e.g. discrimination in somatic treatment, employment or insurance discrimination) around the globe for people with mental disorders (for a review: Voldby et al., 2022).

In line with this, individuals in treatment for their mental health problems often report perceived stigmatization as a common adverse effect of mental health treatment (Ladwig et al., 2014; Rozental et al., 2016; Strauss et al., 2021).

### ***Internet-based treatment and prevention of depression***

Over two decades ago, internet- and mobile based interventions (IMIs) have been suggested as possibly effective interventions to overcome many of the barriers to mental health treatment (Ritterband et al., 2003) and have been defined as follows:

“Internet interventions are typically behaviorally or cognitive-behaviorally-based treatments that have been operationalized and transformed for delivery via the Internet. Usually, they are highly structured; self or semi-self guided; based on effective face-to-face interventions; personalized to the user; interactive; enhanced by graphics, animations, audio, and possibly video; and tailored to provide follow-up and feedback.” (Ritterband & Thorndike, 2006, p. 1)

IMIs are accessible at any time, from anywhere and at low costs. Therefore, they were suggested to overcome many structural barriers to traditional mental health treatments (Ritterband et al., 2003) and preliminary evidence suggests that IMIs might indeed be perceived as baring less structural barriers than traditional treatment for depression (Casey et al., 2014).

In addition to structural barriers, IMIs have been proposed to reduce the likelihood of attitudinal barriers. For example, IMIs seem more congruent with many individuals preference to handle their

problems on their own (Clement et al., 2012; Gulliver et al., 2010) and they are suggested to be associated with reduced fear of stigma due to the anonymity of the Internet (e.g. Berger et al., 2005; Cuijpers et al., 2008; Leach et al., 2007).

On average, IMIs for depression consist of eight sessions and are delivered over nine weeks (Karyotaki et al., 2021). IMIs differ by the amount of human guidance provided. Support varies from no or only technical support (“unguided/self-guided interventions”), to support when needed (“adherence-focused guidance/feedback on demand”), to regular support following every session (“guided interventions”). Guidance typically is provided in a written form, but other delivery modes of guidance are increasingly investigated (e.g. Baumeister et al., 2014; Zarski et al., 2016).

Within the last two decades, numerous studies have been conducted assessing the efficacy of IMIs for depression and by now meta-analytical evidence shows the short- and longer-term efficacy of IMIs in the reduction of depressive symptoms in individuals from mild to severe depressive symptoms (Karyotaki et al., 2021), and in individuals with a diagnosed depression (Köhnen et al., 2020; Königbauer et al., 2017).

In a recent individual participant data meta-analysis from Karyotaki et al. (2021), both unguided ( $d = 0.6$ ) and guided ( $d = 0.8$ ) IMIs were significantly effective to reduce depressive symptoms. Guided IMIs showed superior effects to unguided IMIs particularly in those with higher baseline depression levels, although unguided IMIs for those with higher depression levels still showed substantial effects. In individuals with rather mild depressive symptoms, the form of guidance had a minor influence on the overall effect to reduce depression since effects between both guidance formats were more comparable.

Few studies compared IMIs for depression with face-to-face CBT and meta-analyses could not show a significant difference between both forms (Carlbring et al., 2018; Köhnen et al., 2020). However, the generalizability of the results is limited, since face-to-face comparators in these studies differ from face-to-face psychotherapy as offered in routine clinical care in Germany. Moreover, the validity of these studies is limited as evidence from well-conducted non-inferiority studies is lacking.

To conclude, IMIs for depression are suggested to reduce many barriers to mental health treatment and were shown to be effective. Against the backdrop for the evidence on the efficacy of IMIs for depression, they are strongly recommended for the treatment of depression in patients with mild (AWMF et al., 2022) or less severe (NICE, 2022) depression in current national health guidelines for depression. For moderate depression, the German S3 guideline strongly recommends IMIs when pharmacotherapy and face-to-face psychotherapy are rejected by the patient and states that IMIs may be offered in addition to face-to-face psychotherapy or pharmacotherapy in moderate and severely depressed patients. In the British NICE guideline (2022), IMIs are listed as first-line treatment for more severe depression, although it is recommended to carefully consider other treatment choices with more therapist contact first.

Besides of complementing traditional mental health care in treating depression, the potential of IMIs

has also been suggested for universal, selective and indicative prevention, as well as for early interventions for depression, especially due to the possibility to easily disseminate unguided IMIs on a large scale at low costs (e.g. Christensen & Griffiths, 2002; Muñoz et al., 2010). Meta-analytic evidence also shows the efficacy of IMIs in the prevention of depression by reducing depressive symptoms and by preventing the incidence of MDD (Deady et al., 2017; Reins et al., 2020; Rigabert et al., 2020; Sander et al., 2016).

Importantly, meta-analytic evidence also suggests IMIs to be cost-effective for the treatment and prevention of depression (Paganini et al., 2018).

### **Current challenges, remaining gaps in knowledge and the objective of this dissertation**

Despite effective evidence-based and cost-effective IMIs for the treatment and prevention of depression being available and the suggested reduced barriers, acceptance (Philippi et al., 2021) and uptake of IMIs is found to be rather low (e.g. Batterham et al., 2008, 2021; Batterham & Calear, 2017; Cuijpers, 2021b; Musiat et al., 2014). Several factors have been proposed to explain this low uptake.

Social influence, following performance expectancy, was found to have the second largest impact on the intention to use IMIs (Philippi et al., 2021). This finding suggests that “what others might think” seems to be important for the usage of IMIs as well, although the barrier due to fear of stigmatization has long been suggested to be reduced in IMIs (e.g. Berger et al., 2005; Cuijpers et al., 2008; Leach et al., 2007). More specifically, preliminary empirical data suggests that stigma might be a major barrier to use IMIs too (Crisp & Griffiths, 2014) and that attitudes towards seeking professional help seem to play a comparable role in uptake of face-to-face and internet-based interventions (Batterham & Calear, 2017).

With a focus on stigmatization as a possible major barrier also for IMIs for depression, the paradigm of indirect reduction of depression has been raised (Cuijpers, 2021b). The indirect approach has been proposed as an alternative approach that is suggested to be associated with reduced stigmatization and resulting higher uptake. It is defined as follows:

“The basic idea of these “indirect” interventions is that they focus on problems related to depression, but not directly on depression itself. At the same time the participants learn techniques which not only directly affect the problem, but also have an effect on depression or may prevent future depressive symptoms or disorders.” (Cuijpers, 2021b, p. 3)

Thus, in order to reduce fear of stigmatization indirect interventions focus on psychological problems that are suggested to be less stigmatizing, more common and probably better communicable, and it is proposed that this could lead to higher uptake rates. Possible psychological problems for the indirect reduction of depression are numerous, e.g. sleep problems, procrastination, low self-esteem, stress or worry and rumination (Cuijpers, 2021b).

Since depression shows a high comorbidity with other mental disorders, and especially with anxiety

disorders (Kessler et al., 2015; Plana-Ripoll et al., 2019; ter Meulen et al., 2021), it seems valuable to investigate so-called transdiagnostic risk factors (e.g. Schaeuffele et al., 2021) to indirectly target depression.

Stress and RNT are established transdiagnostic risk factors in meta-analytic and/or (systematic) review findings not only for the development and maintenance of depression (A. G. Harvey et al., 2004; Madsen et al., 2017; Watkins, 2008) but also for other mental disorders (A. G. Harvey et al., 2004; S. B. Harvey et al., 2017; van der Molen et al., 2020; Van Laethem et al., 2013; Watkins, 2008). Thus, targeting these common risk factors might be valuable in reducing depression and comorbid mental disorders alike.

However, prior to the commencement of this dissertation, there was limited evidence on the efficacy of indirect IMIs for depression that directly target these transdiagnostic risk factors, and it was not well understood through which mechanisms of change these interventions affect depression.

### **Objectives of this dissertation**

The goals of this dissertation can be divided into overarching and study-specific goals. The overarching goals arose from the commonality of the interventions studied, which can all be understood according to the new paradigm as “indirect interventions to reduce depression” (Cuijpers, 2021b). The study-specific aims arose from the specific interventions examined in each study and the specific gaps in knowledge regarding those specific interventions.

### **Overarching research question of this dissertation**

Thus, the overarching aim of this dissertation was (a) to develop and assess the efficacy and acceptability of three different indirect IMIs for depression, that primarily focus on the reduction of common transdiagnostic risk factors (stress and RNT) for depression, in randomized controlled trials (RCT) and (b) to investigate whether the reduction in these risk factors mediate the reductions in depression.

### **Study-specific research questions of this dissertation**

In addition to this overarching aim, this dissertation pursued other goals that emerged from the individual studies as described below.

#### ***Study I – Internet-based stress- and classroom management for beginning teachers (GetWell.Started)***

Internet-based stress management interventions (iSMI) might be more appealing for some as compared to IMIs for depression, and ‘stress’ at face value seems to be less stigmatizing than “depression” (Cuijpers, 2021b). Stress – work-related and more general – is an established risk factor for the development and maintenance of depression (Burcusa & Iacono, 2007; D. N. Klein & Santiago, 2003; Kraus et al., 2019; Madsen et al., 2017; McLaughlin et al., 2010; Risch et al., 2009; Struijs et al., 2021).

In line with this, stress is a common believed cause of depression within the general population (Angermeyer et al., 2013; Brown et al., 2001; Dunlop et al., 2012) so that a stress management intervention (SMI) might fit with individuals' subjective disease models leading to a congruence between individuals' beliefs about the causes of distress and a theoretically consistent intervention (Dunlop et al., 2012; Khalsa et al., 2011; Meyer & Garcia-Roberts, 2007). Therefore, an SMI appears to be an indirect intervention for depression worth studying.

Although meta-analytical evidence already shows that iSMIs are also effective in reducing depressive symptoms on average, heterogeneity is substantial (Heber et al., 2017; Phillips et al., 2019), with more than half of the individual studies on occupational e-mental health interventions producing insignificant findings on depression at post-intervention (Phillips et al., 2019).

Moreover, before the commencement of this dissertation, no RCT assessed the efficacy of an iSMI tailored to career starters. Starting a career is not only a stressful life event for many (Mäkikangas et al., 2021; Rudman & Gustavsson, 2011), addressing career starters might also be fruitful in order to reach individuals early in life, since half of those with depression report the first onset episode before the age of 30 (Solmi et al., 2022). Indeed, the development of preventive and early interventions for depression is declared as a key priority area for research on psychological interventions by diverse mental health institutions and commissions (Holmes et al., 2018; National Institute of Mental Health, 2021).

Beginning teachers appear to be a particularly suitable target group for an initial investigation of an iSMI for career starters since they are a relatively homogenous group that has been shown to experience high levels of stress at the beginning of their career (Dicke et al., 2015; Goddard et al., 2006; Harmsen et al., 2019; Klusmann et al., 2012). Additionally, in Germany, beginning teachers are suggested to experience particular high barriers to seek mental health services when in need, due to fear of stigmatization and discrimination for their career as civil servants (Krauch, 2020; Wegert, 2022), although high-quality studies on beginning teachers' barriers to mental health services have yet to be conducted.

Moreover, no RCT assessed the efficacy of an SMI complemented with a work-related skills training and evidence on the exact mechanism of change in SMIs that are developed according to Lazarus and Folkman's (1984) transactional stress theory is scarce.

The first study of this dissertation specifically aimed to (a) tailor an iSMI for beginning teachers, (b) to complement it with a newly developed work-related skills training and to assess its feasibility, (c) to assess the program's short- and longer-term efficacy in reducing perceived stress as a primary and depression and further measures as secondary outcomes as compared to a WLG in an RCT in distressed beginning teachers, (d) to test if the iSMI that was developed according to Lazarus and Folkman's (1984) transactional stress theory actually works by changing emotion- and problem-focused coping and (e) to investigate if the reduction in stress actually mediates the reduction in depression.



***Study II – Internet- and app-based gratitude intervention (GET.ON Gratitude)***

RNT has also been identified as a risk factor for depression and further mental disorders (A. G. Harvey et al., 2004; Watkins, 2008). It has mostly been studied in the form of rumination – repetitive negative thoughts about the past – or worry – repetitive negative thoughts about the future (Ehring et al., 2011; Watkins, 2008).

A growing number of intervention studies assess the efficacy of RNT-focused CBT in reducing RNT and depression (L. Cook et al., 2019; Teismann et al., 2014; Watkins et al., 2011) and CBT for depression has also been shown to reduce RNT (Spinhoven et al., 2018).

Another valuable way to tackle RNT directly and depression indirectly might be a positive psychological approach. Positive psychological interventions might – due to their focus on the positive – be more appealing for those that are reluctant to use CBT interventions due to e.g. emotional concerns or perceived misfit to their needs (Mohr et al., 2010).

Gratitude is one promising positive psychological characteristic (Park et al., 2004; Peterson et al., 2007) with preliminary evidence suggesting that single exercise gratitude interventions (e.g. gratitude diary) might be helpful for reducing depression (Dickens, 2017) or specific forms of RNT (Geraghty et al., 2010a; Otto et al., 2016; Shao et al., 2016).

However, before the commencement of this dissertation, no registered RCT has assessed the efficacy of a complex, multicomponent, internet- and app-based gratitude intervention that combines several gratitude exercises to reduce RNT as a primary outcome. Moreover, research on the mechanisms of change of gratitude interventions is scarce and it is not known how gratitude interventions exert their effect on depression and anxiety symptoms and if RNT is a mediator of change within this relationship.

This dissertation's second study-specific goals were to (a) assess the short- and longer-term efficacy of a complex internet-based gratitude intervention to reduce RNT as a primary and depression and further measures as secondary outcomes as compared to a WLG in an RCT in adults of the general population with elevated RNT and (b) to investigate whether both, a reduction in RNT and improvements in resiliency explain change in depression and anxiety symptoms in a dual pathway model.

***Study III – Internet-based intervention during the COVID-19 pandemic (Get.calm and move.on – GCMO)***

At the beginning of the COVID-19 pandemic, many individuals of the general population experienced anxiety and worries (Betsch et al., 2020; S. Taylor et al., 2020). Research of previous epidemics and/or pandemics has highlighted the consequences of epidemics/pandemics for mental health and in particular claimed an increased risk for the development of depression due to the pandemic (Brooks et al., 2020).

Furthermore, the consequences of the pandemic itself and the governmental responses to it might be classified as a stressful life event for some individuals (Buckman, Saunders, Arundell, et al., 2022) and

might thus be associated with an increased risk for depression (McLaughlin et al., 2010; for a meta-analysis: Risch et al., 2009).

Therefore, at the beginning of the COVID-19 pandemic, numerous calls for action to develop interventions for mental health have been raised (e.g. Gruber et al., 2020; Holmes et al., 2020; Xiang et al., 2020). IMIs have been suggested as especially promising in this regard since they can be conducted at home by keeping physical distance to others (e.g. Holmes et al., 2020; Wind et al., 2020). However, at the beginning of the COVID-19 pandemic, no IMI for the pandemic had been developed, nor studied.

Worry – as a specific form of RNT – is a risk factor for the development of depression and other mental disorders (A. G. Harvey et al., 2004; Watkins, 2008) and worry seemed to be one common psychological problem in the general population at the beginning of the pandemic (Betsch et al., 2020; S. Taylor et al., 2020), Therefore, it seemed promising to develop an IMI to tackle worries in the pandemic.

Since inexpensive mental health advice was rapidly available at the beginning of the pandemic for the general population, it seemed reasonable to use an active control group receiving this information in this trial as comparator.

The development of the COVID-19 pandemic resulted in the following study-specific goals for the third study of this dissertations: To (a) develop an IMI to reduce worries in the general population during the COVID-19 pandemic and assess its short-term efficacy in an RCT as compared to a mental health advice-active control group to reduce worry as a primary and depression and other measures as secondary outcomes (b) to examine the longer-term effects of the intervention and to (c) investigate if the reduction in worrying mediates the intervention's effect on depression.

## **Method**

To allow for an examination of the research questions, three separate randomized controlled studies were conducted that were registered in a primary registry of the World Health Organization.

Participants were randomized to either the IGs or the (active) WLGs.

In accordance with the CONSORT guidelines, primary and secondary outcomes were specified. The primary outcomes were all transdiagnostic risk factors for depression. The secondary outcomes included depression and further mental health and work-related health outcomes. The primary endpoint for all three studies was at post-intervention. In the GetWell.Started and the Get.On Gratitude study, a 3-MFU was conducted in both groups and an extended 6-MFU for the individuals in the IG. Participants of the WLG received access after the 3-MFU. Within the get.calm and move.on study (GCMO), participants of the active WLG received access after post-assessment and 2- and 6-MFU were assessed within both groups.

Analyses of covariance (ANCOVAs) within the intention-to-treat samples were conducted to examine the efficacy regarding primary and secondary outcomes. For a more detailed description of the study-specific methods, see the Methods section in the individual papers.

To be able to sufficiently answer to the overarching research question of this dissertation, the following additional analyses were conducted for each study:

- (a) The proportion of participants with depressive symptoms below or above threshold was calculated for each assessment point.
- (b) The proportion of participants who reported a minimal important clinical change in depressive symptoms was calculated. For this purpose, results of an anchor-based approach to determine the minimal important clinical difference for different baseline severity levels were used (Haase et al., 2022). With these, the corresponding minimal important clinical percentage change was calculated for individuals with moderate and severe depression levels, since the minimal important clinical difference depends on the baseline severity of depression (Bauer-Staeb et al., 2021). A reduction of 33% from baseline to T2 corresponded to a minimal clinical important difference for individuals with moderate and severe depression levels. Chi<sup>2</sup>-tests and numbers needed to treat (NNTs) were calculated for these proportions.
- (c) The proportion of participants reporting reliable deterioration was calculated based on the Reliable Change Index (Jacobson & Truax, 1991).
- (d) To assess the mediating role of the transdiagnostic risk factors that were primarily targeted (GetWell.Started: perceived stress; GCMO: worry) in the interventions' effects on depression, simple mediation analyses were performed. Within the GetWell.Started study, in order to establish temporal precedence, the T2 scores of the mediator stress and the 3-MFU score of the outcome depression were used. Within the GCMO study for both, the mediator worry and the outcome depression, the post-intervention values were used. In line with the recommendations of Hayes and Rockwood (2017), the baseline scores of the mediator and outcome variables were included as covariates. An effect can be considered significant if its 95% confidence interval (95% CI) excludes zero.

## **Chapter Overview**

Embedded in a general introduction and discussion, this dissertation is formed of three papers that have been published or have been submitted for publication. Together, the papers provide three examples of different IMIs that all tackle common transdiagnostic risk factors as their primary outcome and indirectly address depressive symptoms. Additional analyses of the studies' data as described above are depicted at the end of each particular chapter.

### **Chapter 2: Study I – Internet-based stress- and classroom management for beginning teachers (GetWell.Started; *N* = 200)**

This chapter describes the short- and longer-term results of an RCT regarding the efficacy of an iSMI as compared to a WLG in distressed beginning teachers to reduce stress as a primary outcome. Depression and further secondary outcomes such as anxiety, insomnia and work-related health measures were assessed. The intervention in this study was tailored to beginning teachers and complemented by a newly developed classroom management training. In addition to the efficacy of the intervention regarding stress as the primary outcome, the feasibility of complementing the iSMI with a work-related skills training is described. Furthermore, the results of a parallel mediation analysis to test the mechanisms of change of the intervention according to Lazarus and Folkman's (1984) transactional stress theory are presented.

### **Chapter 3: Study II – Internet- and app-based gratitude intervention (Get.On Gratitude; *N* = 262)**

This chapter describes the short- and longer-term results of an RCT regarding the efficacy of an internet- and app-based gratitude intervention as compared to a WLG in adults of the general population with elevated RNT. The primary outcome was RNT. Secondary outcomes included depression, insomnia, anxiety and other measures. Furthermore, the results of two parallel mediation analyses to test whether both, reductions in RNT and improvements in resiliency, mediate the intervention's effect on depression and generalized anxiety are described.

### **Chapter 4: Study III - Internet-based intervention during the COVID-19 pandemic (Get.calm and move.on – GCMO; *N* = 351)**

This chapter describes the short- and longer-term results of an RCT to assess the efficacy of a newly developed IMI to tackle worries in the general population during the COVID-19 pandemic as compared to an active control group receiving mental health advice. The primary outcome was worry. Secondary outcomes included depressive and generalized anxiety symptoms, resiliency and well-being, and others.

## **Chapter 2 – Internet-based stress- and classroom management for beginning teachers**

**Manuscript – Efficacy of an internet-based stress management intervention complemented by a classroom management training for beginning teachers and mechanisms of change: results of a randomized controlled trial**

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**Efficacy of an internet-based stress management intervention complemented by a classroom management training for beginning teachers and mechanisms of change: results of a randomized controlled trial**

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HH initiated the study, tailored the intervention to beginning teachers and developed and programmed the classroom management training, conceptualized the study, was responsible for the conduct of the study, prepared, analyzed and interpreted the data, wrote the first draft, and critically reviewed and edited the manuscript. DL supervised the whole process of intervention development and evaluation and critically reviewed and edited the manuscript. We thank Leif Boß for his support with technical issues related to the training platform and Sandy Hannibal and Patricia Nixon for proof-reading and feedback on an earlier version of this paper.

This study's design, hypotheses and analysis plan were preregistered at the German Clinical Trials Registry (reference number: DRKS00013880); see <https://drks.de>. Individual participant data that underlie the results reported in this article, after de-identification, will be made available upon request with researchers who provide a methodologically sound proposal.

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## **Abstract**

The university-to-work transition is associated with insecurities and increased stress for many career starters. While meta-analytical evidence shows the efficacy of internet-based stress management interventions (iSMIs) for experienced employees as well as for university students, there is a gap in research on the efficacy of iSMIs tailored to career starters. The teaching profession and the career start as a teacher was shown to be highly stressful which has consequences for teachers' mental health, their occupational well-being and work performance. We investigated whether an iSMI that was developed according to transactional stress theory, tailored to beginning teachers and complemented by a classroom management (CRM) skills training is effective in reducing perceived stress. Participants were 200 high strain beginning teachers during German teacher induction that were randomized to intervention group or a wait-list control group. Outcomes were assessed at baseline, post-intervention, 3- and 6-month follow-up. In the intention-to-treat analysis, the intervention group reported significant and sustained improvements in perceived stress of moderate size as well as in secondary outcomes. We also found improvements in CRM self-efficacy. Adding an internet-based CRM training to an iSMI was found a feasible way to tailor an individual-focused intervention to employees' stressors and needs. Furthermore, in a parallel mediation analysis we could show that the iSMI exerted its effect on reduced perceived stress via both improved problem- and emotional-focused coping, highlighting the importance of teaching both coping strategies and strengthening the interventions program theory that is based on transactional stress theory. (Trial registration: DRKS00013880).

*Keywords:* stress; career-starters; internet-based intervention; mechanisms of change; RCT.

### **Educational Impact and Implications Statement**

Although beginning teachers' stress has been highlighted from the start of research on teachers' mental health, the number of well conducted randomized controlled intervention studies tailored to beginning teachers is scarce. A randomized controlled trial with N = 200 beginning teachers was used to assess the efficacy of an internet-based stress management intervention that was tailored to beginning teachers and complemented by an internet-based classroom management intervention. Beginning teachers receiving the intervention program reported significantly reduced perceived stress, improved mental health, self-efficacy and coping skills immediately following the intervention and up to six months later. A 7-week tailored internet-based stress management intervention complemented by an internet-based classroom management intervention may be an effective and scalable approach to support beginning teachers within a highly demanding transition phase into school life and might have positive consequences for teachers long-term health, occupational performance and might also translate to improved student outcomes.

### **Stress in teachers**

The importance of mental health and stress in school teachers was highlighted decades ago (Kyriacou & Sutcliffe, 1977), including the most influential publication by Maslach and Leiter (1999) on teacher burnout. Noteworthy, the vulnerability of beginning teachers, was identified as a key topic right from the start of research on teachers' mental health (Kyriacou & Sutcliffe, 1977; Simpson, 1962). While those calls for research led to numerous observational studies on factors associated with teachers' mental health, the body of interventional research still is surprisingly scarce. A recent meta-analysis (Iancu et al., 2018) identified only 10 trials investigating interventions for teachers' mental health employing an adequate randomization procedure (also see: Klingbeil & Renshaw, 2018; Oliveira et al., 2021). Besides the quality of trials, the efficacy of the interventions was modest at best and investigations aiming to test theory-based mechanisms underlying the interventions' efficacy were missing (Iancu et al., 2018). The present research aims to address these gaps.

#### ***Stress in teachers and its beginning***

Teaching is repeatedly described as a stressful profession and a significant proportion of teachers feel chronically stressed and burned-out (Cramer et al., 2014; Hinz et al., 2016; Iriarte Redín & Erro-Garcés, 2020; Johnson et al., 2005). A significant body of research has investigated the determinants of teachers' stress and found individual factors such as active and passive coping or emotional instability (Kim et al., 2019; Montgomery & Rupp, 2005) as well as stressors in the working environment such as overall workload, demands concerning the preparation of a lesson as well as emotional demands for example due to student misbehavior (Aloe, Shisler, et al., 2014; Hakanen et al., 2006; Montgomery & Rupp, 2005; Schmidt et al., 2017; Varol et al., 2021) to be associated with teachers' chronic stress and exhaustion.

When examining the onset of chronic stress, longitudinal studies suggest an increase of chronic stress and emotional exhaustion with teachers' entry into working life (Dicke, Parker, et al., 2015; Goddard et al., 2006; Harmsen et al., 2019; Klusmann et al., 2012; Schmidt et al., 2016; Voss et al., 2017; Voss & Kunter, 2020). This transition from the education system to work has also been described as a "praxis-shock" (Veenman, 1984). Similarly, career transitions and newcomer socialization across professions are assumed to be associated with an increase in stress due to many uncertainties (Ashforth, 2001; Dunford et al., 2012; Ellis et al., 2015; Gruman & Saks, 2013; Latack, 1984; Mikal et al., 2013) and longitudinal studies reported first years of employment to be associated with increased instability of employees' well-being (Mäkikangas et al., 2016).

While some studies suggest the initial increase in teachers' emotional exhaustion to be followed by subsequent decrease after the transition period (Voss et al., 2017; Voss & Kunter, 2020) other studies do not find a significant improvement following the transition period (Goddard et al., 2006; Klusmann et al., 2012; Schmidt et al., 2016) and rather find beginning teachers' exhaustion levels at the end of the transition phase to be as high as those of established in-service teachers (Klusmann et al., 2012; Schmidt et al., 2016). By assessing trajectories of change, Hultell et al. (2013) in a 3-year longitudinal

study of beginning teachers, suggest that there is no universal development of chronic stress. While for some burnout symptoms seem to decrease after one to two years, they stay stable moderate or stable high or even continue to increase for a significant proportion. Similar patterns of heterogeneous burnout development were also found for non-teaching career starters (Mäkikangas et al., 2021; Rudman & Gustavsson, 2011). This highlights that transition into working life can be challenging for many career starters and furthermore be associated with an increase in stress levels which does not seem to rebound following the transition period but instead becomes chronic for many individuals.

### ***Stress and adverse consequences for teachers' health***

Chronic work-related stress across professions is a known risk factor for the development of both, adverse mental and physical health. With regard to mental health, several meta-analyses of prospective studies showed an increased risk of chronic work-related stress on developing mental health problems such as anxiety, depression or stress-related mental disorders and sleeping problems (Harvey et al., 2017; Madsen et al., 2017; van der Molen et al., 2020; Van Laethem et al., 2013). Regarding physical health, work-related stressors were meta-analytically shown to be associated with an increased risk for coronary heart disease (Dragano et al., 2017; Kivimäki et al., 2012) as well as an increased risk for metabolic syndrome (Kuo et al., 2019) and an unhealthy lifestyle (Heikkilä et al., 2013).

Although the above illustrated results come from studies of the general working population, evidence from individual, mostly cross-sectional studies examining teachers suggest that the relationships also apply to teachers. For example, studies in teachers show high job strain to be associated with decreased recovery following work due to poorer sleep quality and increased work-related rumination (Aronsson et al., 2003; Cropley et al., 2006; Varol et al., 2021), symptoms of depression, anxiety, and burnout (Cropley et al., 1999; Seibt & Kreuzfeld, 2021; X. Shen et al., 2014; Steinhardt et al., 2011; Zhong et al., 2009), psychosomatic symptoms (K. Howard et al., 2017) and major depression disorder (Lehr et al., 2009). Regarding physical health, individual studies on teachers show an association of high job strain with factors that are linked to increased cardiovascular risk status such as higher physiological stress responsivity and sustained blood pressure as compared to low job strain teachers (Chida & Steptoe, 2010; Steptoe, 2000; Steptoe et al., 1999).

### ***Teachers' stress and work behavior***

Besides the consequences on teachers' individual health and well-being, chronic stress is also theorized to affect teachers' work performance and work behavior (Jennings & Greenberg, 2009; Maslach & Leiter, 1999; Roeser et al., 2013) and empirical evidence shows chronic stress in teachers to be associated with poorer work engagement, lower organizational commitment (Hakanen et al., 2006) and lower job satisfaction (Klassen & Chiu, 2010). Chronically stressed teachers also show higher rates of absenteeism and presenteeism (J. T. Howard & Howard, 2020), intentions to quit and teacher attrition (Madigan & Kim, 2021), found in both beginning (Harmsen et al., 2018) or experienced teachers that retire early (Beutel et al., 2018).

With regard to teachers' performance in the classroom, a recently published study from Klusmann et al. (2021) could show that teachers' reduced instructional quality mediated the negative effect of their emotional exhaustion on a range of students' outcomes. A growing body of evidence suggests that teachers' mental health is associated with worsened students' perception of the learning climate, their perception of reduced teachers' support and lower school satisfaction, reduced motivation and self-concept (Arens & Morin, 2016; Klusmann et al., 2021; B. Shen et al., 2015), as well as lower achievements in standardized tests (Arens & Morin, 2016; Klusmann et al., 2016, 2021) and deteriorated students' mental health and well-being (Harding et al., 2019; Oberle & Schonert-Reichl, 2016).

To conclude, the above illustrated findings underscore the importance of preventing chronic work-related stress in teachers, for teachers' health and well-being and for students' academic and socio-emotional development and well-being. Past research suggests that chronic work stress begins at the very beginning of their career for many teachers and that it may not decrease with experience for a significant proportion. Thus, developing stress management interventions (SMI) for beginning teachers in order to reduce perceived stress and prevent stress-related symptoms and disorders right from the beginning is important. Following the recent guideline of the Medical Research Council for developing and evaluating complex interventions (Skivington et al., 2021) such as SMIs, research should address the benefit of the intervention for the participant, i.e., efficacy and effectiveness of interventions, but at the same time contribute to a better understanding of theory by investigating how the intervention leads to its effects.

## **Occupational e-mental health**

### ***Previous evidence on occupational e-mental health***

In the last two decades, research on the efficacy of internet-based SMIs (iSMIs) developed as part of the emerging field of occupational e-mental health. Occupational e-mental health describes the application of e-mental health in the work domain and includes delivering interventions as well as professional education by using the Internet for workers' mental health (Lehr, Geraedts, et al., 2016). Internet interventions are "typically behaviorally or cognitive-behaviorally-based treatments that have been operationalized and transformed for delivery via the Internet. Usually, they are highly structured; self- or semi-self-guided; based on effective face-to-face interventions; personalized to the user; interactive; enhanced by graphics, animations, audio, and possibly video; and tailored to provide follow-up and feedback" (Ritterband & Thorndike, 2006, p. 1). iSMIs, as compared to traditional SMIs, are conducted individually, instead of in group; they are easily accessible and can be conducted in a self-paced manner without disclosing personal information to colleagues. iSMIs thus may overcome barriers to traditional SMIs (Lehr, Geraedts, et al., 2016).

Meta-analytic evidence shows the efficacy of iSMIs in the reduction of perceived stress and other mental health symptoms such as depressive and anxiety symptoms in university students before career start (Amanvermez et al., 2020; Harrer et al., 2019) as well as in employees with averagely two

decades of job-experience (Heber et al., 2017; Phillips et al., 2019; Stratton et al., 2017). However, there is a lack of studies investigating the efficacy of iSMIs during the challenging period of career start. Moreover, reviewing the state of research in occupational e-mental health interventions for teachers, Lehr, Heber et al. (2016) reported interventions addressing work-related rumination, insomnia and depression in teachers, but there was no iSMI that was evaluated solely in teachers. To the best of our knowledge, no randomized controlled study assessed the efficacy of an iSMI neither in career starters in general nor in beginning teachers in particular.

### ***Tailoring occupational e-mental health***

Although iSMIs for employees were shown to be effective in reducing stress in the general working population, meta-analyses found large heterogeneity between those interventions (Heber et al., 2017; Phillips et al., 2019; Stratton et al., 2017) that might be explained by a suboptimal fit of the interventions to specific stressors of the respective job. Likewise, the meta-analysis by Iancu et al. (2018) assumes that considering stressors specific to the teaching environment could increase the low efficacy of interventions on teachers' mental health. Tailoring internet-based interventions to individuals' characteristics and needs has also been suggested a possible way to increase the person-intervention fit and to reduce typically high attrition in such (Lehr, Geraedts, et al., 2016; D. C. Mohr et al., 2013). In Clinical Psychology, tailoring mainly focuses on coping with comorbidities (Păsărelu et al., 2017). With regard to occupational e-mental health, tailoring could be conducted regarding the specific stressors of particular groups of employees or occupations or within specific career phases and thus – in addition to fostering more general stress coping skills – aim at increasing their self-efficacy to deal with those occupation- or phase-specific stressors. Since self-efficacy in dealing with work-specific stressors is known to buffer against work-related stress (Shoji et al., 2016) such tailoring could additionally reduce stress. Increasing work-related self-efficacy could be of particular importance for job newcomers (Saks, 1994) and accordingly organizational socialization programs typically train newcomers in relevant work-related skills which is suggested to strengthen their work-related self-efficacy and also to reduce newcomers' stress (Saks & Gruman, 2012).

A major occupation-specific stressor for teachers in general and beginning teachers in particular is students' disruptive behavior and coping with this stressor requires specific professional problem-focused coping skills (Aldrup et al., 2018; Harmsen et al., 2018; Schmidt et al., 2017). Those classroom management- (CRM) specific coping skills are lower in beginning teachers as compared to experienced teachers (Gold & Holodynski, 2015; Klassen & Chiu, 2010; König & Kramer, 2016) and were shown to predict reduced classroom disturbances and additionally to buffer the effect of classroom disturbances on emotional exhaustion (Aloe, Amo, et al., 2014; Dicke et al., 2014, 2018). Promising results for promoting professional skills in career starters were reported by Dicke, Elling et al. (2015) investigating a CRM intervention in a non-randomized controlled study in beginning teachers. However, to the best of our knowledge, there is no trial that complemented an iSMI with an

employee skills development training, or more specifically a CRM module. Moreover, no internet-based CRM training has been evaluated to date.

### **Intervention theory and mechanisms of change**

So far, research on iSMIs focused on efficacy and effectiveness. At the same time, program theory remained largely under-investigated, a pattern often seen in complex interventions creating an impediment to theoretical progress (Skivington et al., 2021). Although theory-based interventions may not be more effective compared to non-theory-based interventions, “theory provides a coherent and explicit framework for designing, evaluating, and optimizing interventions [...] and a means for accumulating evidence over time” (Dalgetty et al., 2019, p. 352). Knowing whether the theorized program elements of an intervention actually exert their effect on the outcome as mechanism of change is important for successful development, refinement and tailoring of interventions and theory (Dalgetty et al., 2019; Holmes et al., 2018). Understanding mechanisms might also be helpful to identify moderators of intervention efficacy and to possibly allow for a better match between interventions and individuals (Holmes et al., 2018).

Lazarus and Folkman’s transactional stress theory distinguishes problem-focused as well as emotion-focused coping and provides a useful framework to develop iSMIs. Problem-focused coping “is directed at managing or altering the problem causing the distress” (Lazarus & Folkman, 1984, p. 150) and was meta-analytically shown to be associated with fewer psychopathology such as anxiety or depressive symptoms (Aldao et al., 2010). Following the definition of Lazarus and Folkman (1984), CRM represents a specific problem-focused coping strategy as it aims to manage or change distress caused by challenging classes and students. Meta-analytical evidence also shows the efficacy of training problem-focused coping for mental health (Cuijpers et al., 2018). Emotion-focused coping “is directed at regulating [the] emotional response to the problem” (Lazarus & Folkman, 1984, p. 150), but evidence on the long-term health benefits of emotion-focused coping is ambiguous (for a review: Austenfeld & Stanton, 2004; Semmer & Meier, 2009). These ambiguous findings might have contributed to many researchers’ “erroneous conclusion” (Lazarus, 2006, p. 124) that problem-focused coping is superior to emotion-focused coping. A closer examination of the construct and operationalization of emotion-focused coping, however, shows that emotion-focused coping is an umbrella term, comprising a multitude of strategies – ranging from putatively adaptive (e.g., acceptance, re-appraisal) to putatively maladaptive (e.g., avoidance, suppression) strategies (Aldao et al., 2010; Kraiss et al., 2020). With the third-wave cognitive behavioral therapy, strategies such as mindfulness and acceptance (e.g. S. C. Hayes et al., 1999; Teasdale et al., 2000) were argued to be adaptive emotion-focused coping strategies and found to be associated with mental health (Aldao et al., 2010; Berking & Wupperman, 2012; Diedrich et al., 2014, 2016; MacBeth & Gumley, 2012). This seems to be a rehabilitation of emotion-focused coping and interventional research in occupational health psychology accordingly has shifted towards fostering emotion-focused coping especially through teaching mindfulness and acceptance (Bartlett et al., 2019; Estevez Cores et al., 2021).

However, latest research points in the direction that there is no “either...or” regarding problem-focused and emotion-focused coping and that the efficacy of coping strategies depend on the situation and it is rather the ability to flexibly use both that seems important (Achnak & Vantilborgh, 2021; Aldao & Nolen-Hoeksema, 2012). After many years of research, it seems that research is in line again with Lazarus & Folkman’s conceptualization of coping. While they assumed the emotion-focused part to be helpful with rather unsolvable problems, the problem-focused-part is assumed to be stress-reducing with rather controllable problems (Lazarus & Folkman, 1984). Thus, in a complex world, the dynamic use of both strategies seems to be adaptive for successful coping.

Along this line of reasoning, Heber et al. (2016) developed an iSMI for the general working population including three sessions focusing on problem-focused coping and three on emotion-focused coping. Although the iSMI demonstrated its effectiveness in several randomized controlled trials (Ebert et al., 2021; Ebert, Heber, et al., 2016; Ebert, Lehr, et al., 2016; Heber et al., 2016; Nixon et al., 2021) this cannot be accounted as proof of the theoretical assumptions made, since knowing that the intervention works does not say why it works.

To the best of our knowledge, no study has investigated these coping strategies as mechanisms of change in a SMI or iSMI in concert. Thus, we do not know whether teaching both coping strategies actually leads to reduced stress by changing both coping orientations.

### **Aims of the current study**

The aim of the current study is threefold. First, to assess the efficacy of an iSMI tailored to beginning teachers and complemented by a newly developed CRM skills intervention with regard to perceived stress as the primary outcome and further secondary outcomes in beginning teachers struggling with the transition into working life. We hypothesized that the iSMI would decrease perceived stress (primary outcome) as well as further secondary mental and work-related health outcomes (e.g. depression, anxiety, work-related rumination) and improve coping skills and self-efficacy. The second aim was to assess the feasibility of a newly developed CRM module, as an optional work-related skills training to complement an iSMI. The third aim was to assess whether an iSMI that relies on transactional stress theory helps to reduce perceived stress through fostering problem- and emotion-focused coping. We hypothesized that problem- and emotion-focused coping are mediators of change in the intervention’s effect on perceived stress.

## **Methods**

### **Transparency and Openness**

We report how we determined our sample size, all manipulations, and all measures in the study, and we follow JARS (Kazak, 2018) and CONSORT (Moher et al., 2010). Individual participant data that underlie the results reported in this article, after de-identification, will be made available upon request with researchers who provide a methodologically sound proposal. Data analysis was performed using R (Version 4.0.2) and the following packages: tidyverse Version 1.3.1 (Wickham et al., 2019), mice Version 3.14.0 (van Buuren, 2014), mitml Version 0.4.3 (Grund et al., 2019), lavaan Version 0.6.10



(Rosseel, 2012), semTools Version 0.5.5 (Jorgensen et al., 2018). The Ethics Committee of the University of Lüneburg, Germany approved the study and the trial's design and its analysis were pre-registered at the German Clinical Trials Registry (reference number: DRKS00013880).

### **Study Design**

A two-arm randomized controlled trial (RCT) was conducted, examining the efficacy of an iSMI complemented by CRM modules (intervention group; IG), as compared to a waitlist control group (WLG). The CRM modules were offered as optional modules. Participants in the WLG obtained access to the intervention after the 3-month follow-up. The IG and the WLG had access to usual care.

In accordance with the CONSORT-guidelines (also see OSM) for parallel group randomized trials (Moher et al., 2010), we pre-specified a primary outcome and secondary outcomes.

Based upon the effect sizes found in a meta-analysis for internet-based interventions for perceived stress (Heber et al., 2017) as well as the effect size found in a previous version of the training that only included the stress management module and that was conducted in the general working population (Heber et al., 2016), an effect size of  $d = 0.4$  was anticipated. An effect of that size reflects a difference of 2.45 points on the PSS when assuming a  $SD$  of 6.12 (pooled  $SD$  at T2 in the study of Heber et al., 2016). A Delta exceeding 2 points on the PSS is regarded as practically meaningful (Boß et al., 2021). To detect an effect of that size an a priori power analysis for a two-tailed test with a power ( $1 - \beta$ ) of 0.80 and a significance level of 0.05 indicated a required sample size of  $N = 200$  individuals.

### **Participants and Procedures**

All participants were beginning teachers in Germany taking part in a highly structured trainee program lasting 1.5-2 years (so-called *referendariat*). The *referendariat* is an induction phase and a mandatory element of teacher education after university and before becoming an actual teacher in Germany. In this phase teachers gradually begin to teach independently and are repeatedly examined and graded on their teaching. At the same time they attend courses on teaching (Dicke et al., 2014). Participants were recruited both directly (via social media groups for beginning teachers) and indirectly (by contacting the beginning teachers mandatory study seminars and asking them to share information on the study). Participants were screened for eligibility if they expressed their interest between August 2018 and May 2019 online on the study's landing page. Interested individuals were sent a link to a screening questionnaire and were given further information regarding the conditions of participation as well as about the processing and handling of personal data. After providing their consent, the following inclusion criteria were assessed: (a) being part of the *referendariat*; (b) elevated perceived stress, as indicated by a score  $> 21$  on the Perceived Stress Scale (Cohen et al., 1983); (c) not on a waiting list to receive or currently receiving psychotherapy; (d) no changes in dosage of psychopharmacological treatment over the preceding 30 days; and (e) no reported acute suicidal tendencies (suicidality item from the Beck-Depression-Inventory II  $< 2$ ; Hautzinger et al., 2009) or (f) dissociative symptoms. Eligible individuals were then sent a link to the baseline questionnaire (T1). After completing the

baseline questionnaire, participants were randomly assigned to one of the two study arms. Randomization was conducted anonymously, without any personal contact between study personnel and participants using a computer-generated randomization list with a ratio of 1:1 and a block size of two. The list was generated by a member of our department who was not otherwise involved in the study. Blinding to group allocation was infeasible since participants knew if they were randomized to the IG or the WLG. Participants in the IG received immediate access to the training program and a message from their eCoach instructing them about guidance. Individuals in the WLG group were granted access to the program after the 3-month follow-up.

### **Measures**

Data collection took place at the time of screening (T0), at baseline (T1), at post-intervention (eight weeks after randomization; T2) and at a 3-month follow-up (3-MFU) in both groups. Among participants in the IG outcomes were also assessed at an additional 6-month follow-up (6-MFU). Demographic variables were collected at T0. Outcomes measuring participants' satisfaction with the training program and usage of care as usual were assessed at T2. Internal consistencies for this study are reported for T1, unless otherwise stated. All instruments were self-report measures assessed online and in German.

#### ***Primary outcome measure***

The Perceived Stress Scale (PSS; Cohen et al., 1983) was used to measure perceived stress. This scale consists of 10 items (e.g., "In the last month, how often have you felt nervous and "stressed"?"). Items are rated from 0 (*never*) to 4 (*very often*). The total score of the scale ranges from 0 to 40, with higher scores indicating greater perceived stress. A score > 21 indicates an above-average level of stress (Heber et al., 2016). The PSS has good psychometric properties, as demonstrated by a Cronbach's alpha ranging from .74 to .91 (E.-H. Lee, 2012) and was .71 at T1 in this study.

#### ***Secondary outcome measures***

##### **Mental health outcomes.**

***Symptoms of depression.*** Symptoms of depression were measured with the short version of the Centre for Epidemiological Studies Depression Scale (CES-D; Hautzinger et al., 2012; Radloff, 1977), consisting of 15 items (e.g., "During the last week I was depressed."), each rated from 0 (*rarely or not at all*) to 3 (*most of the time, all the time*). Internal consistency is reported to be high, with Cronbach's alpha ranging between  $\alpha = .87 - .92$ , and was .89 in the present sample. A total score  $\geq 18$  indicates clinically-significant levels of depression (Lehr et al., 2008).

***Symptoms of anxiety.*** Generalized anxiety symptoms were measured with the 7-item version of the Generalized Anxiety Disorder Scale (GAD-7; Löwe et al., 2008), each item (e.g., "Over the last 2 weeks, how often have you been bothered by the following problems ...Feeling nervous, anxious or on edge.") is rated from 0 (*not at all*) to 3 (*nearly every day*). Internal consistency is reported to be high (Cronbach's  $\alpha = .92$ ; in the present sample .80). A score  $\geq 10$  indicates moderate to severe levels of anxiety.

**Insomnia severity.** Insomnia severity was measured with the Insomnia Severity Index (Morin et al., 2011) which measures the severity of nighttime and daytime components of insomnia. It consists of seven items (e.g., “How satisfied/dissatisfied are you with your current sleep pattern?”), each rated from 0 (*no problem/very satisfied*) to 4 (*very severe problem/ very dissatisfied*). The internal consistency is reported to be high ( $\alpha = .90$ ; in the present sample  $.86$ ). A total score  $\geq 15$  indicates moderate to severe levels of insomnia.

**Work-related outcomes.**

**Emotional exhaustion.** Emotional exhaustion was assessed using the emotional exhaustion subscale of the Maslach Burnout Inventory (Maslach & Jackson, 1981) consisting of five items (e.g., “I feel burned out from my work.”), ranging from 1 (*never*) to 6 (*very often*). Internal consistency for the emotional exhaustion subscale was high ( $\alpha = .74$ ; in the present sample  $.81$ ).

**Work-related rumination.** Work-related rumination was measured with the 3-item (e.g., “Even at home I often think of my problems at work.”) subscale of the Irritation Scale (G. Mohr et al., 2006), ranging from 1 (*strongly disagree*) to 7 (*strongly agree*). The subscale shows good internal consistency with Cronbach’s  $\alpha = .87$  (in the present sample  $.88$ ).

**Work-related anxiety.** Anxiety related to the induction program was assessed by a self-developed questionnaire, consisting of eight items (e.g., “When I think about the *referendariat*, I notice how everything in me tenses up.”), ranging from 0 (*does not apply at all*) to 4 (*applies fully*). Internal consistency as measured with Cronbach’s  $\alpha$  was high ( $\alpha = .81$ ).

**Job satisfaction.** Job satisfaction was measured with an adapted subscale from the Job Diagnostic Survey (Hackman & Oldham, 1975; Kunter et al., 2016), consisting of four items (e.g., “If I could choose again, I would immediately become a teacher again.”), that range from 1 (*does not apply*) to 4 (*does apply*) ( $\alpha = .85, .86$  in the present study).

**Work-related effort and reward.** Effort and reward were assessed with the Effort-Reward Imbalance Scale (ERI; Siegrist et al., 2009), ranging from 1 (*strongly agree*) to 4 (*strongly disagree*). The effort-subscale consists of three items (e.g., “I have many interruptions and disturbances while performing my job.”) (Cronbach’s  $\alpha = .74$ , in the present sample  $.4$ ). The reward-subscale consists of seven items (e.g., “Considering all my efforts and achievements, my salary/income is adequate.”) ( $\alpha = .79$ , in the present sample  $.69$ ). Additionally to analyzing the subscales separately, an effort-reward imbalance ratio was calculated according to the formula:  $ERI = \text{effort}/(\text{reward} * c)$  (Siegrist et al., 2004). The factor  $c$  serves as correcting factor for the deviating number of items in the subscales and corresponds to  $0.429$ . A value  $> 1$  was theorized to represent an imbalance between efforts invested and rewards received in return (Siegrist et al., 2004), while a value  $> 0.715$  was empirically derived as optimal cut-off to identify occupational imbalance situations (Lehr et al., 2010).

**Absenteeism and presenteeism.** Days of absenteeism and presenteeism in the past three months (for T2: since beginning of the study; past 8 weeks) were assessed using the respective items

of the German Version of the Trimbos/iMTA Questionnaire for Costs Associated With Psychiatric Illness (TiC-P; Hakkaart-van Roijen et al., 2002).

#### **Coping Orientation and Self-efficacy.**

***Problem-focused coping.*** To assess orientation towards problem-focused coping, the subscales negative problem orientation and avoidance style from the revised version of the Social Problem-Solving Inventory (SPSI-R; D’Zurilla et al., 2002; Graf, 2003) were used. The sumscore was calculated by adding the two subscales ( $\alpha = .84$  in the present study). The composite scale consists of 10 items rated from 0 (*does not apply to me at all*) to 4 (*applies to me very much*). Negative problem orientation describes the tendency for appraising problems in a pessimistic and negative way, feeling threatened when confronted with problems and doubting one’s ability to solve problems (e.g., “I feel threatened and anxious when I have an important problem to solve.”). The avoidance style describes a tendency to delay or avoid solving problems instead of facing them (e.g., “I put off solving problems until it is too late to do anything about them.”). Low values represent high orientation towards problem-focused coping.

***Emotion-focused coping.*** To measure adaptive emotion-focused coping, three subscales of the Emotion Regulations Skills Questionnaire (ERSQ) were used (Berking & Znoj, 2008). According to the manual (Berking & Znoj, 2008) the sumscore was calculated by adding the three subscales ( $\alpha = .67$  in the present study). In line with the emotion-focused skills taught within the iSMI the subscales comprised understanding (e.g., “I was aware of why I felt the way I felt.”) and acceptance (e.g., “I accepted my emotions.”) of one’s emotions as well as emotional self-support when facing emotions (e.g., “I supported myself in emotionally distressing situations.”). The scale consists of nine items that are rated from 0 (*not at all*) to 4 (*almost always*).

***Classroom management self-efficacy.*** To assess CRM self-efficacy, the respective subscale of the Ohio State Teacher Efficacy Scale (Kunter et al., 2016; Tschannen-Moran & Hoy, 2001) was used. The subscale consists of eight items (e.g., “How much can you do to control disruptive behavior in the classroom?”, “How well can you respond to defiant students?”) that are rated from 1 (*very bad/very little*) to 6 (*very good/very much*). Internal consistencies ranged between .84 to .92 in the German sample (in the present study  $\alpha = .86$ ).

***Work-related self-efficacy.*** To assess more general work-related self-efficacy the Teacher-Self-Efficacy Scale was used (Schwarzer & Schmitz, 1999), consisting of 10 items (e.g., “I trust myself to inspire the students for new projects.”), each rated from 1 (*is not true*) to 4 (*is exactly true*) ( $\alpha = .76 - .82$ , in the present study .78).

#### **Further measures.**

***Clients’ satisfaction.*** Clients’ satisfaction with the whole training program was measured with the Client Satisfaction Questionnaire (Attkisson & Zwick, 1982), adapted to and validated within the online context (CSQ-I; Boß et al., 2016). The CSQ-I consists of eight items (e.g., “The training has met my needs.”). The CSQ-I ranges from 0 to 4, higher values correspond to greater satisfaction.

Reliability is high, as indicated by McDonald's  $\omega$  ranging from .93 to .95 (Cronbach's  $\alpha$  in the current study's IG at T2: .93).

To measure participants' satisfaction with the optional and newly developed CRM module, participants were asked to rate helpfulness, ability of transfer as well as the experience of positive and negative consequences of the CRM module in general at T2 (see Table 5 in the OSM). Additionally at the end of each CRM session participants rated the usefulness as well as the easiness to complete each session (see Table 7 in the OSM). Moreover participants were given the opportunity to describe in open questions what they liked and did not like in each CRM session and to make suggestions about how they would have profited more from each CRM session.

### **Study Conditions**

#### ***Waitlist control group***

Participants in the WLG had full access to usual care and were offered access to the training program after the 3-MFU.

#### ***Intervention group***

Participants in the IG received immediate access to the internet-based intervention named "Starting calm through the induction phase". The training combines an iSMI with an optional internet-based CRM module.

The iSMI consisted of general information, interactive and writing exercises, quizzes, pictures, videos, audio-files and was specially tailored to beginning teachers in the German induction phase. Throughout the whole intervention participants were accompanied by three fictitious example characters to facilitate social learning. Those also were beginning teachers within the induction phase reporting about their difficulties, showing how they completed the exercises and what helped for them. Every participant received their own password-protected learning environment in which they logged in and where their entries were saved. Homework in between the sessions was assigned in order to integrate what was learned into daily life.

The iSMI entailed seven 1-week sessions, each averaging 45-60 minutes in duration. The iSMI was developed according to Lazarus and Folkman's transactional model of stress (Lazarus & Folkman, 1984) and aims on fostering two main coping strategies: problem-focused and emotion-focused coping. In session one, participants received psycho-education on stress. In session two and three, participants were introduced to a 6-step-procedure to systematically solve problems to foster problem-focused coping. From sessions four to six, participants learned different emotion-focused coping skills that help to foster the understanding and acceptance of difficult emotions as well as emotional self-support when feeling stressed. In session seven, participants could make a plan for the future usage of the learned coping strategies. Moreover, in every session participants were given information on the importance of daily positive activities and were asked to plan those for the upcoming week. Participants were furthermore given optional short informational materials related to stress-related topics (e.g., psychological detachment from work, sleep hygiene, worrying and breaks). A more

Table 1  
*Session content of the stress management intervention complemented by the optional classroom management intervention.*  
 Stress management intervention

Session	Objectives	Exercises	Classroom management intervention
1. Psycho-education	Introduction and giving basic information on stress	Quiz on stress. Stress-analysis, stress-diary and identification of personal stressors. Definition of goals and motivation for the training. Planning positive activities.	1. Introduction
2. Problem-focused coping I	Enhancing problem-focused coping skills	Stress-analysis. Differentiation between controllable and uncontrollable stressors. Working on a six-step problem solving plan.	2. Classroom design
3. Problem-focused coping II	Enhancing problem-focused coping skills	Taking stock of the six-step problem solving plan from the previous session and either continue working on it or working on a new six-step problem solving plan. Identifying obstacles to training and ways to overcome them.	3. Rules
4. Emotion-focused coping I	Learning muscle and breathing relaxation	Taking stock of the six-step problem solving plan. Learning muscle and breathing relaxation technique with an audio file.	4. Routines
5. Emotion-focused coping II	Fostering understanding and acceptance of one's unpleasant emotions.	Finding the positive function behind unpleasant emotions, working on a 5-step plan to accept and tolerate unpleasant emotions and training it with an audio file.	5. Disruptive-preventive Classroom management
6. Emotion-focused coping III	Fostering emotional self-support.	Strengthening a positive self-evaluation, self-care and self-compassion.	6. Managing problem behaviour
7. Plan for the future	Reflecting on helpful strategies and planning them for the future	Choosing valuable strategies for the future.	7. Reflection and planning for the future

*Note.* Also see Heber et al. (2013) for a more detailed description of the stress management intervention. For a more detailed description of the optional Classroom management modules see Table 1 in the OSM.

detailed description of the iSMI can be found in Table 1 and in a previous publication from Heber et al. (2013).

In addition to the stress management sessions, participants could use a newly developed 7-session CRM module including topics such as classroom design, establishing rules and routines, disruption-preventive CRM and how to manage disruptive behavior that was offered at the same time as the iSMI. A more detailed overview of the CRM sessions can be found in the online supplement material (OSM Table 1).

Throughout training, participants received written personalized feedback on every completed session from an eCoach (undergraduate psychology students previously trained and continuously supervised by the first author). eCoaches also sent up to three reminders to complete the next session when not completed within 10 days after finishing the previous session. Feedback provision was manualized. Feedback was provided within 48 hours after a session was completed. Each feedback comprised about 500 words and was sent via e-mail. The feedbacks were worded in a validating, motivating and supporting way. The average time the eCoaches spent per feedback was 30 minutes.

### **Statistical Analyses**

In accordance with the CONSORT guidelines (Moher et al., 2010), data was analyzed on the intention to treat-sample (ITT), including all participants that were randomized, regardless of the amount of treatment (if any) they have received. An additional per-protocol sensitivity analysis was performed for the primary outcome. A two-tailed significance level of  $p \leq .05$  was used for all inferential tests.

### **Missing data**

As recommended by Schafer and Graham (2002), missing data were estimated with multiple imputations, with 20 estimates calculated for each missing datum. The imputed data sets were analyzed separately and finally the parameter estimates and hypothesis tests were pooled. Existing data of the primary and secondary outcomes, as well as the grouping variable and sociodemographic variables, were used in the imputation model.

### **Intervention effect**

To analyze between-group differences immediately post intervention (T2) and at 3-MFU, analyses of covariance (ANCOVA), with the respective baseline values of the particular outcome as covariates, were used. In a simulation study comparing different approaches in the analysis of pre-post data in clinical settings, ANCOVAs with baseline scores as covariates were shown to be the most optimal (O Connell et al., 2017). Between-group Cohen's *ds* were calculated for T2 and 3-MFU with the esc-package based on the *F*-values from the pooled ANCOVAs of the multiply imputed datasets. In order to assess long-term efficacy at 6-MFU, within-subject comparisons were employed. For this purpose, repeated-measures analyses of variance were performed between T1 and 6-MFU for each outcome variable. Within-group Cohen's *ds* were calculated by controlling for correlations within samples.

### ***Response analysis***

For the primary outcome, reliable change and corresponding numbers needed to treat (NNT) were calculated at T2 and 3-MFU in order to assess the practical relevance of the effects (Jacobson & Truax, 1991). To calculate reliable change, the reliable change index reported by Heber et al. (2016) was used. They calculated the reliable change index based on the norm populations' standard deviation ( $SD = 6.2$ ) and the reliability of the PSS-10 scale of .91 (Cohen & Janicki-Deverts, 2012). Thus, participants were defined as having reliably deteriorated if their PSS score increased more than 5.16 points from T1 to T2 or from T1 to 3-MFU, and as having reliably improved if their PSS score had decreased by more than 5.16 points from T1 to T2 or from T1 to 3-MFU. Based on reliably changed participants, the corresponding NNTs were calculated. The NNT is an epidemiological effect size indicating the number of participants who must be given access to an intervention in order to generate one additional reliably changed participant in comparison to the control condition. The NNT is used to communicate treatment effects more comprehensively (Laupacis et al., 1988).

### ***Sensitivity analysis***

In addition to the preregistered analyses of the ITT sample per-protocol analyses were performed for the primary outcome at T2 and 3-MFU to assess the robustness of the results obtained with the ITT analyses. To estimate an intervention's potential, only those individuals of the IG that followed the intervention's protocol are included in per-protocol analyses. Participants who completed five or more of the seven sessions of the iSMI were considered as having followed the protocol.

### ***Feasibility analysis of the CRM module***

Several indicators were used to assess the feasibility of the CRM module. To assess the feasibility of complementing the iSMI with the newly developed optional CRM module the CSQ-I was used, measuring the satisfaction with the whole training program. To assess the satisfaction with the CRM module in particular participants, that indicated to have used the optional module, were asked about their satisfaction with it in a general manner and uptake and usage of the particular CRM sessions were assessed. To assess the feasibility of each particular session of the CRM module, participants' rating on usefulness and easiness to complete each session was analyzed, as well as open feedback questions. The open feedback was analyzed in two steps: first for each CRM session similar themes were categorized if a similar theme occurred more than once (see Table 8 in the OSM). In a second step overarching aspects across all CRM sessions were categorized (see Results section). Finally, feasibility was assessed in terms of efficacy of the intervention to change CRM self-efficacy, especially in those individuals that more intensively used the CRM module.

### ***Mediation analysis***

To examine the hypothesized mediating role of improved (1) problem-focused and (2) emotion-focused coping in the intervention's effect on perceived stress (primary outcome), a parallel multiple mediations analysis was calculated. The change in mediators from T1 to T2 as well as the 3-MFU score of the outcome were used to establish temporal precedence (Kazdin, 2007). Following the



recommendations of Hayes & Rockwood (2017), the baseline score for the outcome variable was included as covariate.

## Results

### Participants

The flow of participants through the study is shown in Figure 1. Of the 487 individuals that applied for participation, 145 did not fill out the screening questionnaire, while 342 were assessed for eligibility. Of those screened for eligibility, 115 were ineligible (mostly because of a PSS score under the defined score of  $> 21$ ). Of the 227 individuals that satisfied the eligibility criteria, 27 did not fill out the mandatory baseline questionnaire. The remaining 200 were randomized to either the IG ( $n = 100$ ) or the WLG group ( $n = 100$ ).

### Baseline characteristics

Table 2 and 3 show the baseline characteristics of the sample. Participants were on average 29 years old ( $SD = 4.7$ ), predominantly female (85.5%), mostly either in partnership or married (70.0%) and not (yet) having children (80.0%). Participants had been in the induction phase for an average of 7.4 months ( $SD = 4.8$ ) at baseline. The median of independently taught lessons by participants was 10 per week with a median class size of 25 and with a median of 4 students rated as challenging (range of challenging students: 0-20). Participants were mostly teaching at grammar school (36.0%), followed by primary school (23.0%). The most frequently taught subjects were German (38.0%), Math (26.5%) and English (18.5%). Around one third of the participants at baseline reported an imbalance of efforts invested and rewards received in return (OSM Table 2) based on the theoretical derived cut-off of  $> 1$  (Siegrist et al., 2004). Based on an empirical derived cut-off of  $> 0.715$  (Lehr et al., 2010) nearly all participants (97.0%) at baseline reported an occupational imbalance risk situation. Moreover, the sample was highly distressed at baseline. A majority reported clinical symptoms of depression (59.0%) and/or moderate or severe symptoms of anxiety (59.0%) and more than one third reported clinical symptoms of insomnia (38.5%). Most of them indicated to have been working during the last three months although they felt impaired in health (76.0%). Most of the participants reported not having any experience with health trainings (94.0%) and not having consulted a doctor for the same problems because of which they participate in the training (94.5%) and not having undergone psychotherapy in the past (82.0%). A minority (17.7%) said that they had thought about undergoing psychotherapy at time of baseline. The most frequently cited reason for not doing so was concern about having problems when applying as a civil servant (48.3%). For more detailed description of the sample see Table 3 and 4 in the OSM.

### Missing data

Baseline data were available for all participants. Overall, data for the primary outcome were missing for 13.0% of all participants at T2 (IG: 16.0%; WLG: 10.0%), 20.0% of all participants at 3-MFU (IG: 27.0%; WLG: 13.0%) and 39.0% of those in the IG at 6-MFU. The two groups (IG and WLG) did not differ with regard to missing data at T2 ( $\chi^2 = 1.1, p = .29$ ), but differed at 3-MFU ( $\chi^2 = 5.3, p = .02$ ).

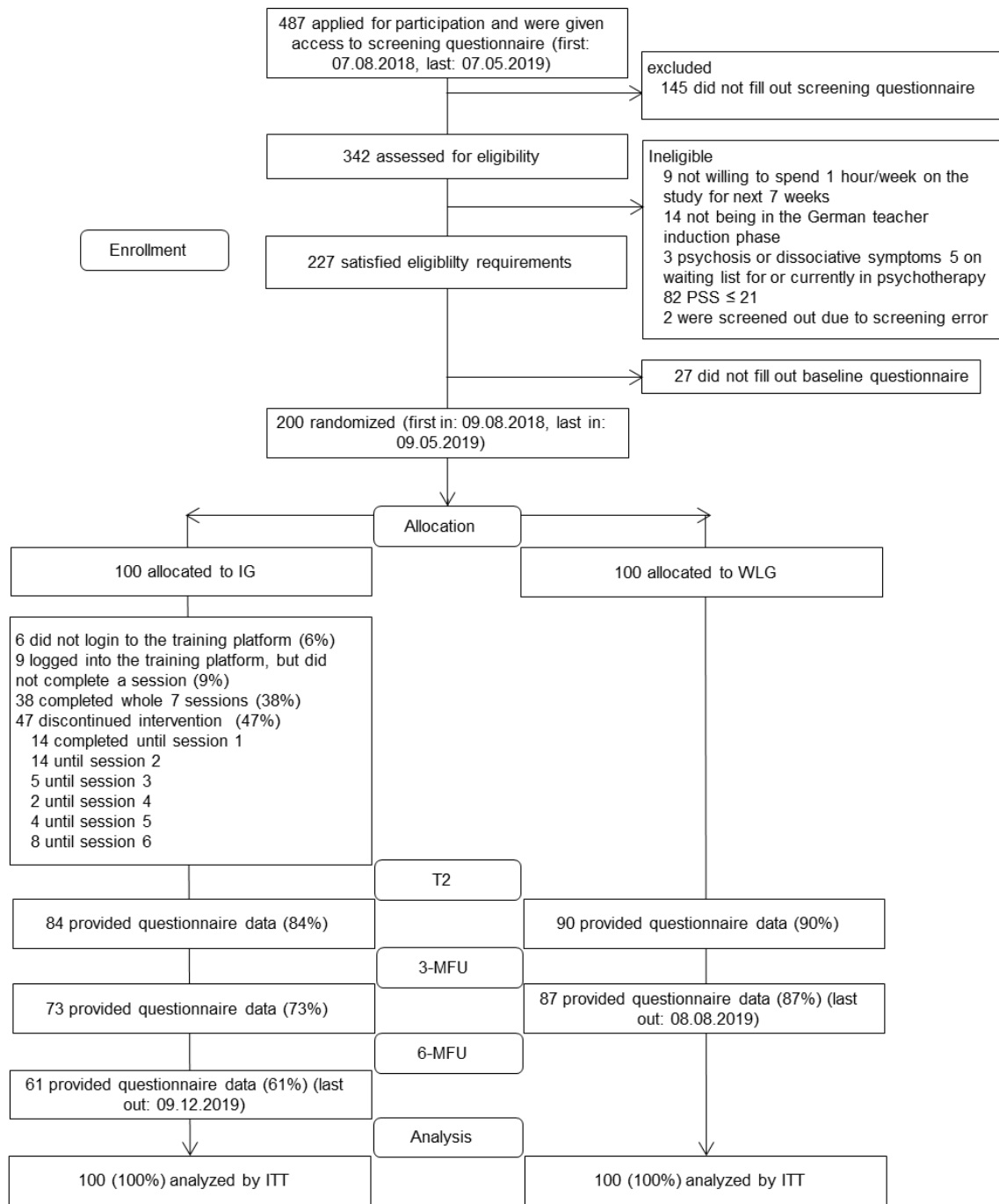


Figure 1. Flow of participants. IG = intervention group; WLG = wait list control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up. The 6-MFU was only assessed in the IG; PSS = Perceived Stress Scale; ITT = Intention to treat Analysis.

Table 2  
*Demographic characteristics of the sample*

	Total ( <i>N</i> = 200)		IG ( <i>n</i> = 100)		WLG ( <i>n</i> = 100)	
	<i>N</i>	%	<i>n</i>	%	<i>n</i>	%
Age ( <i>M/SD</i> )	29.4	4.7	29.4	4.8	29.4	4.6
Sex						
Men	29	14.5	13	13.0	16	16.0
Women	171	85.5	87	87.0	84	84.0
Relationship						
Single	58	29.0	25	25.0	33	33.0
In partnership	93	46.5	52	52.0	41	41.0
Married	47	23.5	21	21.0	26	26.0
Divorced or separated	2	1.0	2	2.0	-	-
Having children						
Yes	40	20	20	20.0	20	20.0
No	160	80	80	80.0	80	80.0
Type of school						
Primary school	46	23.0	25	25.0	21	21.0
Grammar school	72	36.0	31	31.0	41	41.0
Comprehensive school	20	10.0	12	12.0	8	8.0
Technical school	31	15.5	17	17.0	14	14.0
Special needs school	16	8.0	8	8.0	8	8.0
Other	15	7.5	7	7.0	8	8.0
Duration of induction phase						
24 months	51	25.5	24	24	27	27
18 months	149	74.5	76	76	73	73
Presenteeism in past 3 months						
Yes	152	76	85	85	67	67
No	48	24	15	15	33	33
Absenteeism in past 3 months						
Yes	92	46	50	50	42	42
No	108	54	50	50	58	58
Class size ( <i>Md/range</i> )	25	0-30	25	0-30	25	7-32
Challenging students ( <i>Md/range</i> )	4	0-20	4	0-20	4	0-20
Independently taught lessons ( <i>Md</i> )/range	10	0-19	10	0-19	10	2-18
Experience with health training						
Yes	12	6	7	7.0	5	5.0
No	188	94	93	93.0	95	95.0
Consulted doctor for same problems						
Yes	11	5.5	9	9	2	2
No	189	94.5	91	91	98	98
Psychotherapy in the past						
Yes	36	18	24	24	12	12
No	164	82	76	76	88	88
Months in induction phase ( <i>M/SD</i> )	7.4	4.8	8.4	5.1	6.5	4.2

*Note.* IG = intervention group; WLG = wait list control group; *Md* = Median.

Table 3

*Means and standard deviations of the outcomes – intention to treat sample*

Outcome	T1						T2 <sup>a</sup>						3-MFU <sup>a</sup>						6-MFU <sup>a</sup>					
	IG		WLG		IG		WLG		IG		WLG		IG		WLG		IG		WLG		IG			
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD		
Primary outcome	26.5	4.2	25.7	4.4	20.4	6.8	23.5	6.0	18.7	7.7	22.6	6.1	17.1	7.3										
Perceived Stress																								
Secondary outcomes																								
Mental health																								
Depression	20.8	8.3	19.0	8.5	14.2	7.8	19.2	9.0	14.2	9.1	18.1	8.9	13.3	8.9										
Anxiety	11.4	4.3	11.2	4.8	8.0	4.4	10.8	5.0	7.6	4.5	10.4	5.2	6.6	5.2										
Insomnia	12.9	6.0	11.4	6.0	10.1	5.6	11.8	6.3	9.4	5.5	10.9	6.1	7.3	4.8										
Work related outcomes																								
Emotional Exhaustion	23.4	4.2	22.9	4.4	21.1	5.3	23.0	5.1	20.4	5.5	22.5	4.8	18.6	5.3										
Work-related rumination	17.7	3.6	17.9	3.1	15.7	4.5	18.1	3.0	15.0	4.4	17.0	3.5	12.4	4.8										
Work related anxiety	20.6	6.0	19.0	6.5	15.3	7.4	18.2	7.0	15.9	8.5	17.9	6.9	14.4	10.2										
Job satisfaction	10.6	3.2	10.9	3.0	11.4	3.3	10.4	3.1	11.4	3.2	10.7	3.1	11.8	3.4										
Effort	9.4	1.6	9.2	1.3	8.6	1.7	9.2	1.6	8.8	1.8	9.1	1.7	7.6	2.0										
Reward	17.8	3.4	18.4	3.7	18.4	3.4	17.9	3.8	18.3	3.9	17.5	3.7	18.3	4.3										
Absenteeism days <sup>b,c</sup>	2.7	5.5	3.8	16.0	2.5	4.0	1.8	4.6	2.0	3.1	2.2	3.3	3.7	16.5										
Presenteeism days <sup>b,c</sup>	12.3	15.9	7.5	11.5	10.7	15.7	9.5	15.7	9.8	17.9	9.4	15.7	5.4	13.0										
Coping and self-efficacy																								
Emotion-focused Coping	19.9	6.0	19.3	4.8	24.8	5.3	21.0	5.1	25.7	5.6	21.0	5.6	26.0	5.2										
Problem-focused Coping <sup>d</sup>	19.5	6.1	18.7	5.9	14.5	6.4	17.6	6.8	14.3	7.2	17.5	7.1	12.0	6.4										
Classroom Management self-efficacy	30.9	6.0	30.0	5.4	33.5	5.6	30.8	6.0	34.9	5.6	32.1	6.0	34.8	7.1										
Work-related self-efficacy	27.5	4.3	26.9	10.9	30.0	4.4	27.6	4.2	31.6	3.9	27.9	4.7	30.4	5.0										

Note. IG = intervention group; WLG = wait list control group; T1 = baseline; T2 = 3-month follow-up; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up. The 6-MFU was only assessed in the IG.

<sup>a</sup> Missing values were imputed by multiple imputations. <sup>b</sup> Missing values were not imputed for absenteeism and presenteeism days. <sup>c</sup> Absenteeism and presenteeism days during the past three months for T1, T2 and 6-MFU, for T2 since the beginning of the study (i.e. past eight weeks). <sup>d</sup> Lower values represent higher orientation towards problem-focused coping.

A MANOVA indicated that there was no meaningful difference in baseline outcomes of participants with and without missing data at 3-MFU ( $F_{1,13} = 1.09, p = .37$ ).

### **Intervention usage and client satisfaction**

At T2, 72.0% of participants answered the CSQ-I, measuring the satisfaction with the whole training program. Overall satisfaction with the program was high ( $M = 27.31, SD = 4.31$ ). A majority of 64.0% of the respondents stated that they would definitely recommend the training to a friend in need and 26.3% would rather recommend it. The majority (88.8%) felt that the training had helped them to deal with their problems more effectively (44.4% strongly agreed, 44.4% rather agreed), while 9.7% rather not and 1.4% not agreed.

Regarding intervention usage, of the 100 individuals randomized to the IG, 6 did not login to the training platform, while 9 logged into the training platform, but did not complete at least one session.

### ***Stress management intervention***

The numbers of participants who completed each session of the iSMI were as follows; session one: 85, session two: 71, session three: 57, session four: 52 of participants, session five: 50, session six: 46 of the 100 participants randomized to the IG. The whole intervention with its seven sessions was completed by 38 of participants. Reasons for dropout were reported by 17 participants of the IG. Most of them indicated lack of time (70.6%), lack of motivation (58.8%) and lack of personal contact (35.3%). On average participants completed 4 ( $SD = 2.9$ ) of the 7 sessions. This corresponds to 57.1% of the whole intervention. The median of written words within the training program was 1314 (range: 0 - 9496 words).

### ***Optional CRM skills module***

At least one session of the CRM module was worked through by 57 of the 100 participants in the IG, at least two sessions by 47 participants, at least three sessions by 30 participants, at least four sessions by 19 participants, at least five sessions by 13 participants, at least six sessions by 11 participants and all seven sessions by six participants. Participants on average wrote 267 words ( $SD = 504$ ). The median was 46 words; word range was 0 to 2850 words. For an overview of the particular sessions used, please see Table 7 in the OSM. At T2 the majority of users found the additional CRM module helpful (12.5% *rather agree*, 42.5% *mostly agree*, 25.0% *completely agree*), while 10.0% could *rather not* and 10.0% *mostly not agree*. The majority indicated that they were able to implement the tasks/exercises from the CRM module (27.5% *rather agree*, 42.5% *mostly agree*, 7.5% *completely agree*) and also a majority stated to have noticed positive consequences of implementing the tasks/exercises from the CRM module (17.5% *rather agree*, 42.5% *mostly agree*, 4.0% *completely agree*) (also see Table 5 in the OSM). The particular CRM sessions were on average all rated as rather useful, with exception of CRM session two that was rated as moderately useful. All CRM sessions were on average rated as rather or very easy to complete. The open question feedback was analyzed for each CRM session (see Table 8 in the OSM). Overall feedback included very positive statements, but also critique and suggestions for further development. Summarizing the feedback across the

particular CRM sessions, the concreteness of the information and examples (e.g., “Super concrete examples.” or “The example characters are always helpful when I need a little inspiration.”) as well as the transfer-promoting exercises (e.g., “As always, it's great that there is a certain commitment to get things done.”) were rated as helpful and as beneficial for self-efficacy (e.g., “[...] I have the feeling that I am already doing a lot of things right when it comes to rule implementation and that I am on the right track.”). A critical point of the CRM module emerging in several CRM sessions seems to be associated with the reduced decision latitude of many beginning teachers, limiting the possibilities in developing a comprehensive CRM system (e.g., “As a trainee teacher, I do not have my own class or classroom. Therefore, [...] is not feasible at this time.”), as well as the impression that some content was not applicable for some teachers’ particular students (e.g., “The activities and material reinforcers are mainly for younger students. What can be done with older students?”).

### ***Transfer of training elements in daily life post intervention***

At 3-MFU, participants were asked to what extent they were able to use the different strategies learned in their daily life after the training. Participants most often stated to make use of positive activities, with 39.7% reporting to use them *nearly daily*, 39.7% *often*, 13.8% *sometimes* and 5.2% *rarely*. More than half of the respondents of the IG indicated an almost daily usage of at least one strategy in an almost daily manner (55.2%) and a large majority indicated a frequent usage of at least one strategy (81.0%). For a more detailed description please see Table 6 in the OSM.

### **Usage of care as usual**

Participants reporting to have sought additional other help (e.g., other health training, general practitioner, psychotherapist) due to their stress levels since the start of the study did not differ significantly between groups at T2 (IG: 10/64, WLG: 11/70) or 3-MFU (IG: 7/59, WLG: 10/72) and was 16.0% at T2 and ranged between 12.0% and 14.0% between groups at 3-MFU.

### **Intervention effect**

#### ***Primary outcome analyses***

At T2, individuals in the IG reported significantly less perceived stress than those in the WLG ( $F = 13.6_{1,145}, p < .001$ ). The IG’s mean was 3.1 points lower than that of the WLG. The standardized mean difference was  $d = 0.52$ , 95%-CI [0.24, 0.80]. Perceived stress from T1 to T2 decreased by -6.2 points in the IG and by -2.2 points in the WLG.

At 3-MFU, individuals in the IG also reported significantly less perceived stress than those in the WLG group ( $F = 12.0_{1,76}, p = .001$ ). The IG groups mean was averagely 3.9 points lower compared to the WLG. The standardized mean difference was 0.49, 95%-CI [0.21, 0.77]. From 3-MFU to 6-MFU the level of perceived stress in the IG further decreased. A within-subjects ANOVA from T1 to 6-MFU showed a significant effect ( $F = 76.9_{1,43}, p < .001$ ). The within-subjects effect size was large,  $\Delta 6\text{-MFU-T1} = -9.4$ ;  $d = 1.57$ , 95%-CI [1.16, 1.95]. Table 4 shows the intervention effects for primary and secondary outcomes at all assessment points. Figure 2 shows both groups’ course on the PSS from baseline to 6-MFU.

Table 4  
Results of AN(C)OVAs and Cohen's *ds* for primary and secondary outcomes – intention to treat sample

Outcome	Differences between IG and WLG				Differences within IG			
	T2		3-MFU		6-MFU		6-MFU	
	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI]	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>a</sup>	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>a</sup>	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>a</sup>
Primary outcome	13.6 <sub>1,145</sub> ***	0.52 [0.24,0.80]	12.0 <sub>1,76</sub> ***	0.49 [0.21,0.77]	76.9 <sub>1,43</sub> ***	1.57 [1.16,1.95]		
Secondary outcomes								
Mental health								
Depression	21.8 <sub>1,77</sub> ***	0.66 [0.38,0.94]	11.2 <sub>1,92</sub> ***	0.47 [0.19,0.75]	32.2 <sub>1,62</sub> ***	0.87 [0.58,1.15]		
Anxiety	23.3 <sub>1,98</sub> ***	0.68 [0.40,0.97]	16.3 <sub>1,85</sub> ***	0.57 [0.29,0.85]	39.5 <sub>1,53</sub> ***	1.00 [0.71,1.28]		
Insomnia	18.0 <sub>1,166</sub> ***	0.60 [0.32,0.88]	5.7 <sub>1,55</sub> *	0.34 [0.06,0.62]	36.4 <sub>1,33</sub> ***	1.02 [0.77,1.24]		
Work-related health								
Emotional Exhaustion	12.1 <sub>1,82</sub> ***	0.49 [0.21,0.77]	8.4 <sub>1,57</sub> **	0.41 [0.13,0.69]	26.1 <sub>1,26</sub> ***	0.99 [0.75,1.21]		
Work-related Rumination	18.3 <sub>1,90</sub> ***	0.60 [0.32,0.89]	10.3 <sub>1,67</sub> **	0.45 [0.17,0.74]	44.6 <sub>1,29</sub> ***	1.23 [0.94,1.50]		
Work-related Anxiety	23.3 <sub>1,158</sub> ***	0.68 [0.40,0.97]	7.4 <sub>1,71</sub> **	0.38 [0.10,0.66]	13.5 <sub>1,29</sub> **	0.70 [0.47,0.92]		
Job Satisfaction	14.9 <sub>1,147</sub> **	0.55 [0.26,0.83]	8.8 <sub>1,107</sub> **	0.42 [0.14,0.70]	8.1 <sub>1,35</sub> **	0.36 [0.21,0.51]		
Effort	8.6 <sub>1,87</sub> **	0.42 [0.14,0.70]	2.3 <sub>1,63</sub> n.s.	0.21 [-0.07,0.49]	25.4 <sub>1,34</sub> ***	1.01 [0.72,1.29]		
Reward	3.2 <sub>1,113</sub> n.s.	0.25 [-0.03,0.53]	4.4 <sub>1,73</sub> *	0.30 [0.02,0.57]	0.33 <sub>1,24</sub> n.s.	0.13 [-0.06,0.31]		
Absenteeism days <sup>b,c</sup>	1.5 <sub>1,152</sub> n.s.	0.20 [-0.12,0.51]	0.15 <sub>1,128</sub> n.s.	0.07 [-0.28, 0.41]	0.66 <sub>1,51</sub> n.s.	0.16 [-0.23,0.55]		
Presenteeism days <sup>b,c</sup>	0.06 <sub>1,152</sub> n.s.	0.04 [-0.27,0.36]	0.54 <sub>1,112</sub> n.s.	0.13 [-0.22,0.47]	5.07 <sub>1,51</sub> *	0.40 [0.05,0.74]		
Coping and self-efficacy								
Emotion-focused coping	23.8 <sub>1,130</sub> ***	0.69 [0.40,0.98]	26.0 <sub>1,88</sub> ***	0.72 [0.43,1.01]	57.2 <sub>1,52</sub> ***	1.08 [0.80,1.35]		
Problem-focused coping	16.5 <sub>1,152</sub> **	0.57 [0.29,0.86]	12.3 <sub>1,93</sub> ***	0.50 [0.21,0.78]	54.4 <sub>1,43</sub> ***	1.20 [0.86,1.52]		
CRM self-efficacy	8.0 <sub>1,115</sub> **	0.40 [0.12,0.68]	7.6 <sub>1,83</sub> **	0.39 [0.11,0.67]	18.0 <sub>1,34</sub> ***	0.58 [0.42,0.74]		
Work-related self-efficacy	14.1 <sub>1,89</sub> ***	0.53 [0.25,0.81]	24.3 <sub>1,55</sub> ***	0.69 [0.41,0.98]	16.0 <sub>1,33</sub> ***	0.62 [0.41,0.81]		

Note. IG = intervention group; WLG = wait list control group; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up; CI = Confidence Interval; CRM=Classroom Management.

<sup>a</sup> Cohen's *ds* for within-subject effects were calculated by controlling for dependence within samples. <sup>b</sup>Missing values were not imputed for absenteeism and presenteeism days. <sup>c</sup>Absenteeism and presenteeism days during the past three months for T1, T2 and 6-MFU, for T2 since the beginning of the study (i.e. past eight weeks). n.s., non-significant; \*  $p \leq .05$ ; \*\*  $p \leq .01$ ; \*\*\*  $p \leq .001$ .

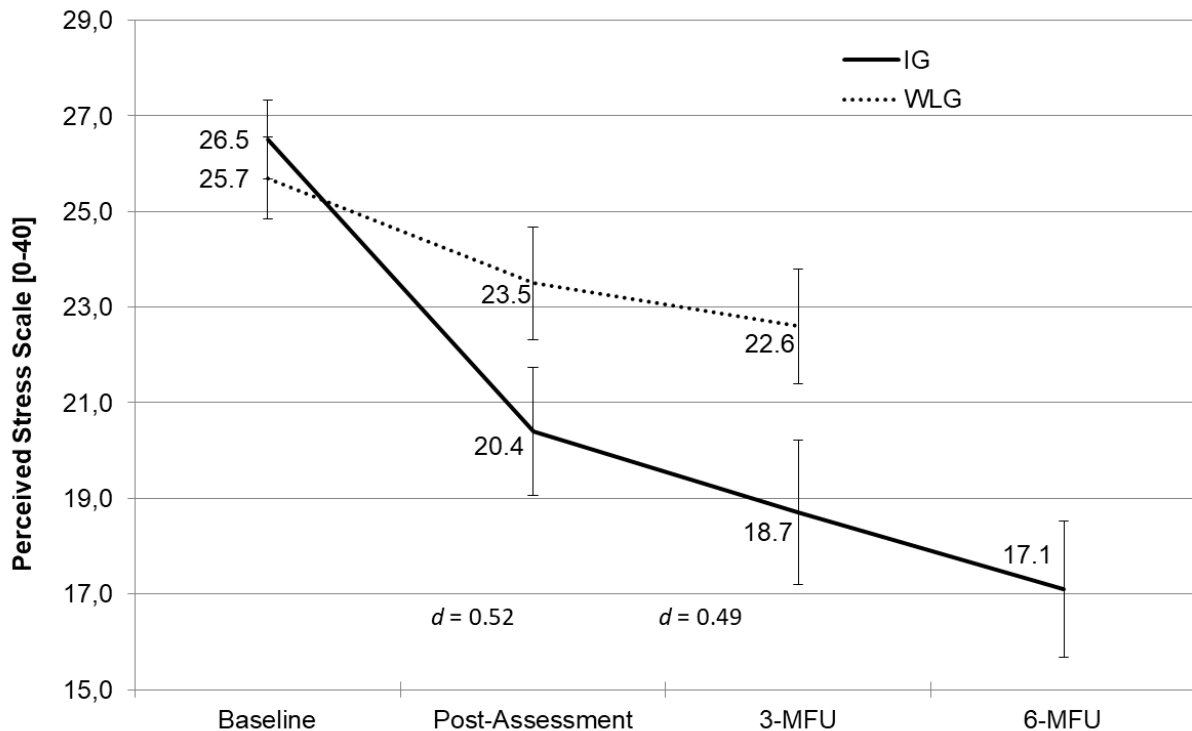


Figure 2. Means with 95% confidence intervals on the primary outcome measure (intention-to-treat;  $N = 200$ ). IG = intervention group; WLG = wait list control group.

**Response analysis.** At T2, 50.3% of the participants in the IG reported reliable improvement as compared to 22.9% in the WLG. 4.6% in the IG reported reliable deterioration as compared to 8.7% in the WLG, while 45.1% in the IG and 68.4% in the WLG reported no reliable change. At 3-MFU, 60.5% in the IG and 33.2% in the WLG reported reliable improvement, while 4.2% in the IG and 6.4% in the WLG reported reliable deterioration. At 3-MFU 35.3% in the IG and 60.4% in the WLG reported no reliable change. This corresponds to a NNT of 3.70, 95% CI [2.51, 7.05] at T2 and 3.70, 95% CI [2.48, 7.30] at 3-MFU. Thus, in order to receive one participant with a reliable improvement, as compared to the waiting group, access to the intervention needs to be given to 4 individuals. At 6-MFU 67.1% of the participants in the IG reported a reliable improvement, while 6.0% had reliably deteriorated and 26.9% not having a reliable change.

**Sensitivity analysis.** Analyzing only participants that adhered to the protocol and have finished at least 5 sessions (50.0% of participants), the ANCOVA at T2 showed a significant difference to the WLG,  $F = 40.5_{1,141}$ ,  $p < .001$ . The between groups effect size was large  $\Delta IG_{T2} - WKG_{T2} = -6.0$  points on the PSS,  $d = 1.1$  [0.74, 1.46].

**Dose-response analysis.** In a simple regression model, the sessions conducted significantly predicted the reduction on the PSS score from T2 to T1,  $b = -1.2$ ,  $p < .001$ , indicating that every session conducted led to a reduction of 1.2 points on the PSS scale. This indicates a dose-response relationship.



### **Secondary outcome analyses**

**Mental health outcomes.** At T2 and 3-MFU, individuals in the IG reported significantly less symptoms of depression, anxiety and insomnia than participants in the WLG. At T2, effect sizes were moderate to large and ranged between  $d = 0.60$  for insomnia severity to  $d = 0.68$  for anxiety symptoms. At 3-MFU, effect sizes were small to moderate and ranged between 0.34 for insomnia severity to 0.57 for anxiety symptoms. Within-subjects effect sizes at 6-MFU were large, ranging between  $d = 0.87$  for depression to  $d = 1.01$  for insomnia severity.

**Work-related outcomes.** With regard to work-related outcomes, individuals in the IG reported significantly less emotional exhaustion (T2:  $d = 0.49$ , 3-MFU:  $d = 0.41$ ), work-related rumination (T2:  $d = 0.60$ , 3-MFU:  $d = 0.45$ ) and work-related anxiety (T2:  $d = 0.68$ , 3-MFU:  $d = 0.38$ ) at T2 and 3-MFU. From 3-MFU to 6-MFU, scores further decreased in the IG and within-subjects effect sizes were large, ranging between  $d = 0.70$  for work-related anxiety to  $d = 1.23$  for work-related rumination at 6-MFU. Job satisfaction improved significantly in participants of the IG at T2 ( $d = 0.55$ ) and 3-MFU ( $d = 0.42$ ). The within-subjects difference between T1 and 6-MFU was significant with an effect size of  $d = 0.36$ . The IG reported significantly reduced effort at T2, but not at 3-MFU. For reward, the observed pattern was the other way around, with a significantly increased reward at 3-MFU in the IG, but insignificant findings at T2. No significant between groups differences were found for sickness absence and presenteeism days neither at T2 nor at the 3-MFU.

**Coping Orientation/Self-efficacy.** Participants in the IG showed significantly reduced detrimental problem-solving orientation of moderate size as compared to the WLG at T2 ( $d = 0.57$ ) and 3-MFU ( $d = 0.50$ ). Participants in the IG also reported significantly improved emotion-focused coping of moderate size at T2 ( $d = 0.69$ ) and of moderate to large size at 3-MFU ( $d = 0.72$ ) on the ERSQ. Teacher general self-efficacy as well as CRM self-efficacy were significantly higher in the IG at T2 and at 3-MFU as compared to the WLG. The effect on general teacher self-efficacy can be regarded as moderate to large, T2: 0.53; 3-MFU: 0.69, and small to moderate regarding CRM self-efficacy, T2:  $d = 0.40$ ; 3-MFU:  $d = 0.39$ . Within-subjects analyses comparing T1 and 6-MFU showed significant effects of moderate to large size. Within-subjects effect sizes ranged between  $d = 0.58$  for CRM self-efficacy to  $d = 1.20$  for problem-focused coping orientation.

In a per-protocol analysis of the CRM module, including only those participants that engaged in the optional CRM module more intensively ( $N = 24$ ; who wrote  $\geq$  words than the average of 267) the between-groups effect sizes were slightly larger. On CRM self-efficacy at T2 the between-groups effect was moderate to large,  $\Delta$  IGT2 -WKGT2=2.8;  $d = 0.62$ , 95% CI [0.17, 1.08] and on general teacher specific self-efficacy it was large  $d = 0.91$ , 95% CI [0.45, 1.37].

### **Mediation analysis**

A parallel multiple mediation analysis showed that improvements from T1 to T2 in problem-solving orientation,  $a_2b_2 = -0.77$ , 95% CI [-1.50, -0.04], as well as improvements in emotion-focused coping,

$a_1b_1 = -0.97$ , 95% CI [-1.73, -0.22] significantly mediated the effect of the intervention on stress levels at 3-MFU. The direct effect of the intervention reducing stress at 3-MFU remained significant, after the mediators were incorporated into the model,  $c' = -2.40$  [-4.55, -0.24]. See also Figure 3.

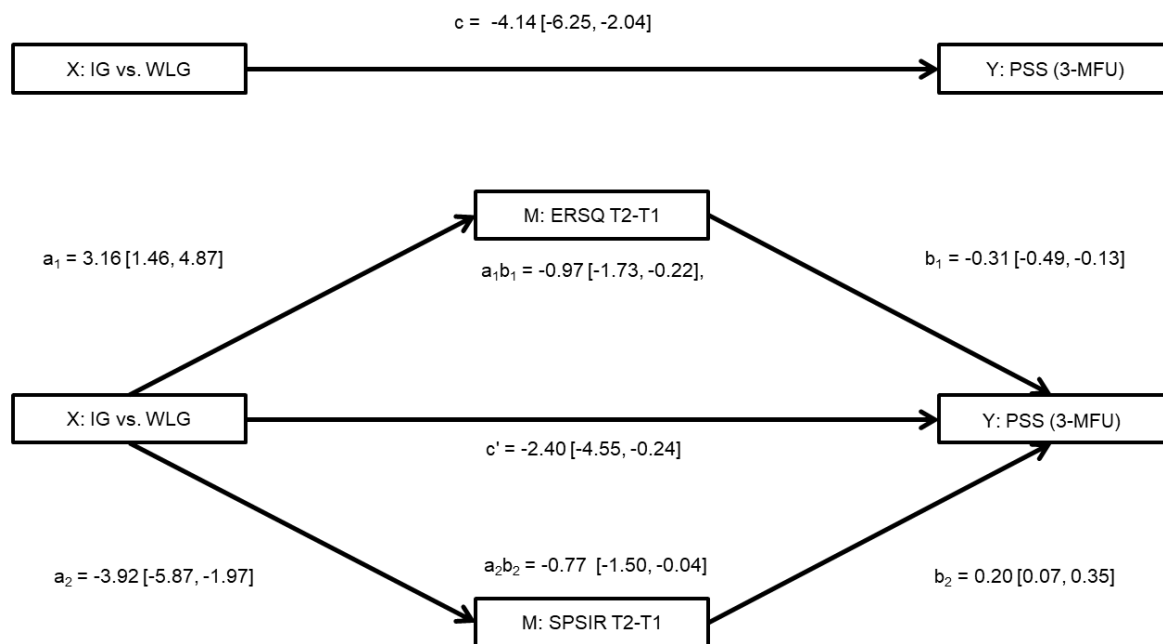


Figure 3. Parallel multiple mediation model with 3-MFU anxiety scores as the outcome variable, posttreatment repetitive negative thinking and resilience scores as mediators and baseline values of mediators and outcome as covariates. Treatment is coded 0 = wait list control group, 1 = intervention group. Path diagrams representing statistically significant mediated effects. Unstandardized beta coefficients are shown, with 95% confidence intervals in brackets. IG = intervention group; WLG = wait list control group; PSS = Perceived Stress Scale; ERSQ = Emotion Regulations Skills Questionnaire; SPSIR = Social Problem-Solving Inventory; T2 = post-intervention; 3-MFU = 3-month follow-up.

## Discussion

The purpose of the current study was threefold; evaluating the efficacy of an iSMI for beginning teachers, investigating the feasibility of complementing an iSMI with an optional work-related skills training and examining the underlying mechanisms of change. Results suggested that the present guided iSMI complemented with a CRM intervention is effective in reducing perceived stress in career starters. Combining the iSMI with CRM training was feasible and furthermore accepted by beginning teachers. Finally, there was evidence that problem- and emotional focused coping are mechanisms that work in concert to produce the beneficial effect on stress as predicted by the transactional stress theory (Lazarus & Folkman, 1984).

With regard to the first aim, the results of the study suggest an even larger effect on perceived stress in beginning teachers at post-intervention than what was expected a priori. The Delta between the intervention and control group was 3.1 points on the PSS scale, representing a reduction of 13.2%. The Delta clearly exceeded the threshold for practically meaningful effects (Boß et al., 2021) and likewise the reduction can be regarded as a practically important benefit in a non-clinical sample

(Bauer-Staeb et al., 2021). The effect was still evident at the 3-MFU and sustained at 6-MFU. Significant effects at all assessment points were also found for various mental health-related secondary outcomes such as depression, anxiety and insomnia, as well as for most work-related health outcomes such as emotional exhaustion, work-related rumination, work-related anxiety and job satisfaction, but were only partly significant with regard to perceived effort and reward and non-significant for presenteeism and absenteeism.

In the following, the study's results regarding the primary outcome perceived stress will be discussed in light of previous meta-analytic evidence on occupational e-mental health interventions and evidence from trials of a generic version of the current intervention conducted in the general working population as well as in light of studies on teachers' mental health. The effect size ( $d = 0.52$ ) regarding perceived stress at post intervention is comparable to the moderate effect sizes found in meta-analyses of occupational e-mental health interventions in the general working population ( $g = 0.3 - 0.54$ ; Heber et al., 2017; Phillips et al., 2019; Stratton et al., 2017), but slightly smaller than effects found in subgroup analyses of guided iSMIs in the general population ( $g = 0.64$ ; Heber et al., 2017), face-to-face SMIs ( $g = 0.73$ ; Richardson & Rothstein, 2008) or individual-focused, predominantly face-to-face occupational health interventions ( $g = 0.65$ ; Estevez Cores et al., 2021).

The efficacy of the same but untailed iSMI was assessed with different forms of guidance in the general working population. The present effect size ( $d = 0.52$ ) for perceived stress is somewhat smaller than effects ranging from  $d = 0.71$  to  $d = 0.96$  in the general working population with guidance (Heber et al., 2016), as well as with adherence-focused guidance (Ebert, Lehr, et al., 2016; Nixon et al., 2021) and in self-help (Ebert et al., 2021; Ebert, Heber, et al., 2016; Nixon et al., 2021). While there was a Delta between intervention and control group of 3.1 points on the PSS scale, the other trials showed differences mostly larger than 5 points, which is just about large enough to be of practical importance (Boß et al., 2021). There might be several reasons for this discrepancy.

First, results of the current study are in line with research that identified younger age to be associated with lower efficacy. Participants in the current study were on average about 13 years younger than the average samples of the previous trials on the same iSMI. Younger age was meta-analytically found to be associated with a reduced treatment effect (Phillips et al., 2019; Reins et al., 2020). Phillips and colleagues (2019) found an effect for occupational e-mental health interventions in employees younger than 40 years of  $g = 0.29$ , while Harrer and colleagues (2019) found that internet interventions in university students with an average age of 24 years led to stress reductions with an effect of  $g = 0.20$ . Although the present intervention compares favorably to those interventions in younger people, it is an unsolved question why younger age seems to be a limiting factor regarding efficacy.

Second, another reason for lower effects might be lower adherence. There is meta-analytic evidence for lower intervention adherence to be associated with lower efficacy (Karyotaki et al., 2017) and lower age to predict lower adherence (Karyotaki et al., 2015). Participants in the current study completed 1.7 main sessions less than participants in the study from Heber et al., (2016) although

considerable effort was undertaken to increase adherence (guidance (Zarski et al., 2016), interactive exercises (Kelders et al., 2012), tailoring (Beatty & Binnion, 2016) and email-reminders (Carolan et al., 2017)). Comparing the per-protocol analyses of all trials of the iSMI, considering only participants with the recommended dosage of the training, all studies found almost the same effect (Ebert, Heber, et al., 2016; Ebert, Lehr, et al., 2016; Heber et al., 2016; Nixon et al., 2021)  $d = 0.96 - 1.1$  vs. current trial  $d = 1.1$ ).

Third, although research on moderators on the interplay between efficacy and adherence so far focused on intervention design e.g., guidance (Saleem et al., 2021) or individual factors e.g., age (Karyotaki et al., 2015), work-related and organizational factors such as the psychosocial safety climate of an organization (Dollard & Bakker, 2010) could also have moderated adherence and efficacy, but has rarely been considered. In the current study, all participants — in addition to facing the common demands as teachers for the first time — went through an 18 to 24 months long transition phase of induction. This trainee phase is characterized by repeated classroom visits, evaluations and exams. As this is time consuming and positive evaluations are essential for subsequent tenure, the trainee phase is often described as highly demanding (e.g., Dicke, Parker, et al., 2015; Schmidt et al., 2017; Voss et al., 2017). At the same time, the organizational context of participation might indicate a low psychosocial safety climate, since the main reason for non-adherence reported by the beginning teachers in the present study was lack of time and participants could not partake within their working time. Moreover, receiving a diagnose that reflects psychological distress during the trainee phase can be a reason not to receive tenure as civil servants, also indicating a low psychosocial safety climate. Insufficient time and a poor work environment have been suggested as an adherence-reducing factor (Andersen, 2011; Beatty & Binnion, 2016; Ryan et al., 2018) and is discussed as hindering factor to occupational learning (Tannenbaum & Wolfson, 2022) and training transfer (Ford et al., 2018).

Finally, regarding intervention efficacy, the results should be discussed in context of interventional research on teachers' mental health. Effects for stress reduction found in meta-analyses varied from  $d = 0.53$  for mindfulness-based interventions for in-service teachers (Zarate et al., 2019) and  $d = 0.27$  for interventions employing cognitive-behavioral therapy and relaxation to  $d = 0.15$  for cognitive-behavioral therapy only (Denuwara et al., 2021). With regard to burnout, Iancu et al. (2018) reported an effect of  $d = 0.18$ , while Oliveira et al. (2021) found effects ranging from  $g = 0.11$  to  $g = 0.18$  for social and emotional learning interventions. Noteworthy, effects of interventions for teachers seem to be lower as compared to digital and face-to-face interventions for other occupational groups (Estevez Cores et al., 2021; Heber et al., 2017; Phillips et al., 2019; Stratton et al., 2017), highlighting the need for special consideration of the educational sector. Results of the present study compare favorably to most teacher-focused interventions (Denuwara et al., 2021; Iancu et al., 2018; Oliveira et al., 2021) and suggest that an internet intervention for pre-service teachers is at least as effective as existing interventions for in-service teachers mainly delivered face-to-face.

The second aim of this trial was to assess the feasibility of complementing the iSMI with an optional employee work-related skills development training for those who felt not sufficiently equipped with CRM skills. While the problem-solving module can be applied to identify coping strategies for all changeable stressors (D’Zurilla & Nezu, 2010), the CRM module focuses on changing a very specific stressor, namely students’ behavior. We are not aware of any trial that assessed the efficacy of neither an iSMI complemented with an optional CRM module, nor with any other employee work-related skills development training. Regarding the concept of the program of complementing the stress management modules with optional CRM modules, the satisfaction was high and comparable to that of previous trials (Boß et al., 2016). Around 90% indicated that they would recommend the intervention to a friend. Regarding uptake of the CRM sessions, more than half (57.0%) of the participants had worked through one or more sessions of the CRM module. The uptake as well as the feedback on usefulness of the sessions suggest an existing need and interest in CRM training in beginning teachers and is in line with studies that identified challenging situations in the classroom as a major stressor for many teachers (Aldrup et al., 2018; Harmsen et al., 2018; Schmidt et al., 2017). The feedback on easiness of conduct suggests that it is feasible to teach CRM as part of an online intervention. Furthermore, the majority perceived the additional module as helpful and also indicated to have implemented what they had learned with noticeable positive consequences. This is particularly noteworthy, suggesting that participants already seemed to have transferred what they had learned and to have even experienced first positive effects. In line with this, the IG significantly increased their CRM self-efficacy at T2 and 3-MFU and the effects sustained at 6-MFU. Looking only at those individuals that spent more time using the CRM module, the effects on CRM self-efficacy and general teacher related self-efficacy were greater, indicating a dose-response relationship. Thus, it seems that the optional CRM module is a feasible and potentially effective way to complement and tailor an iSMI for beginning teachers.

The current findings on the feasibility of the CRM module extend previous research on stand-alone CRM trainings that found heterogeneous effects on CRM self-efficacy, partly showing significant (Dicke, Elling, et al., 2015), partly non-significant effects (R. Hayes et al., 2020). Results of the present study suggest that a combination of such work-related skills development trainings and SMIs might be a fruitful avenue to support teachers. In the present study, participants of an iSMI benefited from the option of an additional skills development module and participants of skills development trainings might also benefit from an additional (i)SMI. Nevertheless, the open participant feedback suggests that the beginning teachers’ decision latitude is an important limiting factor of the efficacy of the CRM module which should be subject to future refinement.

The third aim was to investigate problem-focused and emotion-focused coping as mediators of change in a SMI. According to the intervention’s program theory, participants significantly increased both, i.e., their problem-focused as well as emotion-focused coping skills. To the best of our knowledge, we could for the first time demonstrate that in line with transactional stress theory (Bond & Bunce, 2000;

Lazarus & Folkman, 1984), change from pre- to post-intervention in both problem-focused and emotion-focused coping significantly mediated the intervention's effect on subsequent levels of perceived stress. These findings strengthen the rationale for combining elements in SMIs aiming to empower participants to actively change stressors e.g., problem-solving (D'Zurilla & Nezu, 2010) or CRM, with elements aiming at accepting unpleasant feelings arising from non-changeable stressors (Berking & Whitley, 2014). The latter focus is in the tradition of mindfulness and acceptance-based interventions (S. C. Hayes et al., 1999; Teasdale et al., 2000). While for decades the active, problem-solving approach was dominant the value of emotion-focused strategies was underestimated (cf. Cuijpers et al., 2018; Hofmann et al., 2010). With the rise of mindfulness-based interventions, there was a shift toward teaching emotional coping strategies, with particular emphasis on acceptance, thereby under-investigating coping strategies aimed at active change (Bartlett et al., 2019; Bostock et al., 2019; Estevez Cores et al., 2021). For example, emotion-focused coping skills were found as mechanism of change in a simple mediation model on perceived stress (Ebert, Lehr, et al., 2016) and depressive symptoms (Berking et al., 2019) but active coping strategies were not considered as mechanisms of change in these studies. The value of the present research is to empirically show that a balanced repertoire of problem- and emotion-focused coping strategies can be achieved and improvements in both coping orientations mediated the effect on stress-reduction. These results are in line with transactional stress theory and findings suggesting that context-dependent use of both, problem-focused and emotion-focused coping, is superior to usage of either problem-focused or emotion-focused coping (Achnak & Vantilborgh, 2021; Aldao & Nolen-Hoeksema, 2012).

### **Limitations of the current study**

Several limitations have to be considered. First, the results regarding the efficacy as well as the mechanisms of change should be considered in light of the studied population which comprised mostly female beginning teachers that all went through a highly demanding transition phase aiming to receive tenure as civil servants at the end of the trainee phase. Since this transition and trainee phase is not typical for other countries than Germany the generalization to career starting teachers in other countries might be limited.

Second, the intervention was successful in reducing a major risk-factor for mental disorders and depressive and anxiety symptoms, but it is unclear if the intervention has the potential to reduce later incidence of mental disorders when teachers are in service. However, similar internet-based interventions already demonstrated that reduction of incidence of mood disorders is possible in workers (Buntrock et al., 2016; Imamura et al., 2015).

Third, as not all participants used the work-related skills module, the intervention was not the same for all. This could be regarded as a limitation to internal validity. However, responding to the personal needs of participants and tailoring and individualizing interventions requires interventions to be flexible (Lehr, Geraedts, et al., 2016; D. C. Mohr et al., 2013; Păsărelu et al., 2017; Schaeuffele et al., 2021).

Fourth, the study design does not allow to draw conclusions regarding the specific effect of particular elements of the intervention. It cannot be ruled out that participants could solve classroom related problems using the problem-solving module and that the more stressor specific CRM module did not add a practically relevant effect. However, participants that were more engaged in the CRM module benefitted more from the intervention with regard to work-related self-efficacy. This study could show the feasibility of adding an internet-based CRM training to an iSMI. As a next step, future studies should evaluate the incremental benefit regarding acceptance and efficacy by comparing the iSMI with and without the iCRM.

### **Implications for future research and practice**

There are several implications for future research and practice. First, a practical implication of the results is that it might be fruitful to adapt SMIs to specific professions and contexts and in addition to teach more general stress management skills to identify profession- and role-specific stressors and tackle those in skills development trainings. Future studies should assess the value of such tailoring in comparison to untailored versions regarding uptake, acceptability and efficacy. With regard to the CRM module the participants' suggestions for further refinement should be taken into account.

Second, it is not clear whether the improvement in CRM self-efficacy also translates to improved CRM skills as rated by e.g. independent observers and whether the intervention's effect also has a positive impact on students' outcomes. Future studies should assess whether the exposure to the intervention also impacts teachers' behavior in the classroom and impacts students' outcomes.

Third, an important implication of the present study is that "it takes two to tango" and stress management interventions should include problem- and emotion focused coping strategies, an assumption already made by Lazarus and Folkman (1984). Interventions that rely solely on problem-focused elements such as problem solving may put participants at risk of frustration of trying to change unchangeable stressors. Likewise, interventions highlighting acceptance may lead to a premature termination of efforts to change changeable stressors. Future studies should assess the (perceived) controllability of stressors (Semmer & Meier, 2009) as a moderator of efficacy of problem-focused, emotion-focused interventions or interventions combining both foci. Controllability of stressors might also explain the considerable heterogeneity found in meta-analyses on SMIs so far (Estevez Cores et al., 2021; Heber et al., 2017; Phillips et al., 2019; Stratton et al., 2017).

Fifth, with regard to implementation it is noteworthy that many participants in our study stated to not have sought professional help for mental health issues before, because they were concerned of negative professional consequences when applying for tenure. Therefore, it was appreciated that the intervention was provided by a university as an external institution and that participants were allowed to take part anonymously. Together with the fact that participation was not possible during working time, this is another indicator of low psychosocial safety climate in the educational sector (Dollard & Bakker, 2010). Thus, it seems worthwhile to investigate the assumption proposed by Dollard and Bakker (2010) that interventions are more successful if they are embedded in organizations with high

psychosocial safety climate. Additionally, future research should assess psychosocial safety climate as a moderating factor influencing the effect of individual directed occupational interventions (Lawrie et al., 2018) or accompany individual directed interventions with organizational directed safety climate interventions (J. Lee et al., 2019). In the educational sector such measures could ensure that participation without fear of negative consequences is possible and time resources are available.

### **Conclusion**

In conclusion, the present study adds to the growing evidence on iSMIs that these are also effective in beginning teachers during a highly demanding transition phase. Beginning teachers receiving the training program reported significantly reduced perceived stress, depression and anxiety and the effects were sustained until six months later. The study also suggests the importance of considering the organizational context as potential moderating factor on the efficacy of individual directed interventions in the educational sector and it shows the feasibility of adding an internet-based CRM training tailored to beginning teachers' needs to an iSMI. Furthermore, we could show problem- and emotion-focused coping as mechanisms of change in an iSMI strengthening Lazarus and Folkman's transactional stress theory and making important contributions for the development and refinement of future SMIs for teachers.



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**Online Supplementary Material – Efficacy of an internet-based stress management intervention complemented by a classroom management training for beginning teachers and mechanisms of change: results of a randomized controlled trial**

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– under review –

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## Online Supplementary Material

Table 1

<i>Session content of the optional internet-based classroom management module</i>	
Session	Objectives
1. Introduction	Giving basic information on classroom management and the importance of a good teacher-pupil relationship
2. Classroom design	Principles of disruption-preventive classroom design
3. Rules	Importance of rules, how to word rules and ways to introduce them in the classroom
4. Routines	Importance of routines
5. Disruptive-preventive Classroom management	Prevention of disruptions in the classroom
6. Managing problem behaviour	How to deal with problem behaviour
7. Reflection and planning for the future	Reflecting on helpful strategies and planning them for the future

### Exercises

Planning how to strengthen pupil-teacher-relationship

Designing a classroom according to the principles of classroom design

Word rules and decide on a way to introduce them in your classroom

Plan and establish a routine in your class

Plan disruption preventive behaviour

Develop your own step-by-step approach in dealing with problem behaviour

Choose valuable strategies for the future

Table 2

*Effort reward imbalance in the sample at baseline – intention to treat sample*

Outcome	T1		T2 <sup>a</sup>		3-MFU <sup>a</sup>		6-MFU <sup>a</sup>							
	IG		WLG		IG		WLG							
	N	%	N	%	N	%	N	%						
ERI-cut-off > 1 <sup>a</sup>														
ERI-Ratio > 1	79	79	69	69	61	61	76	76	57	57	77	77	43	43
ERI-Ratio ≤ 1	21	21	31	31	39	39	24	24	43	43	23	23	57	57
ERI-cut-off > 0.715 <sup>b</sup>														
ERI-Ratio > 0.715	97	97	99	99	95	95	97	97	91	91	95	95	79	79
ERI-Ratio ≤ 0.715	3	3	1	1	5	5	3	3	9	9	5	5	21	21

Note. IG = intervention group; WLG = wait list control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up. The 6-MFU was only assessed in the IG; ERI = Effort-Reward-Imbalance.

<sup>a</sup> cut-off score according to the theoretical conceptualization by (Siegrist et al., 2004), <sup>b</sup> empirically derived cut-off according to Receiver-operating characteristic analyses (Lehr et al., 2010).

Table 3

*Psychopathological symptoms in the sample at baseline*

	Total		IG		WLG	
	(N = 200)		(n = 100)		(n = 100)	
	N	%	n	%	n	%
Depressive symptoms						
< 18	82	41	34	34	48	48
≥ 18	118	59	66	66	52	52
Anxiety symptoms						
< 10	82	41	39	39	43	43
≥ 10	118	59	61	61	57	57
Insomnia symptoms						
< 15	123	61.5	55	55	68	68
≥ 15	77	38.5	45	45	32	32

Note. For depressive symptoms a score ≥ 18 indicates clinically-significant levels of depression. For anxiety symptoms a score ≥ 10 indicates moderate to severe levels of anxiety. For insomnia symptoms a total score ≥ 15 indicates moderate to severe levels of insomnia.

Table 4

*Further characteristics of the sample*

	N	%
<b>Grades taught</b>		
1-4	57	28.5
5-6	69	34.5
7-10	118	59
11-13	84	42
<b>Classes taught</b>		
German	76	38
Math	53	26.5
English	37	18.5
General studies	31	15.5
Art	25	12.5
Biology	22	11
History	21	10.5
Religion	20	10
Other Subjects	128	64
<b>Federal state</b>		
North Rhine-Westphalia	49	24.5
Bavaria	30	15.0
Lower Saxony	27	13.5
Baden-Wuerttemberg	23	11.5
Hesse	18	9.0
Berlin	13	6.5
Saxony	8	4.0
Other	32	16

Table 5

*Usage and satisfaction with the classroom management add-on module*

	Not agree at all	Not agree	Rather not agree	Rather agree	Agree	Completely agree
I found the additional module "Classroom Management" helpful.	0 (0.0%)	4 (10.0%)	4 (10.0%)	5 (12.5%)	17 (42.5%)	10 (25.0%)
I was able to implement the tasks/exercises from the additional module "Classroom Management".	0 (5.0%)	3 (7.5%)	4 (10.0%)	11 (27.5%)	17 (42.5%)	3 (7.5%)
I have noticed positive consequences of implementing the tasks/exercises from the additional module "Classroom Management".	2 (5.0%)	3 (7.5%)	7 (17.5%)	7 (17.5%)	17 (42.5%)	4 (10.0%)
I have noticed negative consequences of the implementation of the tasks/exercises from the additional module "Classroom Management".	28 (70.0%)	6 (15.0%)	3 (7.5%)	1 (2.5%)	0 (0.0%)	2 (5.0%)

*Note.*  $N = 40$  of the participants that answered the assessment at T2 stated to have worked through the add-on classroom management module.

Table 6

*Transfer and usage of strategies learned in daily life, assessed at 3-MFU in the intervention group*

	Not at all	Rarely	Sometimes	More often	Almost daily	Do not remember
Positive/recreational activities	0 (0.0%)	3 (5.2%)	8 (13.8%)	23 (39.7%)	23 (39.7%)	1 (1.7%)
Problem solving strategies	7 (12.1%)	11 (19.0%)	19 (32.8%)	12 (20.7%)	5 (8.6%)	4 (6.9%)
Relaxation exercises	5 (8.6%)	8 (13.8%)	13 (22.4%)	18 (31.0%)	8 (13.8%)	6 (10.3%)
Strategies for acceptance of emotions	8 (13.8%)	2 (3.4%)	20 (34.5%)	13 (22.4%)	4 (6.9%)	11 (19.0%)
Strategies for self-support	2 (3.4%)	8 (13.8%)	9 (15.5%)	17 (29.3%)	10 (17.2%)	12 (20.7%)
Classroom management strategies	6 (10.3%)	8 (13.8%)	9 (15.5%)	17 (29.3%)	5 (8.6%)	13 (22.4%)
Strategies from the Info Corner <sup>a</sup>	3 (5.2%)	7 (12.1%)	15 (25.9%)	16 (27.6%)	10 (17.2%)	7 (12.1%)

*Note.* Answering the following item: "To what extent have you been able to use the following strategies in your daily life since the end of the training?"

<sup>a</sup> Strategies from the Info-Corner included: Time management, consciously planning breaks, switching off from work, strategies for reducing brooding and worry, sleeping better, social support, nutrition, and exercise.



Table 7

*Overview of completed CRM sessions and rated usefulness and easiness of each session*

CRM session	CRM 1		CRM 2		CRM 3		CRM 4		CRM 5		CRM 6		CRM 7	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Completed session	56	56.0	29	29.0	43	43.0	17	17.0	14	14.0	18	18.0	6	6.0
Gave feedback within session	43	76.8	27	93.1	18	41.9	12	70.6	11	78.6	11	61.1	6	100.0
General usefulness <sup>1</sup>														
not at all	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
rather not	5	11.6	8	29.6	2	11.1	0	0.0	0	0.0	1	9.1	1	16.7
moderately	5	11.6	10	37.0	2	11.1	2	16.7	2	18.2	0	0.0	2	33.3
rather yes	19	44.2	7	25.9	10	55.6	5	41.7	5	45.5	6	54.5		0.0
very	14	32.6	2	7.4	4	22.2	5	41.7	4	36.4	4	36.4	3	50.0
Easy to complete <sup>2</sup>														
not at all	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
rather not	1	2.3	1	3.7	1	5.6	1	8.3	0	0.0	0	0.0	0	0.0
moderately	2	4.7	4	14.8	2	11.1		0.0	0	0.0	0	0.0	0	0.0
rather yes	16	37.2	8	29.6	6	33.3	5	41.7	4	36.4	2	18.2	1	16.7
very	24	55.8	14	51.9	9	50.0	6	50.0	7	63.6	9	81.8	5	83.3

*Note.* CRM = classroom management. For the particular content of each session see Table 1 in the OSM.<sup>1</sup> Was this session of the optional CRM-module useful for you?<sup>2</sup> Was this session of the optional CRM-module easy for you to go through?

Table 8

*Participants' open feedback on each CRM session categorized in themes*

	Feedback at the end of each CRM session
CRM session 1	
Positive Feedback	
Session in general	<p>“Super concrete examples.” (ID_14)</p> <p>“I found the mixture between clear information [...] and the possibility to reflect on my own behavior very useful. Thank you very much!” (ID_20)</p> <p>“I like the structure between explanation and the formulation of own thoughts for deepening.” (ID_83)</p> <p>“I liked the understandable tasks and the well explained content.” (ID_145)</p> <p>“+ concrete practical suggestions [...] the matter itself (ID_155) (ID_155)</p> <p>“I find CRM a very interesting and important topic.” (ID_171)</p> <p>“[...] so the lesson was very helpful for me.” (ID_171)</p> <p>“The structure is good.” (ID_177)</p> <p>“I liked the concrete examples of praise culture.” (ID_31)</p> <p>“So many examples of how to praise that surely everyone will find something for his own lessons and you can try many.” (ID_117)</p> <p>“I especially liked learning about different types of reinforcement.” (ID_128)</p> <p>“I liked the ideas for reinforcing.” (ID_142)</p> <p>“The list of possible reinforcers was very good.” (ID_143)</p> <p>“Examples of material and activity amplifiers were shown.” (ID_157)</p> <p>“The explanation of the amplifiers was interesting.” (ID_180)</p> <p>“[...] list of literature [...]” (ID_155)</p> <p>“There were some helpful literature references that are important to read up on.” (ID_157)</p> <p>“There are also many books about it, but at the moment I have no time to read.” (ID_171)</p> <p>“It has shown me or confirmed that I already know a lot about classroom management and that I am doing it right.” (ID_61)</p> <p>“The lesson reminded me that I also need to praise the challenging students more in order to establish more positive behavior with them.” (ID_102)</p> <p>“I liked the transcript of the video [...]” (ID_6)</p> <p>“The “example models” are always helpful when I need a little inspiration.” (ID_145)</p>
Concrete examples of reinforcers	
Literature	
Lessons learned	
Other	
Negative Feedback/ Suggestions for development	
Session in general	<p>“Much known and already applied.” (ID_47)</p> <p>“I was already well informed through the pedagogy course at the seminar.” (ID_48)</p> <p>“[...] [the video] was too long for me and I read faster than I listen.” (ID_6)</p>
Video	

	<p>“The information video was a bit slow and too long [...]” (ID_37)</p> <p>“I think that videos in which the person speaking is also seen appeal to me more because then I have more the feeling of participating in a conversation or feel obliged to listen. [...]” (ID_54)</p> <p>“Sometimes the videos don't start immediately then you have to click a few times more.” (ID_145)</p> <p>“The activities and material reinforcers are mainly for younger students. What can be done with older students?” (ID_6)</p> <p>“I would like to have more concrete info on adequate praise or reinforcers by age level.” (ID_14)</p> <p>“More concrete examples for exact differentiated praise after student presentations.” (ID_113)</p> <p>“I have the feeling that my student clientele is a little different than the average here. Students with Down Syndrome, for example, sometimes react according to an inscrutable system... This requires even more special or individual methods.” (ID_177)</p> <p>“Since I am currently teaching three classes, all of which have very different needs and with whom I have built up different relationships, it was difficult for me today to choose the tasks in such a way that I can implement them realistically. I have now always referred mentally to my "problem class" and have also planned the tasks for this. For the other two classes I got rather noncommittal suggestions. For me it would have been better if it had been part of the task to concentrate on one learning group. [...]” (ID_54)</p> <p>“I think that the different ideas could have been better illustrated. For example in the form of a table.” (ID_93)</p>
Not suitable for all students	
Application for different classes difficult	
Other	
<b>CRM session 2</b>	
Positive Feedback	
Session in general	<p>“I found the information interesting [...]” (ID_6)</p> <p>“[...] the information was interesting [...]” (ID_36)</p> <p>“The tips are good [...]” (ID_145)</p> <p>“The powerpoint presentation to try out was totally great!” (ID_14)</p> <p>“I liked the PowerPoint for creating your own classrooms and trying out new seating arrangements.” (ID_50)</p> <p>“I like that there was an opportunity to plan the classroom.” (ID_54)</p> <p>“I liked the PowerPoint template for the classroom.” (ID_102)</p> <p>“The idea to connect the division of the classroom with classroom disruptions was new to me, but on closer inspection quite understandable. Here you can relatively easily without having to act in the lesson in advance already set a few courses for a pleasant classroom atmosphere.” (ID_102)</p>
Power-Point file to plan to rearrange the classroom	
Lessons learned	
Negative Feedback/ Suggestions for development	
Not applicable at this time	<p>“[...] however I cannot implement it at this time as a subject teacher.” (ID_6)</p> <p>“As a trainee teacher, I do not have my own class or classroom. Therefore, [...] is not feasible at this time.” (ID_36)</p> <p>“The relevance to the lesson is more or less relevant to each teacher depending on the number and type of subjects in each class. For me it is rather less the case since I have the classes I teach only 1 -2 times a week.” (ID_37)</p> <p>“I find it difficult to talk about classroom design when a teacher trainee has no possibility to change rooms in a sustainable way. If they do, they have to spend a lot of time changing the "normal" seating arrangement at the</p>

	<p>beginning of the lesson and restoring it at the end. As a trainee teacher one does not have (at least I do not) much freedom of action in this area.” (ID_113)</p> <p>“The classroom is very small but is already used very effectively [...]” (ID_136)</p> <p>“[...] but some of them cannot be implemented even with the best will in the world because the classrooms are very small and the blackboard is mounted on the wall, i.e. cannot be moved.” (ID_145)</p> <p>“As a teacher trainee, there is not much you can do about the classroom constellation because it is not the same classes. You often have to come to terms with the way the class teachers arrange their classrooms.” (ID_158)</p> <p>“As a teacher trainee I have no influence on the classroom design. The respective class teacher introduces his system and this is adopted by all subject teachers.” (ID_180)</p> <p>“Since I have a class of my own, I have already given some thought to the classroom design issues. We even painted the classroom with the class at the beginning of the school year to create a better learning atmosphere.” (ID_31)</p> <p>“[...] so this lesson has little new for me.” (ID_136)</p> <p>“there was little new” (ID_155)</p> <p>“More concrete tips would be good.” (ID_143)</p> <p>“I would have liked to see something about the "decoration" of the classroom, e.g. how the classroom can be beautifully designed but not distracting or hindering learning.” (ID_145)</p> <p>“[...] However, I was a bit confused by the masses [in the power-point file], I would have needed a legend. The numbers in the margin can't be it, can they?” (ID_54)</p>
Already known	
Wishes	
Other	
CRM session 3	
Positive Feedback	
Session in general	“I liked very much that concrete tips are given.” (ID_93)
Different suggestions on rule implementation (closed, semi, open)	<p>“The many suggestions for involving the students in graduation from open to less open I found very helpful.” (ID_14)</p> <p>“I liked the advice to always discuss the rules and to involve the students in them.” (ID_50)</p> <p>“The list of different ways to introduce rules was very interesting. I would not have come up with so many different ideas.” (ID_54)</p> <p>“I liked the factual information about class rules, e.g. that it is important to involve the students or that the rules should be formulated positively.” (ID_145)</p> <p>“Especially helpful was the video on the different forms of rule implementation (e.g. closed / semi-open formats)” (ID_180)</p> <p>“I didn't think about the concrete verbalization of rules before. Thanks to the lesson, that has now changed.” (ID_122)</p> <p>“Tasks for formulating rules were very good.” (ID_143)</p> <p>“[...] I have the feeling that I am already doing a lot of things right when it comes to rule implementation and that I am on the right track.” (ID_61)</p> <p>“Maybe the next time I take over a new course at the latest but when I get my own class I want to implement what I learned today.” (ID_145)</p>
Rule formulation	
Lessons learned	

Other	“As always, it’s great that there is a certain commitment to get things done.” (ID_54)
Negative Feedback/ Suggestions for development	
Already known	“For me there was little new. [...]” (ID_61)
Not applicable at this time	“However, I don’t know when I will be able to use them myself, as a teacher trainee I don’t have my own class and the courses I teach I have been teaching for months, so it is strange when I suddenly want to introduce class rules.” (ID_145)
Not suitable for all students	“I could have benefited even more from this exercise only if I had taken over my class in which I would like to introduce rules (for the new school year) not only since the beginning of the 2nd semester. So I have to wait until next school year to be able to implement “new” rules because the students are currently still too used to old rules and in the middle of the school year it is difficult to wean them off.” (ID_157)
One particular exercise “Dry run”	“I find that working out rules is more suitable for younger students. Older students have already been through this more often and find it boring.” (ID_6)
Wishes	“However, the dry run was too artificial for me.” (ID_50) “I did not like the little “theater piece” as much. I just can’t get to such exercises.” (ID_54) “Here I am missing an idea to involve the students without having them elaborate rules (which are actually clear to everyone) and thus wasting class time.” (ID_6) “If necessary, student reactions to rules would be useful here in order to practice how to react to student criticism when introducing rules.” (ID_50) “I wish that the materials are available in a script. I am currently writing along which is a bit of a hindrance in the editing process. It would be great if everything could be summarized briefly.” (ID_93) “We should formulate rules for our problems. It would have been helpful if they [the problems] had been displayed again, because I was not sure about the order I had given.” (ID_37)
CRM session 4	
Positive Feedback	“I found the info video on the routines particularly helpful.” (ID_180) “I found it very good thank you!” (ID_20) “I find the initial PPP very good with the different hints.” (ID_93) “I really liked the fact that I actively and in detail dealt with a routine that I urgently need to introduce within my class.” (ID_157)
Negative Feedback/ Suggestions for development	
One particular exercise “Dry run”	“I skipped the dry run for now because it feels weird to me and I don’t know exactly how to proceed yet.” “But I still want to make up for it.” (ID_6) “Personally, the dry runs don’t help me that much. I do not feel safer but I am aware of the purpose of the exercise in the unit and for others it is certainly useful.” (ID_37)
Wishes	“Maybe more examples for possible routines for the described situations where there can be difficulties.” (ID_14) “That as a PDF document for the folder would be great. I also often wonder if I can still access these documents after

<p>Other</p>	<p>the program is finished.” (ID_93)          “The lesson was a bit longer than usual, [...]” (ID_54)          “I don’t like the idea of the photo of the classroom. For me this exercise is too abstract and therefore has a low learning effect.” (ID_93)</p>
<p>CRM session 5</p>	
<p>Positive Feedback</p>	<p>“I find all the ideas really super useful and reasonable.” (ID_93)          “Tips for group-focused instruction Tips for cognitively activating instruction Note on less predictable calling behavior in the classroom.” (ID_143)          “I really liked this lesson because it practically addresses a ubiquitous topic.” (ID_36)          “The examples for group focusing were good.” (ID_14)</p>
<p>Negative Feedback/ Suggestions for development</p>	<p>“Unfortunately, I have now first autumn vacations and can only then try out everything.” (ID_14)          “The safe stem exercise was not relevant to me personally.” (ID_36)          “As before, I wish you could get this information as a PDF file.” (ID_93)</p>
<p>CRM session 6</p>	
<p>Positive Feedback</p>	<p>“[...] but it did me a lot of good to read them [the tips of the session] again so that I feel more confident to actually enforce sanctions.” (ID_20)          “I liked the tips on non-verbal reminders.” (ID_36)          “I found that this lesson was very pleasant without a long video. Instead with practical instructions.” (ID_93)          “good: many examples of (non )verbal admonitions and sanctions the reference to the importance of staying calm.” (ID_117)          “Well liked: Overview "samples" of the measures.” (ID_143)</p>
<p>Negative Feedback/ Suggestions for development</p>	<p>“I already know the tips [...]” (ID_20)          “Sanctions are regulated uniformly in our school, so I couldn’t take much away in this area.” (ID_36)          “I found the lesson rather superficial. In fact, I did not learn much.” (ID_37)          “Practice with case studies, i.e. exact situations, and then apply certain strategies from this lesson.” (ID_50)</p>
<p>CRM session 7</p>	
<p>Positive Feedback</p>	<p>“All in all I liked the additional module very much and it was pragmatic.” (ID_50)          “The general summary of the last weeks. Once again to have an overview of everything is good.” (ID_93)</p>
<p>Negative Feedback/ Suggestions for development</p>	<p>“I could have profited more from case studies where one could have tried out one’s own handling of the problem behavior for a troublesome student, for example. Also the reflection on certain cases could lead to new solutions with</p>

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own problem students.” (ID\_50)

*Note.* CRM = classroom management. For the particular content of each session see Table 1 in the OSM.

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## Additional analyses

### Above threshold depressive symptoms

Table M1 shows the proportion of participants with a value  $< 18$  or  $\geq 18$  on the short-version of the Center for Epidemiological Studies Depression Scale. At T2 and 3-MFU significantly more participants in the IG, as compared to the WLG, scored under the clinical cut-off for depression. The proportions correspond to an NNT of 4.2 at T2. At the same time 32% of the IG, after having received the intervention, scored above the cut-off for clinical depression.

Table M1: Proportion of participants with depressive symptoms  $\geq$  clinical cut-off vs.  $<$  clinical cut-off.

	IG				WLG				<i>p</i>	NNT [95% CI]
	$< 18$		$\geq 18$		$< 18$		$\geq 18$			
	n	%	n	%	n	%	n	%		
T1	34	34	66	66	48	48	52	52		
T2	68	68	32	32	44	44	56	56	**	4.2 [2.7; 9.4]
3-MFU	68	68	32	32	51	51	49	49	*	5.9 [3.3; 27.8]
6-MFU	70	70	30	30						

Note. Depression was measured with the short-version of the Center for Epidemiological Studies Depression Scale (CES-D). A value  $\geq 18$  indicates clinically significant levels of depression.

IG = intervention group; WLG = waitlist control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

### Clinically relevant change in depressive symptoms

Table M2 shows the proportion of participants with and without a clinically relevant change in depressive symptoms from baseline. At T2 and 3-MFU significantly more participants in the IG, as compared to the WLG, reported a clinically relevant change in depressive symptoms. While

Table M2: Proportion of participants with a change in depressive symptoms  $< 33$  vs.  $\geq 33\%$  from baseline.

	IG				WLG				<i>p</i>	NNT [95% CI]
	$< 33\%$		$\geq 33\%$		$< 33\%$		$\geq 33\%$			
	n	%	n	%	n	%	n	%		
T2	51	51	49	49	77	77	23	23	***	3.9 [2.6; 7.6]
3-MFU	47	47	53	53	76	76	24	24	***	3.5 [2.4; 6.2]
6-MFU	42	42	58	58						

Note. IG = intervention group; WLG = waitlist control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

at T2 49% in the IG reported a clinically relevant change, only 23% in the WLG reported a clinically relevant change. This equals an NNT of 3.9 at T2. At the same time 51% of the IG at T2 did not

experience a clinically relevant change despite having received access to the intervention.

**Reliable deterioration**

From T1 to T2  $n = 3$  (3%) in the IG, as compared to  $n = 12$  (12%) in the WLG, reported a reliable deterioration ( $p < 0.05$ ). From T1 to 3-MFU  $n = 8$  (8%) in the IG, as compared to  $n = 15$  (15%) in the WLG, reported a reliable deterioration ( $p > 0.05$ ).

**Mediation analysis**

As shown in Figure M1, stress at T2,  $a_1 b_1 = -2.35$ , 95% CI [-3.66, -1.04], significantly mediated the effect of the intervention on depression at 3-MFU. The direct effect of the intervention reducing depression did not remain significant after the mediator was incorporated into the model,  $c' = -2.30$ , 95% CI [-4.86, 0.26].

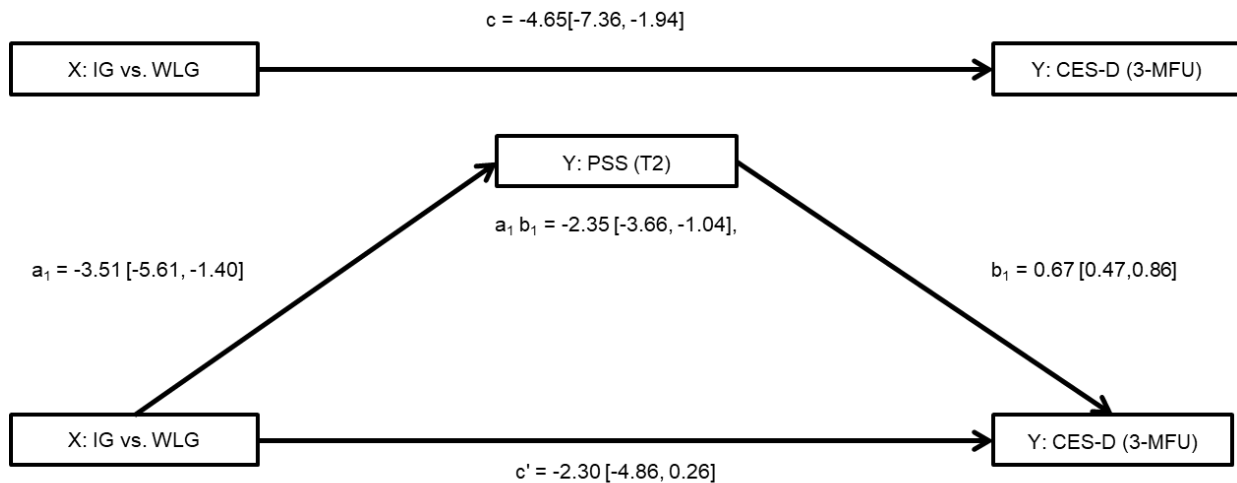


Fig. M1. Simple mediation model. Treatment is coded 0 = waitlist control group, 1 = intervention group. Path diagrams representing statistically significant mediated effects. Unstandardized beta coefficients are shown, with 95% confidence intervals in brackets. IG = intervention group; WLG = waitlist control group; PSS = Perceived Stress Scale; CES-D = Depression as measured with Center for Epidemiological Studies Depression Scale; T2 = post-intervention; 3-MFU = 3-month follow-up.

**Chapter 3 – Internet- and app-based gratitude intervention**

**Published Paper – Efficacy of an internet and app-based gratitude intervention in reducing repetitive negative thinking and mechanisms of change in the intervention's effect on anxiety and depression: Results from a randomized controlled trial**

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# Efficacy of an internet and app-based gratitude intervention in reducing repetitive negative thinking and mechanisms of change in the intervention's effect on anxiety and depression: Results from a randomized controlled trial



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## ABSTRACT

Repetitive negative thinking (RNT) has been identified as a transdiagnostic process that is involved in various forms of psychopathology, including anxiety and depression. This randomized controlled trial compared a 5-week internet and app-based gratitude intervention (intervention group; IG) with adherence-focused guidance against a wait list control group (WLG) in reducing RNT in a sample with elevated RNT.

**Method:** A total of 260 individuals were randomized to either the IG or the WLG. Data were collected at baseline (T1), within one week post intervention (T2), and at three (3-MFU) and six-months of follow-up (6-MFU; for IG only). The primary outcome was RNT. Secondary outcomes included other mental health outcomes and resilience factors.

**Results:** Participants of the IG reported significantly less RNT at T2 ( $d = 0.61$ ) and 3-MFU ( $d = 0.75$ ) as compared to WLG. Improvements were sustained until 6-MFU. Significant, small to moderate effect sizes were identified for most secondary outcomes at T2 and 3-MFU. Furthermore, results of mediation analyses revealed that the gratitude intervention exerts its effect on anxiety and depression by reducing the risk factor of RNT, while the mediating role of resilience was less clear.

**Conclusions:** The gratitude intervention investigated in this study was found to be effective in reducing RNT. Gratitude interventions might affect mental health by two parallel pathways: increasing resources and reducing risk factors.

**Reference number Ethics Committee of the University of Lueneburg:** EB 201701-03-Lehr.

**Clinical trial registration number:** DRKS00011862.

The trial protocol can be assessed at: [https://www.drks.de/drks\\_web/navigate.do?sessionId=51277E5748C93910E2D323B4A8998D75?navigationId=results](https://www.drks.de/drks_web/navigate.do?sessionId=51277E5748C93910E2D323B4A8998D75?navigationId=results).

Efficacy of an internet and app-based gratitude intervention in reducing repetitive negative thinking and mechanisms of change in the intervention's effect on anxiety and depression: Results from a randomized controlled trial.<sup>1</sup>

*Repetitive negative thinking* (RNT) is a cognitive process that plays a role in various forms of psychopathology and is considered a transdiagnostic risk factor (Harvey, Watkins, Mansell, & Shafran, 2004). It has been shown to be involved in the development and maintenance of

mood and anxiety disorders (for a review, see Watkins, 2008) and partly explains their comorbidity (e.g., Drost, van der Does, van Hemert, Penninx, & Spinhoven, 2014). Therefore, interventions targeting the transdiagnostic process of RNT might have the potential to prevent the development and positively affect symptoms of depression and anxiety disorders.

Ehring and Watkins (2008) define RNT as a transdiagnostic cognitive process that is repetitive in nature, perceived as difficult to

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<sup>1</sup> WLG: wait list control group, IG: intervention group, ITT: Intention to treat, NNT: Number needed to treat, PTQ: Perseverative Thinking Questionnaire, RNT: Repetitive negative thinking, T0: Screening, T1: Baseline, T2: Post-Intervention, 3-MFU: 3-month follow-up, 6-MFU: 6-month follow-up.

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disengage from, and focused on negative content. In the past, it has largely been studied in the forms of worry (e.g., Borkovec, Robinson, Pruzinsky, & DePree, 1983) and rumination (e.g., Nolen-Hoeksema, 1991), often referred to as content-dependent forms of RNT. Evidence shows that content-dependent forms of RNT overlap extensively, and that common rather than content-dependent aspects of RNT predict depressive and anxiety symptoms (Spinhoven, Drost, van Hemert, & Penninx, 2015). Although there is no gold standard yet, meta-analytic evidence documented that interventions based on cognitive-behavioural (CBT) and mindfulness-based cognitive therapy (MBCT) can be effective at reducing RNT (Querstret & Cropley, 2013; Spinhoven et al., 2018). Moreover, the results of individual studies suggest that reductions in RNT predict depressive and anxiety symptom reductions (e.g., Kertz, Koran, Stevens, & Björqvinnson, 2015; Newby, Williams, & Andrews, 2014).

However, not only are studies investigating interventions that specifically target *transdiagnostic* RNT scarce, but so also are studies evaluating so called positive psychological or well-being interventions focusing on this transdiagnostic process.

Learning to disengage from negative information and training to shift one's attentional focus and to notice and appreciate positive things in life, is at the core of gratitude interventions (Wood, Froh, & Geraghty, 2010). Consistent with various theories of RNT, training to switch the attentional focus to a positive perspective might help to reduce RNT. For example, training to shift the attentional focus might reduce an impaired disengagement from negative aspects of life.

According to the impaired disengagement hypothesis, impaired disengagement may lead to increased RNT (Koster, De Lissnyder, Derakshan, & De Raedt, 2011). Focusing on the positive could also induce a positive mood. According to the mood congruence cognition bias, positive mood decreases the likelihood of negative—mood incongruent—cognitions (Gaddy & Ingram, 2014; Matt, Vázquez, & Campbell, 1992). Besides the hypothesized effect of mood on the valence of cognition, attentional scope theory suggests that a positive mood broadens one's attentional scope and could, thereby, make repetitive thoughts less likely (Whitmer & Gotlib, 2013).

In line with this reasoning, previous randomized controlled trials (RCT) have uncovered beneficial effects of gratitude interventions on content-dependent forms of RNT, such as worry and rumination (e.g., Geraghty, Wood, & Hyland, 2010b; Otto, Szczeny, Soriano, Laurenceau, & Siegel, 2016; Shao, Gao, & Cao, 2016). Furthermore, beneficial effects of gratitude interventions have been discovered for mental conditions in which RNT is suggested to play a role, such as depression (Cheng, Tsui, & Lam, 2015; Lambert, Fincham, & Stillman, 2012) and anxiety (Kerr, O'Donovan, & Pepping, 2015).

Besides results indicating efficacy, positive interventions also might foster intervention uptake. By focusing on the positive, gratitude interventions might reduce emotional barriers that prevent some individuals from using existing interventions, such as a perceived misfit of therapy to needs, and stigma-related or emotional concerns (Mohr, Ho, et al., 2010). In addition to increasing uptake, individuals seem to easily understand, complete and enjoy gratitude interventions, like a gratitude journal (Davis et al., 2016; Geraghty, Wood, & Hyland, 2010a). Thus, such interventions may be especially indicated when adherence is challenging (Wood et al., 2010). With internet-interventions, particularly when users are provided with less personal guidance and support, this often is the case (Beatty & Binnion, 2016).

However, apart from the suggested potential for uptake and adherence and promising results gleaned from individual studies, two recent meta-analyses were only able to detect limited promise of gratitude interventions (Davis et al., 2016; Dickens, 2017). Nevertheless, Davis et al. (2016) claim that the full potential of gratitude interventions has not yet been achieved and call for further research on more effective interventions. Since previous gratitude interventions mostly included only one gratitude exercise (for an overview, see Davis et al., 2016; Dickens, 2017), one way to potentially increase effectiveness

would be to combine multiple gratitude exercises.

Internet-based interventions are one way to offer a battery of gratitude exercises in a practical format. Besides being practical, offering interventions over the internet might reduce structural barriers to intervention uptake and dissemination (e.g., Casey, Wright, & Clough, 2014; Mohr, Siddique, et al., 2010).

GET.ON Gratitude is a newly-developed 5-session, internet and app-based gratitude intervention that specifically targets transdiagnostic RNT. Consistent with claims made by Davis et al. (2016), GET.ON Gratitude incorporates a variety of strategies that target different aspects of gratitude; rendering it more intensive than interventions used in previously-published studies and covering the complex psychological structure of gratitude. In the initial RCT evaluating this program, a fully-guided version of the intervention was found to be effective at reducing RNT (Lehr et al., submitted). Intensive guidance limits the reach of interventions, and less-intensive guidance formats, such as adherence-focused guidance, have been developed that include adherence monitoring and feedback on demand (Zarski et al., 2016). Less intensive guidance, like adherence-focused guidance, has been found to be effective at delivering internet interventions (e.g., Ebert et al., 2016), using fewer resources, thereby increasing the intervention's potential reach. Since less guidance tends to be associated with decreased adherence (for a review, see Beatty & Binnion, 2016) and smaller effect sizes (for a review, see Baumeister, Reichler, Munzinger, & Lin, 2014; Johansson & Andersson, 2012; Richards & Richardson, 2012), the first aim of the current study was to assess the efficacy of GET.ON Gratitude, combined with adherence-focused guidance, at reducing RNT.

Besides efficacy, little is known about the underlying mechanisms by which gratitude interventions impact mental health. Therefore, mediation analyses have been used to better understand the mechanisms through which gratitude interventions affect depression and anxiety. The impact of gratitude interventions on psychopathology can be described by two different pathways. Gratitude interventions can reduce psychopathology by reducing risk factors like RNT. This mechanism can be referred to as a “risk reduction pathway”. As outlined above, in agreement with various theories of RNT, it seems plausible that a gratitude intervention could reduce RNT, and reduced RNT has been shown to predict reductions in depression and anxiety symptoms (Kertz et al., 2015; Newby et al., 2014). This reasoning is also supported by findings from Petrocchi and Couyoumdjian (2016), who found that forms of RNT about self mediated the impact of gratitude on depression and anxiety.

Gratitude interventions might also impact psychopathology by encouraging users to build up resources like resilience. This second mechanism can be labeled a “resource building pathway”. There is some evidence to support the existence of this second pathway. In agreement with the positive activity model (Lyubomirsky & Layous, 2013), previous studies have identified positive processes as mediators of gratitude interventions' effect on well-being, such as gratitude, perceived friendship quality, positive affect, and positive coping strategies (Emmons & McCullough, 2003; Lambert et al., 2012; O'Connell, O'Shea, & Gallagher, 2017; Wood, Joseph, & Linley, 2007). These mediators all stand for different resilience factors (for an overview of resilience factors, see Helmreich et al., 2017), together representing resilience. Thus, another way by which a gratitude intervention could exert its effects on depression and anxiety might be by building transdiagnostic protective resources like resilience (e.g., Kalisch, Müller, & Tüscher, 2014).

Gratitude interventions might also work via both pathways; by decreasing risk factors and increasing resources in concert. We hypothesized a dual pathway by which the gratitude intervention examined here exerts its effect on psychopathology: first, by reducing RNT, as a transdiagnostic risk factor; and second, by increasing resilience, as a transdiagnostic protection factor. To the best of our knowledge, to date, neither a dual pathway of efficacy of gratitude interventions, nor RNT and resilience as mediating mechanisms, have been investigated

together. For this reason, the second aim of the current study was to examine the mediating role of these transdiagnostic mechanisms in the intervention's effects on the symptoms of depression and anxiety.

## 1. Methods

### 1.1. Study design

The current study was conducted as a two-arm, randomized controlled trial, examining the efficacy of a smartphone and online-based gratitude training (intervention group; IG), as compared to a wait list control group (WLG). Both groups had access to usual care. Participants in the WLG were given access to the intervention after the 3-month follow-up.

Based upon the effect sizes found in previous positive psychological interventions (Bolier et al., 2013; Davis et al., 2016; Dickens, 2017) and meta-analyses revealing lower effect sizes for studies with less guidance (Baumeister et al., 2014; Johansson & Andersson, 2012; Richards & Richardson, 2012), an effect size of  $d = 0.35$  was anticipated. An a priori power analysis for a two-tailed test with 80% power and a significance level of 5%, indicated a required sample size of  $N = 262$  individuals to detect an effect of that size.

The study was approved by the Ethics Committee of the University of Lueneburg, Germany and the trial was registered at the German Clinical Trials Registry (reference number: DRKS00011862).

### 1.2. Participants and procedures

All participants were recruited from the community, mainly via an article on gratitude in a well-known online German news magazine ("Spiegel-Online"). The article appeared in December of 2016 and contained information on gratitude, as well as a link that interested individuals could use to register for the study. Participants were assessed for eligibility if they expressed their interest between December 2016 and mid-February 2017. Once someone indicated their interest online, an individual profile on the training platform was created for them and they were directed to a screening questionnaire. This questionnaire assessed the following inclusion criteria: (a) elevated RNT, as indicated by a score  $> 33$  on the Perseverative Thinking Questionnaire; (b) not on a waiting list to receive or currently receiving psychological help; (c) no changes in dosage of psychopharmacological treatment over the preceding 30 days; and (d) no reported acute suicidal tendencies or (e) dissociative symptoms. Individuals meeting these criteria were then directed to a baseline questionnaire (T1) and received further information regarding the conditions of participation, as well as an informed consent form.

After submitting their informed consent form and completing the baseline questionnaire, participants were randomized to one of the two study arms, using a computer-generated randomization list with a ratio of 1:1 and a block size of two. The randomization list was generated and randomization performed by two employees in our department who were not otherwise involved in the current study. Blinding to group allocation was not feasible. Participants in the IG received immediate access to the training program and a message from their eCoach informing them about adherence-focused guidance. Individuals in the WLG were promised access to the program after the 3-month follow-up.

### 1.3. Measures

All instruments were self-report measures assessed online and in German. Data assessment took place at the time of screening (T0), at baseline (T1), at post-intervention (six weeks after randomization; T2); at a 3-month follow-up (3-MFU); and, among subjects in the IG, at an additional 6-month follow-up (6-MFU). Demographic variables were collected at T0. Variables measuring participants' satisfaction with the intervention and usage of care as usual were collected at T2. Internal

consistencies for this study are reported for T1, unless otherwise stated.

#### 1.3.1. Primary outcome measure

The *Perseverative Thinking Questionnaire* (PTQ; Ehling et al., 2011) was used to measure RNT. This scale was conceptualized as a transdiagnostic measure and consists of 15 items (e.g., "My thoughts repeat themselves."). Items are rated with response options that range from 0 (*never*) to 4 (*almost always*). The total score of the scale ranges from 0 to 60, with higher scores indicating greater symptom severity. A score  $> 33$  indicates an above-average level of RNT and a higher level of psychological distress. The PTQ scale has good psychometric properties, as demonstrated by a Cronbach's alpha of .95 in the validation sample (0.89 in the present sample) and high concurrent validity, with established measures of disorder-specific RNT. Items capture the core characteristics of RNT (repetitiveness, intrusiveness, difficulties to disengage), its unproductiveness, and the extent of mental capacity used.

#### 1.3.2. Secondary outcome measures

**1.3.2.1. Mental health outcomes.** Secondary mental health outcomes included depression severity, measured with the *Centre for Epidemiological Studies Depression scale* (CES-D; Hautzinger, Bailer, Hofmeister, & Keller, 2012; Radloff, 1977), consisting of 20 items, each rated from 0 to 3 ( $\alpha = 0.87$ – $0.92$ ; in the present sample 0.89). A total score  $\geq 16$  indicates subclinical levels of depression, while a score  $\geq 23$  suggests clinically-significant levels of depression.

Generalized anxiety severity was measured with the 7-item version of the *Generalized Anxiety Disorder scale* (GAD-7; Löwe et al., 2008), each item rated from 0 to 4, with a total score that ranges from 0 to 28 ( $\alpha = 0.89$ ; in the present sample 0.80). A score from 5 to 9 indicates mild, from 10 to 14 moderate, and  $\geq 15$  severe levels of anxiety.

Resilience was measured with the 10-item *Connor-Davidson Resilience Scale* (CD-RISC; Campbell-Sills & Stein, 2007), that is measured on a 0–4 Likert scale ( $\alpha = 0.85$ ; in the present sample 0.82).

Insomnia severity was measured with the *Insomnia Severity Index* (ISI; Morin, Belleville, Bélanger, & Ivers, 2011), which consists of seven items, each rated from 0 to 4 ( $\alpha = 0.74$ ; in the present sample 0.86).

Worry was measured with the ultra-brief, 3-item version of the *Penn State Worry Questionnaire* (PSWQ; Berle et al., 2011), with response options for each item ranging from 0 to 6 ( $\alpha = 0.85$ ; in the present sample, 0.82).

**1.3.2.2. Resilience factors.** Perceived social support was measured with the perceived available support subscale of the *Berlin Social Support Scales* (BSSS; Schulz & Schwarzer, 2003). This subscale consists of eight items, each rated on a 1–4 Likert scale ( $\alpha = 0.83$ ; in the present sample, 0.93).

Gratitude was measured with the *Gratitude Questionnaire-6* (GQ-6; McCullough, Emmons, & Tsang, 2002), which was adapted for retrospective assessments using a one-week time frame to capture more state than trait gratitude (e.g., "I have so much in life to be thankful for."). Unlike the original measure, in the present study the six items each were rated on a 1–5 Likert Scale. The 1–7 Likert version of the GQ-6 has shown good internal consistency  $\alpha = 0.82$  (in the present sample,  $\alpha = 0.81$  for the 1–5 Likert Scale).

Dispositional optimism was measured with the revised version of the *Life Orientation Test* (LOT-R; Glaesmer, Hoyer, Klotsche, & Herzberg, 2008), which consists of 10 items (four filler items that are not used for calculating the summation score), and has response options that range from 0 to 4 ( $\alpha = 0.59$ ; in the present sample, 0.78).

**1.3.2.3. Further measures.** To measure clients' satisfaction with the training, a validated version of the *Client Satisfaction Questionnaire* (Attkisson & Zwick, 1982), adapted to the online context, was used (CSQ-I; Boß et al., 2016). The CSQ-I consists of eight items (e.g., "The training has met my needs."), ranging from 0 to 4, with higher values corresponding to greater satisfaction. Reliability has been reported to



be high, as indicated by McDonald's  $\omega$  ranging from 0.93 to 0.95 (Cronbach's  $\alpha$  in the current study's IG at T2: 0.95).

1.4. Study conditions

1.4.1. Wait list control group

Participants in the WLG had full access to whatever usual care was offered by routine healthcare services, and were offered access to the same training that the IG received after the 3-MFU.

1.4.2. Intervention group

Participants in the IG were offered immediate access to GET.ON Gratitude. The gratitude intervention combines an online gratitude training (weekly sessions) with a mobile gratitude app (daily exercises). The gratitude app should be used in a daily manner alongside the online sessions.

Throughout training, participants were in contact with an eCoach, from whom they received reminders to complete the next session, feedback on demand regarding difficulties or ambiguities in conducting individual exercises as well as support on demand with technical difficulties (referred to as adherence-focused guidance). The online gratitude training entailed five weekly sessions, each averaging 45–60 min in duration.

The training exercises address four core elements of gratitude, which were developed based upon an “upwardly-spiralling” working model of gratitude (Lehr, 2015). See Table 1 for an overview of the individual sessions. One main component of the exercises promotes the perception of positive moments in everyday life and within one's biography (Awareness). In further exercises, evaluating such events as being positive and thankworthy is encouraged and a modification of the users' dysfunctional cognitions concerning gratitude is offered (Cognition). A third element aims to intensify the emotional experience of gratitude (Emotion). The fourth core element encourages participants to express their feelings of gratitude and take action (Behavior). At the end of each session, participants summarize their own take-home message. Meanwhile, at the beginning of the second through fifth session, they review their progress with the last week's exercises. These exercises were designed, based upon positive psychological, resource-oriented and cognitive-behavioural principles, and were adapted to the gratitude realm.

In the first session of the online training, participants were instructed to install the Gratitude-App on their mobile devices and to use the app daily from then on in addition to the weekly online sessions.

**Table 1**  
Session content of the online and app-based gratitude intervention.

Session	Objectives	Exercises
1. Being aware of the positive  Gratitude-App (daily usage from now on)	To get acquainted with the training and the app, as well as with the concept of gratitude and its interconnectedness with well-being.  To use the app as a gratitude journal.	<ul style="list-style-type: none"> <li>● Analysis of the current state of gratitude.</li> <li>● Experiment on the selectivity of perception.</li> <li>● Perceiving the good in different areas of life.</li> <li>● Side effects of gratitude and your good reason for training.</li> <li>● Take pictures or notes of positive moments.</li> <li>● Recall positive moments and their sources in the evening within a gratitude meditation.</li> </ul>
2. Experiencing gratitude	To learn to draw the attention to positive events and to intensify the experience of gratitude.	<ul style="list-style-type: none"> <li>● Perceive and intensify feelings of gratitude through imagination exercises.</li> <li>● Gratitude throughout your life.</li> <li>● Experience gratitude with all senses.</li> </ul>
3. Receiving and accepting the good	To develop positive attitudes to grateful events and to further perceive positive events in life.	<ul style="list-style-type: none"> <li>● How gratitude, rumination and worrying are connected.</li> <li>● Hindering attitudes towards gratitude and modification of the users' dysfunctional cognitions concerning gratitude.</li> </ul>
4. Expressing gratitude	To encourage participants to actually express gratitude.	<ul style="list-style-type: none"> <li>● Gratitude within one's own biography.</li> <li>● Discover the sources of the good.</li> <li>● Catching someone doing good.</li> </ul>
5. Consolidating gratitude in everyday life	To consolidate and to look back what has been learnt so far and to make a plan for future.	<ul style="list-style-type: none"> <li>● Expressing gratitude (e.g. gratitude letter, gratitude visit).</li> <li>● Review of the sessions' personal summaries and integrating gratitude in future life.</li> </ul>

The app is a modification of the “count-your-blessings” exercise (Emmons & McCullough, 2003). During the day, participants were encouraged to use the app as a gratitude journal and to take photos or write short notes recording positive moments. In the evening, participants had the opportunity to reflect on their positive moments and their sources, aided by their collected photos, notes and a gratitude meditation.

1.5. Statistical analyses

Data were analysed on the intention to treat-sample (ITT). Data analysis was performed using R (version 3.5.2). Additional sensitivity analyses were performed for the primary outcome. A two-tailed significance level of  $p \leq .05$  was used for all inferential tests.

1.5.1. Missing data and study drop-outs

Missing data were estimated with multiple imputations, with 100 estimates calculated for each missing datum. All existing data of the primary and secondary outcomes, as well as the grouping variable, were used in the imputation model. Pooled means and standard deviations are reported. Statistical analyses were performed for each imputed data set and results were pooled afterwards incorporating the uncertainty about the missing data (van Ginkel, Linting, Rippe, & van der Voort, 2019).

1.5.2. Intervention effect

Between-group differences immediately post intervention (T2) and at 3-MFU were analysed using analyses of covariance (ANCOVA), with the respective baseline values of the particular outcome as covariates. Cohen's  $d$ s with 95% confidence intervals were calculated with *Meta-Essentials* (Suurmond, van Rhee, & Hak, 2017). Between-group Cohen's  $d$ s were calculated using pooled standard deviations. To learn more about the effectiveness of the gratitude training in clinical samples, exploratory subgroup analyses were performed for (a) those who reported clinical symptoms of depression at baseline (scoring > 22 on the CES-D); and (b) those who reported moderate or severe levels of generalized anxiety at baseline.

1.5.3. Long-term efficacy

Since only those in the IG were assessed at 6-MFU, long-term efficacy was examined employing within-subject comparisons. To do this, repeated-measures analyses of variance between T1 and 6-MFU were performed for each pertinent outcome variable. Within-group Cohen's



ds were calculated by controlling for correlations within samples.

#### 1.5.4. Clinical response analyses

**1.5.4.1. Reliable change, symptom-free status, and number needed to treat.** For the primary outcome, reliable change, symptom-free status, and corresponding numbers needed to treat (NNT) were calculated at T2 and 3-MFU (Jacobson & Truax, 1991). To calculate reliable change, the standard deviation ( $SD = 13.23$ ) and Cronbach's alpha ( $\alpha = 0.95$ ) of the PTQ's non-clinical validation sample were used (Ehring et al., 2011). Hence, participants were categorized as having reliably improved if their PTQ score had decreased by more than 8.20 points from T1 to T2 or from T1 to 3-MFU, and as having reliably deteriorated if their PTQ score increased more than 8.20 points between either of these same two time intervals.

Symptom-free status was defined as scoring  $< 2 SD$  below the study sample's mean at T1 ( $M = 39.42$ ;  $SD = 7.24$ ); in this study, this meant having a score  $\leq 24.95$  on the PTQ scale at T2 or at the 3-MFU.

#### 1.5.5. Sensitivity analyses

To assess the robustness of the results obtained via the ITT analyses we conducted two types of sensitivity analyses for the primary outcome at T2 and 3-MFU: Analysis of intervention completers and study completers. Analysis of intervention completers estimates an intervention's potential when the protocol is being followed. For our purposes, we considered participants who completed four or more of the five sessions as having followed the protocol; in this way, intervention completer analysis can be considered a "best-case-scenario" approach to analysis. In analysis of study completers, participants with missing data were excluded so that no kind of imputation had to be used.

#### 1.5.6. Mediation analyses

To assess the mediating role of the transdiagnostic risk factor RNT and the transdiagnostic protective factor resilience, in the intervention's effects on (a) depression and (b) anxiety, parallel multiple mediation analyses were performed. To establish temporal precedence, the T2 scores of mediators and 3-MFU scores of outcomes were used. Following the recommendations of Hayes and Rockwood (2017), baseline scores for the mediating and outcome variables were included as covariates. An indirect effect is considered significant if its 95% confidence interval excludes zero. An additional sensitivity analysis with the study completers was conducted.

## 2. Results

### 2.1. Participants

The flow of participants through the study is depicted in Fig. 1. Of the 1905 individuals who were screened for eligibility, 611 were assessed at baseline. Of these, 262 were randomized to either the IG ( $n = 132$ ) or WLG ( $n = 130$ ). A majority of those interested and fulfilling inclusion criteria were allocated to a different study, which was set up ad-hoc, since the current study's required sample size had already been attained.

### 2.2. Baseline characteristics

Table 2 shows the baseline characteristics of the sample. Participants were predominantly female (58.8%), Caucasian (91.6%), living in Germany (90.8%), and either married or cohabiting (54.2%). A majority reported either subclinical or clinical symptoms of depression (71.8%), while 41.2% reported moderate or severe symptoms of anxiety. Roughly half the sample had prior experience with psychotherapy (48.1%). The subjects' mean age was 42.2 ( $SD = 10.9$ ) years.

### 2.3. Missing data

Baseline data were available for all participants. Overall, data were missing for the primary outcome for 19.8% of all participants at T2 (IG: 31.8%; WLG: 7.7%), 24.8% of all participants at 3-MFU (IG: 38.6%; WLG: 10.8%) and 45.5% of those in the IG at 6-MFU. The two subject groups (IG and WLG) differed with regard to missing data at T2 and 3-MFU (T2:  $\chi^2 = 23.96$ ,  $p < .001$ ; 3-MFU:  $\chi^2 = 27.27$ ,  $p < .001$ ). A MANOVA indicated that baseline scores among participants who failed to provide data were no different than among those who did.

Using valid data for all outcome measures at all assessment points, 100 single imputations were calculated. Group allocation also was included in the multiple imputation model as an auxiliary variable, as recommended by the National Research Council (National Research Council: U.S., 2010). See Table 3 for pooled means and standard deviations at all assessment points.

### 2.4. Primary outcome analysis – repetitive negative thinking

Individuals in the IG reported significantly less RNT than those in the WLG at T2,  $F(1,204) = 32.8$ ,  $p < .001$ ,  $d = 0.61$ ; and at the 3-MFU,  $F(1,190) = 47.6$ ,  $p < .001$ ,  $d = 0.75$ . Effect sizes were ranging from medium to large at both assessment points (see Table 4).

#### 2.4.1. Reliable change, symptom-free status, and number needed to treat

From T1 to T2, 47.2% ( $n = 62.2$ ) of the participants in the IG reported reliable improvement, versus 13.8% ( $n = 17.9$ ) in the WLG. Meanwhile, 48.7% ( $n = 64.3$ ) in the IG failed to exhibit reliable improvement, versus 78.5% ( $n = 102.1$ ) in the WLG. Reliable deterioration was reported by 4.2% ( $n = 5.5$ ) versus 7.7% ( $n = 10.0$ ) among individuals in the IG and WLG, respectively.

Between T1 and 3-MFU, 63.3% ( $n = 83.5$ ) in the IG experienced reliable improvement, versus 18.9% ( $n = 24.6$ ) with reliable improvement in the WLG. The difference in reliable improvement between groups was significant both at T2, pooled  $\chi^2(1, 4632) = 27.8$ ,  $p < .001$ ; and 3-MFU,  $\chi^2(1, 2230) = 40.4$ ,  $p < .001$ . The NNT for one reliably-improved participant at T2 ranged between 2.5 and 4.2 across the 100 imputed data sets. The average NNT across multiply imputed data sets was 3.0, 95% CI [2.3, 4.4]. The NNT for one reliably-improved participant at 3-MFU ranged between 1.9 and 2.8 with a mean of 2.3, 95% CI [1.9, 3.0].

At T2 31.5% of the IG reported being symptom free ( $n = 41.0$ ), versus 9.2% ( $n = 12.0$ ) of the WLG. At 3-MFU, corresponding percentages were 41.7% ( $n = 55.1$ ) and 11.3% ( $n = 14.7$ ) of the IG and WLG, respectively. Inter-group differences in symptom-free status again were significant at both T2,  $\chi^2(1, 5822) = 15.6$ ,  $p < .001$ ; and 3-MFU,  $\chi^2(1, 2865) = 23.9$ ,  $p < .001$ . The corresponding NNT ranged between 3.8 and 6.1, with a mean of 4.6, 95% CI [3.3, 8.3]. At 3-MFU the NNT ranged between 2.7 and 4.3, with a mean of 3.3, 95% CI [2.5, 5.0].

#### 2.4.2. Sensitivity analyses

To assess the robustness of the results, sensitivity analyses were performed. Analyses of intervention completers (number of participants analysed: IG:  $N = 77$ ; WLG:  $N = 130$ ) supported the results obtained with ITT analyses, but generated slightly larger effect sizes at T2,  $F(1,253) = 50.6$ ,  $p < .001$ ,  $d = 0.88$ , 95% CI [0.58, 1.17]; and 3-MFU,  $F(1,248) = 57.2$ ,  $p < .001$ ,  $d = 0.94$ , [0.64, 1.23].

Sensitivity analyses including only study completers (number of participants analysed: IG:  $N = 90$ ; WLG:  $N = 120$ ) corroborated the results of ITT analysis and revealed a highly-significant difference between groups, again at both T2,  $F(1,207) = 55.0$ ,  $p < .001$ ,  $d = 0.86$ , 95% CI [0.57, 1.14]; and 3-MFU,  $F(1,194) = 64.7$ ,  $p < .001$ ,  $d = 0.94$ , [0.64, 1.24]. The effect sizes were larger than those observed with ITT analysis.

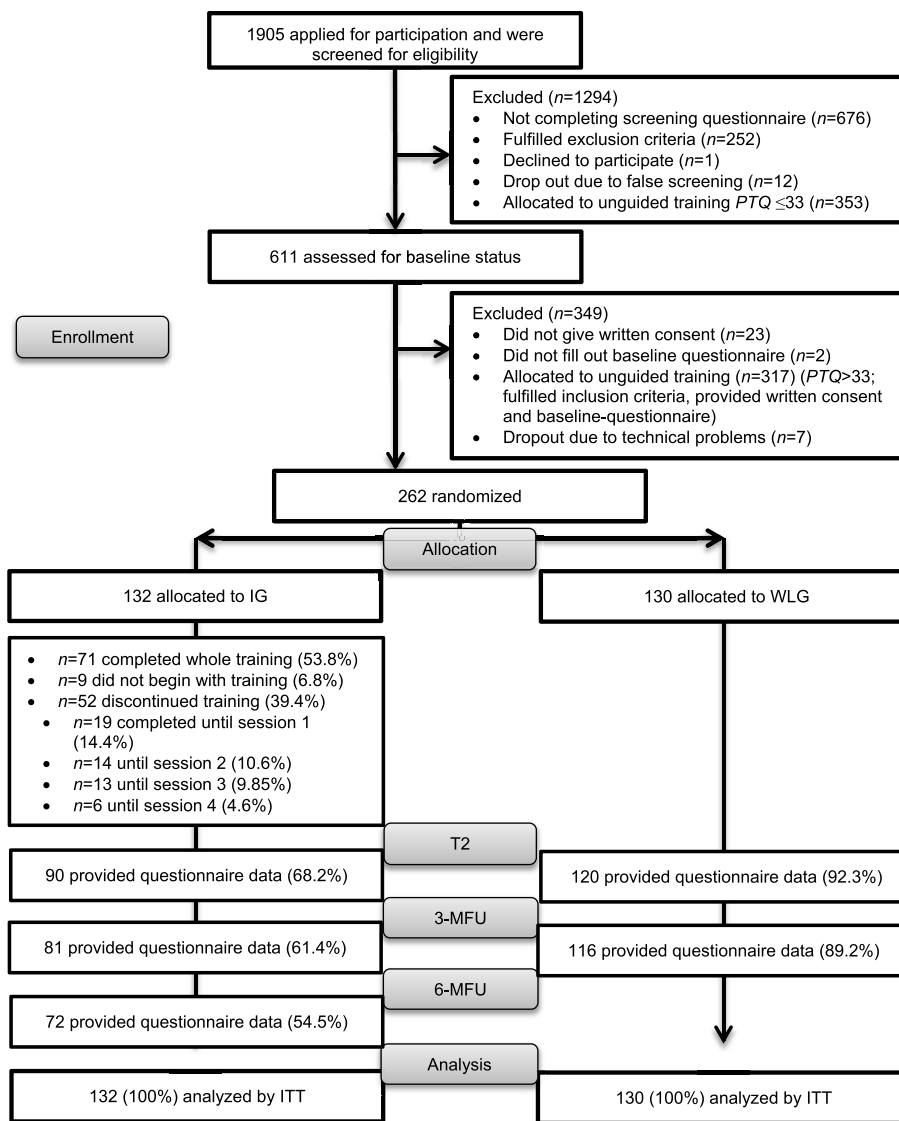


Fig. 1. Flow of participants. Post-intervention: 6 weeks after randomization; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up (only in IG); IG = intervention group; WL = wait list control group; PTQ = Perseverative Thinking Questionnaire; ITT = Intention to treat Analysis.

2.5. Secondary outcome analyses

2.5.1. Mental health outcomes

Significant inter-group differences were identified for depressive symptoms, anxiety, worrying and insomnia, at both T2 and 3-MFU (see Table 4). Differences on resilience were significant at T2, but not at 3-MFU. Effect sizes for those outcomes with significant effects were small to moderate, ranging from  $d = 0.32-0.41$  and from  $d = 0.33-0.40$  at the two data assessment points, respectively.

Subgroup analyses also were conducted. In the subsample with clinically-significant symptoms of depression at baseline (scoring > 22 on the CES-D), significant differences of small to moderate size were apparent for T2 depression scores,  $F(1, 198) = 8.8, p = .003, d = 0.46, 95\% CI [0.09, 0.83]$ .

In the subsample with at least moderate levels of anxiety at baseline (scoring > 9 on the GAD-7), significant, moderate differences were identified for T2 anxiety scores,  $F(1, 213) = 7.0, p = .009, d = 0.62, 95\% CI [0.23, 1.01]$ .

2.5.2. Resilience factors

For gratitude, there was a significant between-group effect at T2 ( $d = 0.44$ ) and at 3-MFU ( $d = 0.38$ ). For perceived available support

there was no significant between-group difference at T2, but a small significant effect at 3-MFU ( $d = 0.29$ ). There was no between-group difference for dispositional optimism.

2.5.3. Long-term effects

All of the significant effects detected on inter-group analyses, at both T2 and 3-MFU, remained significant on repeated-measures ANOVAs comparing baseline and 6-MFU. Overall, within-group effect sizes comparing baseline and 6-MFU tended to be larger than between-group effect sizes at T2 and 3-MFU. For RNT, a large within-group effect size was evident at the 6-MFU ( $d = 1.66$ ). For secondary mental health outcomes, effect sizes ranged from small ( $d = 0.40$  for insomnia) to large ( $d = 1.00$  for worrying). For resilience factors, the effect sizes ranged from small ( $d = 0.31$  for perceived social support) to moderate ( $d = 0.73$  for gratitude).

2.6. Intervention usage and client satisfaction

2.6.1. Intervention usage

Of the 132 participants allocated to the IG, 6.8% did not begin the intervention ( $n = 9$ ), while 93.2% completed session one ( $n = 123$ ), 78.8% session two ( $n = 104$ ), 68.2% session three ( $n = 90$ ), 58.8%

**Table 2**  
Demographic characteristics of the sample.

	Total (N = 262)		IG (n = 132)		WLG (n = 130)	
	N	%	n	%	n	%
Age (M/SD)	42.4	10.9	42.3	10.6	42.6	11.2
Sex						
Men	108	41.2	60	45.5	48	36.9
Women	154	58.8	72	54.5	82	63.1
Relationship						
Single	93	35.5	46	34.8	47	36.2
Married or cohabiting	142	54.2	73	55.3	69	53.1
Divorced or separated	27	10.3	13	9.8	14	10.8
Widowed	0	0	0	0	0	0
Education						
No university degree	63	24	30	23	33	25
University degree	199	76	102	77	97	75
Employment status						
Full-time working	163	62.2	86	65.2	77	59.2
Part-time working	63	24.0	28	21.2	35	26.9
Nonworking	30	11.5	15	11.4	15	11.5
Unemployed/seeking work	5	1.9	3	2.3	2	1.5
On sick leave	1	0.4	0	0	1	0.8
Experience with health training						
Yes	36	13.7	16	12.1	20	15.4
No	226	86.3	116	87.9	110	84.6
Experience with psychotherapy						
No, never	136	51.9	73	55.3	63	48.5
Yes, in the past	126	48.1	59	44.7	67	51.5
Symptoms of depression						
No elevated symptoms	74	28.2	41	31.1	33	25.4
Subclinical symptoms	72	27.5	37	28.0	35	26.9
Clinical symptoms	116	44.3	54	40.9	62	47.7
Symptoms of anxiety						
Minimal level of anxiety	29	11.1	15	11.4	14	10.8
Mild level of anxiety	125	47.7	60	45.5	65	50.0
Moderate level of anxiety	77	29.4	47	35.6	30	23.1
Severe level of anxiety	31	11.8	10	7.6	21	16.2

Note. IG = intervention group; WLG = wait list control group. Symptoms of depression based on CES-D scores: No elevated symptoms = 0–15, subclinical symptoms = 16–22, clinical symptoms = 23–60. Levels of anxiety symptom based on GAD-7 scores: Minimal level = 0–4, mild level = 5–9, moderate level = 10–14, severe level = 15–21.

session four (n = 77), and 53.8% the entire program (n = 71). On average, participants in the IG completed 3.5 of the five sessions (SD = 1.8), which corresponds to 70.5% of the intervention, and used the intervention for an average of 4.0 weeks (SD = 3.3, range 0–15).

**Table 3**  
Means and standard deviations of the outcomes.

Outcome	T1		T2 <sup>a</sup>				3-MFU <sup>a</sup>				6-MFU <sup>a</sup>			
	IG		WLG		IG		WLG		IG		WLG		IG	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Primary outcome														
Repetitive negative thinking	39.8	7.2	39.1	7.3	30.6	12.7	37.2	8.7	27.6	13.4	36.4	9.7	27.3	7.7
Secondary outcomes														
Mental health														
Depression	21.8	9.3	22.3	9.4	16.7	11.5	20.8	10.0	16.2	11.8	20.7	11.0	15.3	7.6
Anxiety	9.1	3.8	9.3	4.1	6.4	4.6	8.2	4.0	6.5	4.9	8.0	4.2	6.3	3.4
Resilience	30.3	6.1	29.6	5.4	32.7	8.3	30.3	6.3	32.0	9.0	30.3	6.6	33.4	6.3
Worrying	8.6	3.8	8.4	3.8	5.8	4.6	7.6	4.1	5.7	5.5	7.3	4.4	5.2	3.2
Insomnia	10.7	5.6	12.0	6.0	9.3	6.8	11.5	6.5	8.4	6.8	11.1	6.7	8.7	4.5
Resilience factors														
Social Support	26.0	4.8	25.5	5.5	26.4	5.5	25.2	5.5	26.9	5.8	25.3	5.6	27.4	4.2
Gratitude	20.5	4.6	20.3	4.9	23.5	5.7	21.2	5.1	23.5	5.7	21.4	5.0	23.7	4.4
Optimism	11.7	2.2	11.5	2.4	11.9	3.9	11.6	2.4	11.9	4.4	11.9	2.9	12.1	2.1

Note. IG = intervention group; WLG = wait list control group; T1 = Baseline; T2 = post-intervention; 3-MFU = 3-month follow-up, 6-MFU = 6-month follow-up.  
<sup>a</sup> Missing data were imputed by multiple imputations. Pooled results are reported.

Among those who discontinued the intervention, n = 9 provided their reasons for dropout: n = 3 dropped out because of a perceived incongruence between training content and their needs; n = 1 because of technical problems; n = 1 because of the lack of motivation; n = 1 because of a lack of time; and n = 3 for other reasons (e.g., comprehension difficulties, unwillingness to use a smartphone).

The eCoaches received a total of 78 messages via the training platform. Of these, the majority (n = 67) were about how the study was being conducted or for technical difficulties. In 11 messages, participants asked for support processing the training; as such, these can be classified as requests for feedback on demand. Requests for feedback on demand included questions such as the following: “( ...) I find it difficult to detect an experience that evokes the feeling of gratitude. How should I continue with the exercise?” or “Is it [the collection of grateful moments within the Gratitude App] about moments where I am grateful to other people ( ...) or also about moments that simply give me joy ( ...)?”. A total of n = 10 individuals (7.6%) took advantage of the feedback on demand offer.

**2.6.2. App usage**

A subgroup of n = 114 individuals in the IG also consented to the collection of app-usage data. Within the first six weeks after randomization, individuals in the IG averagely collected 51.89 gratitude notes (SD = 52.49, range: 0–306), 22.12 gratitude photos (SD = 32.74; range: 0–192) and 15.67 gratitude reviews (SD = 11.67; range: 0–42). This sums to 89.68 (SD = 81.40; range: 1–413) gratitude activities as a whole, and an average of 14.95 gratitude activities per week over the course of the five-week intervention. The number of gratitude activities recorded with the app declined between T2 and 3-MFU, to an average of 20.23 (SD = 60.02) activities over that 6-week time frame. The number of gratitude activities recorded at T2 and 3-MFU were highly correlated (r = 0.69, p < .001).

Exploratory analyses revealed that the number of activities performed with the app also correlated significantly with the number of completed sessions (r = .33, p < .001). The number of activities with the app correlated marginally with change in RNT scores between T1 and T2 (r = 0.17, p = .098), indicating a dose-response relationship with app usage. The number of gratitude activities between T2 and to 3-MFU also significantly predicted change in RNT between T1 and 3-MFU (r = 0.25, p = .01).

**2.6.3. Client satisfaction**

The client satisfaction questionnaire was answered by 68.2% of those allocated to the IG (n = 90). Overall satisfaction with the training

**Table 4**  
Results of AN(C)OVAs and Cohen's *ds* for primary and secondary outcomes.

Outcome	Differences between study conditions				Differences within intervention condition	
	T2		3-MFU		6-MFU	
	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>a</sup>	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>a</sup>	<i>F</i> <sub>df</sub>	Cohen's <i>d</i> [95% CI] <sup>b</sup>
<b>Primary outcome</b>						
Repetitive negative thinking	32.8 <sub>1,204</sub> ***	0.61 [0.36,0.86]	47.6 <sub>1,190</sub> ***	0.75 [0.50,1.00]	230.1 <sub>1,127</sub> ***	1.66 [1.32,1.98]
<b>Secondary outcomes</b>						
<b>Mental health</b>						
Depression	10.6 <sub>1,200</sub> ***	0.38 [0.13,0.62]	11.9 <sub>1,203</sub> ***	0.40 [0.15,0.64]	58.3 <sub>1,127</sub> ***	0.75 [0.53,0.97]
Anxiety	12.9 <sub>1,208</sub> ***	0.40 [0.15,0.64]	8.6 <sub>1,209</sub> **	0.34 [0.09,0.58]	57.0 <sub>1,125</sub> ***	0.80 [0.56,1.03]
Resilience	6.4 <sub>1,196</sub> *	0.32 [0.08,0.57]	1.6 <sub>1,198</sub> <sup>n.s.</sup>	0.20 [-0.04, 0.45]	37.8 <sub>1,125</sub> ***	0.50 [0.33,0.66]
Worrying	16.4 <sub>1,212</sub> ***	0.41 [0.17,0.66]	9.9 <sub>1,213</sub> **	0.33 [0.09,0.58]	74.4 <sub>1,127</sub> ***	1.00 [0.71, 1.26]
Insomnia	4.6 <sub>1,217</sub> *	0.34 [0.10,0.58]	7.2 <sub>1,207</sub> **	0.39 [0.15,0.64]	14.9 <sub>1,127</sub> ***	0.40 [0.19,0.61]
<b>Resilience factors</b>						
Social Support	2.6 <sub>1,213</sub> <sup>n.s.</sup>	0.20 [-0.04,0.45]	5.7 <sub>1,215</sub> *	0.29 [0.05,0.54]	10.1 <sub>1,125</sub> **	0.31 [0.12,0.50]
Gratitude	18.1 <sub>1,207</sub> ***	0.44 [0.19,0.69]	12.3 <sub>1,194</sub> ***	0.38 [0.14,0.63]	57.4 <sub>1,125</sub> ***	0.73 [0.52,0.93]
Optimism	0.5 <sub>1,192</sub> <sup>n.s.</sup>	0.10 [-0.14,0.34]	0.0 <sub>1,188</sub> <sup>n.s.</sup>	0.00 [-0.24,0.24]	2.5 <sub>1,125</sub> <sup>n.s.</sup>	0.18 [-0.05, 0.40]

Note. T2 = post-intervention; 3-MFU = 3-month follow-up, 6-MFU = 6-month follow-up; CI = Confidence Interval.

<sup>n.s.</sup> non-significant; \**p* ≤ .05; \*\**p* ≤ .01; \*\*\**p* ≤ .001.

<sup>a</sup> Cohen's *ds* were calculated by using pooled standard deviation.

<sup>b</sup> Cohen's *ds* for within-subject effects were calculated by controlling for dependence within samples.

was comparable to other, previously-studied interventions ( $M = 25.67$ ,  $SD = 5.6$ , range = 8–32) (e.g., Boß et al., 2016). In an “overall, general sense”, 46.7% ( $n = 42$ ) were very and 40.0% ( $n = 36$ ) mostly satisfied with the training they received, while 8.9% ( $n = 8$ ) were mildly and 4.4% ( $n = 4$ ) quite dissatisfied. Almost half (47.8%,  $n = 43$ ) stated that they would definitely recommend the training to a friend in need, while 35.7% ( $n = 33$ ) were somewhat willing to recommend it. Ten percent ( $n = 9$ ) indicated that they would rather not, and 5.6% ( $n = 5$ ) that they would definitely not recommend the program to a friend.

#### 2.6.4. Usage of care as usual

All individuals in both groups had full access to care as usual, as offered through routine healthcare services. Usage was comparable in the two groups. At T2, 91.5% ( $n = 119$ ) of the WLG and 68.2% ( $n = 90$ ) in the IG provided data on care as usual. 6.7% ( $n = 8$ ) of the WLG reported having received psychotherapeutic support over the past three months (7.6%,  $n = 7$  in the IG), while 4.2% ( $n = 5$ ) of participants in the WLG participated in some other health-oriented training, like yoga or meditation (7.6%,  $n = 7$  in the IG). A further 30% ( $n = 36$ ) of the WLG indicated that they had read a self-help book, versus 25% ( $n = 23$ ) in the IG. Also among participants in the WLG, 5.8% ( $n = 7$ ) reported having spoken with a mental health expert, counselor or pastor (5.4%,  $n = 5$ , in the IG), while 5.0% ( $n = 6$ ) claimed to have attended a course or workshop (7.6%,  $n = 7$ , in the IG), and 10% ( $n = 12$ ) indicated that they had made use of other things that they perceived to be similar to gratitude training, in terms of effectiveness (8.7%,  $n = 8$ , in the IG). In summary, 53.3% of the participants ( $n = 64$ ) in the WLG reported having used some care as usual or self-help approaches, versus 52.2% of the participants in the IG ( $n = 47$ ).

### 2.7. Mediation analyses

#### 2.7.1. Depression

As shown in Fig. 2, RNT,  $a_1b_1 = -1.25$ , 95% CI [-2.42, -0.07] at T2 significantly mediated the effect of the intervention on depression at 3-MFU. The indirect effect through resilience was marginally significant,  $a_2b_2 = -0.56$  [-1.14, 0.02]. The direct effect of the intervention reducing depression did not remain significant, after the mediators were incorporated into the model,  $c' = -2.36$  [-4.92, 0.19]. In a sensitivity analysis with the completer sample both RNT,  $a_1b_1 = -1.84$  [-2.85, -0.83], and resilience,  $a_2b_2 = -0.58$  [-1.05, -0.11], at T2

significantly mediated the effect of the intervention on depression at 3-MFU.

#### 2.7.2. Anxiety

As shown in Fig. 3, the intervention's effect on anxiety at 3-MFU was also significantly mediated by T2 scores of RNT, path  $a_1b_1 = -0.64$ , 95% CI [-1.14, -0.13]. The indirect effect through resilience was not significant,  $a_2b_2 = -0.15$  [-0.33, 0.03]. The direct effect of the intervention on anxiety did not remain significant,  $c' = -0.67$  [-1.72, 0.37]. In a sensitivity analysis with the completer sample both RNT,  $a_1b_1 = -0.92$  [-1.37, -0.48], and resilience,  $a_2b_2 = -0.15$  [-0.30, 0.00], at T2 significantly mediated the effect of the intervention on anxiety at 3-MFU.

### 3. Discussion

The current study had two main aims. The first was to assess the efficacy of a newly-developed internet and app-based gratitude intervention, delivered with adherence-focused guidance, at reducing repetitive negative thinking (RNT). The second was to investigate the interplay of two transdiagnostic factors—RNT and resilience—as underlying mechanisms in the intervention's effect on levels of depression and anxiety.

With regard to the first aim, the present RCT demonstrates the efficacy of the gratitude intervention with adherence-focused guidance at reducing RNT. As hypothesized, participants in the intervention group reported significantly lower RNT immediately after the intervention and at 3-MFU compared to a wait list control group. Effects were of moderate to large size and sustained until the 6-MFU.

Sensitivity analyses corroborated the results from ITT analyses. To estimate the potential of the intervention on a best-case-scenario basis further analyses were conducted. These included only those participants who had completed four or five sessions of training. And, in this group of more adherent subjects, effect sizes were greater than across the ITT sample as a whole. Additionally, we conducted analyses including only study completers and these analyses also corroborated the results from ITT analyses. Effect sizes were larger than those of ITT analysis and comparable to those from the intervention completer analysis.

Reliable change analysis suggested that three individuals need to be given access to the intervention, compared to a wait list control group,



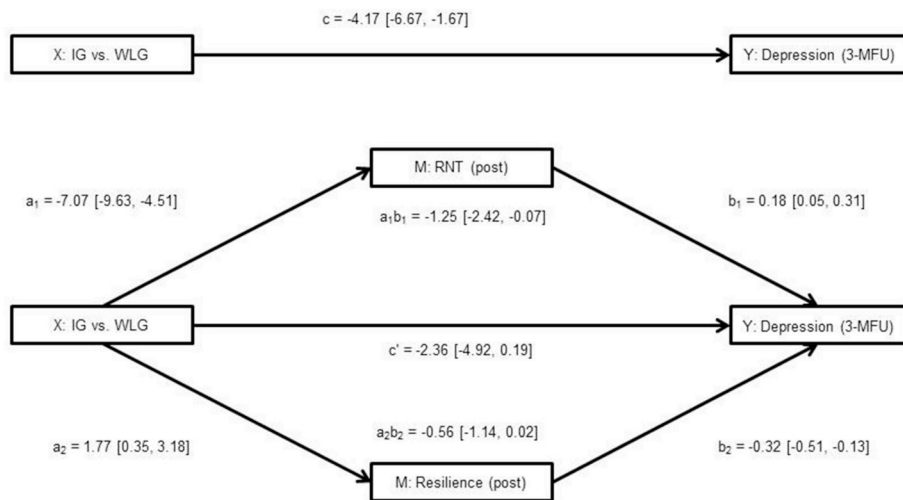


Fig. 2. Parallel multiple mediation model with 3-MFU depression scores as the outcome variable, post-treatment repetitive negative thinking and resilience scores as mediators and baseline values of mediators and outcome as covariates. Treatment is coded 0 = wait list control group, 1 = intervention group. Path diagrams representing statistically significant mediated effects. Unstandardized beta coefficients are shown, with 95% confidence intervals in brackets. IG = intervention group; WLG = wait list control group; RNT = Repetitive negative thinking.

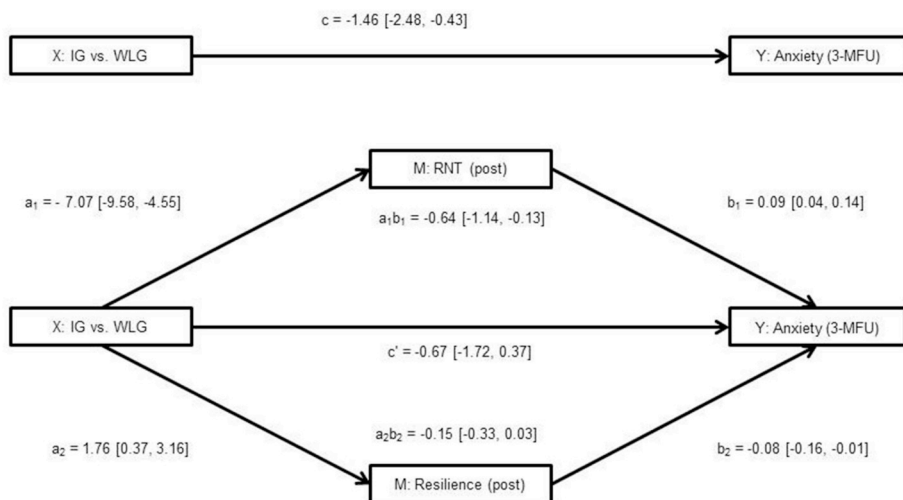


Fig. 3. Parallel multiple mediation model with 3-MFU anxiety scores as the outcome variable, post-treatment repetitive negative thinking and resilience scores as mediators and baseline values of mediators and outcome as covariates. Treatment is coded 0 = wait list control group, 1 = intervention group. Path diagrams representing statistically significant mediated effects. Unstandardized beta coefficients are shown, with 95% confidence intervals in brackets. IG = intervention group; WLG = wait list control group; RNT = Repetitive negative thinking.

for one to experience a reliable improvement immediately upon completion of the program. Significant differences, both short- and long-term, of small to moderate size also were detected for other mental health-related outcomes—like anxiety, depression and insomnia—and for gratitude at T2 and 3-MFU and for perceived social support at 3-MFU. On resilience, effects were significant at T2 and 6-MFU, but failed to reach statistical significance at 3-MFU.

In the following paragraphs, the study's results will be discussed in light of previous intervention studies that (a) examined a gratitude intervention; (b) focused on RNT as an outcome; (c) were internet-based and focused on depression and anxiety; and (d) targeted resilience.

This study is among the first to demonstrate that a gratitude intervention can also be effective at reducing transdiagnostic RNT. Results of the current study are consistent with prior evidence on gratitude interventions that indicate their ability to reduce content-dependent forms of RNT, such as rumination and worry, that were partly obtained from very specific subject samples, like cancer survivors (Otto et al., 2016; Shao et al., 2016) or the completer sample (Geraghty et al., 2010b). The effect sizes detected by the current RCT lie between the moderate effects reported for two studies that employed ITT analyses (Otto et al., 2016; Shao et al., 2016) and the very large (Geraghty et al.,

2010b) effect sizes found in a study in which only those who completed the intervention were analysed.

With regard to meta-analyses on gratitude interventions, this RCT's results are slightly larger than the effects identified for different indicators of mental health and responds to the call for future research with more effective interventions (Davis et al., 2016). There may be several explanations for finding slightly stronger effects as compared to previously-reported gratitude interventions. First, previously-reported interventions were mostly provided as pure self-help. In contrast, participants in the current study had the opportunity to receive support from eCoaches. On the one hand, when taking the amount of requests for support into account, the current intervention could also be regarded as a pure self-help intervention. On the other hand, simply by knowing that someone would care if necessary could enfold a positive effect as predicted by the supportive accountability theory (Mohr, Cuijpers, & Lehman, 2011). Second, the intervention examined here was probably more intense than those used in previous RCTs, which mostly evaluated single exercises, like the count-your-blessings approach. The gratitude intervention evaluated here sprang from a working model of gratitude, and incorporates multiple different exercises that target various aspects of gratitude. Third, the intervention was offered as a computer and app-based hybrid. By offering more than

one medium for use, its efficacy might have been augmented. Fourth, due to the inclusion criteria the sample of the current study had an elevated RNT pattern; and approximately half reported either sub-clinical or clinical symptoms of depression and/or anxiety. Thus, the sample might have had more room to improve.

In terms of reducing RNT, the current study's results are slightly larger than the medium-sized effects generally identified in a meta-analysis that has assessed mostly face-to-face CBT and MBCT interventions for depression (Spinhoven et al., 2018). They also are comparable to the medium to large effects found in the few studies that have specifically targeted RNT (Spinhoven et al., 2018).

Comparing the results and those of studies with the same mode of intervention delivery, the effect sizes we detected for depression were comparable to those of diagnosis-specific, internet-based CBT offering a similar level of support (Karyotaki et al., 2017). Compared to the average effect sizes identified in a meta-analysis assessing internet-based CBT for anxiety (Richards, Richardson, Timulak, & McElvaney, 2015) effects of the current study were smaller. However, almost all of the studies included in that meta-analysis entailed intense therapist support, likely leading to increased efficacy. Furthermore, 58.8% of the currently-studied sample reported minimal to mild levels of anxiety and, as such, had less room to improve than the samples studied in trials explicitly designed for individuals with anxiety.

The effect on resilience that was found in the current study lies between effects meta-analytically found for interventions targeting resilience (Joyce et al., 2018; Vanhove, Herian, Perez, Harms, & Lester, 2016). However, at 3-MFU the effect on resilience did not reach statistical significance.

The effect sizes discovered in this study are comparable to those reported for a previously-conducted RCT that evaluated the same gratitude intervention, but offered more intensive guidance (Lehr et al., submitted).

On subgroup analyses of those reporting clinically-relevant symptoms of depression and anxiety, the gratitude intervention also appeared to be effective, suggesting that it may be useful for highly-distressed individuals as well. The effect sizes on depression and anxiety in this subsample were moderate and larger than those found in the ITT sample. The effect sizes were slightly stronger than those found meta-analytically for self-help interventions on depression (Karyotaki et al., 2017). With regard to anxiety the effect was comparable to a self-help study for individuals with a diagnosed anxiety disorder (Boettcher et al., 2014), but slightly smaller than those found meta-analytically for fully-supported diagnosis-specific internet-based CBT for anxiety (Richards et al., 2015). Even though we did not directly compare diagnosis-specific and gratitude interventions, these results are noteworthy and consistent with results of previously-published gratitude interventions (Geraghty et al., 2010a; 2010b) that found a gratitude intervention to be equally effective as a diagnosis-specific treatment commonly used in psychotherapy. They show that positive psychological interventions might not only be helpful for health promotion and illness-prevention purposes, but also for those who are clinically distressed. In line with Wood and Tarrier's (2010) proposal of a 'positive clinical psychology' these results encourage to incorporate positive psychological interventions in clinical psychology and to conduct future studies with clinical samples recruited from primary and secondary care.

Besides efficacy, we investigated the underlying mechanisms behind this gratitude intervention's effects on depression and anxiety. To date, it remains unknown whether so-called positive interventions enact their effect via some resource-building pathway, a risk-reduction pathway, or a pathway that combines both. Consequently, we investigated both RNT—as a transdiagnostic risk factor—and resilience—as a transdiagnostic protective factor—as underlying mechanisms behind the intervention's effect on anxiety and depression. In line with the conceptualisation of RNT as a transdiagnostic risk factor, on mediational analyses, immediate post-intervention scores for RNT were found to

significantly mediate the intervention's effect on both depression and anxiety at 3-MFU. Results on resilience as a mediator were marginally or non-significant in the ITT sample. In sensitivity analyses with the completer sample both mediators were significant, supporting a dual pathway hypothesis. Results for RNT as a mediator are consistent with prior research, which suggests that reductions in RNT are linked to and mediate reductions in levels of depression and anxiety (Kertz et al., 2015; Newby et al., 2014). They also agree with results reported by Petrocchi and Couyoumdjian (2016), who found that specific forms of RNT about self, mediate the impact of gratitude on depression and anxiety. The current study extends this finding by showing for the first time that content-independent/transdiagnostic RNT also functions as a mediator.

Pertaining to resilience as a mediator, prior research has identified a range of resilience factors (e.g., positive emotions) as mediators of gratitude intervention's effects on well-being (Emmons & McCullough, 2003; Lambert et al., 2012; O'Connell et al., 2017; Wood et al., 2007). The results of the current study also reveal significant differences for specific resilience factors, like gratitude and perceived social support. Analyses are inconclusive but suggest that resilience as a whole—and not just single resilience factors—might also function as a mediator. Being more aware of the mechanisms of change, therapists and eCoaches might be able to become better at monitoring and optimizing therapeutic change (Kazdin, 2007).

### 3.1. Limitations and future directions

The overall encouraging findings of the current study should be interpreted in light of several methodological limitations. First, due to the study's inclusion criteria, the sample studied consisted of individuals with high-level RNT. On one hand, this shows that positive psychological interventions also work in distressed individuals. On the other hand, future research must determine the generalizability of the results in a less distressed sample recruited from a universal preventive setting. Second, the gratitude intervention was offered in a hybrid fashion, combining online with app-based exercises. Thus, no statements can be made with regard to the efficacy of the individual elements. Future research could investigate the efficacy of the gratitude app as a standalone intervention. Third, due to missing data, multiple imputations had to be used. Even though multiple imputations are a state of the art method for dealing with missing data (Schafer & Graham, 2002), biased estimates cannot be ruled out. Nevertheless, sensitivity analyses clearly underlined the robustness of the results found.

On mediation analysis, using RNT and resilience at T2 as mediators and anxiety and depression symptoms at 3-MFU as outcomes, we tried to establish the temporal precedence of mediators. Although this approach provides a stronger test of causality (Kazdin, 2007), we cannot rule out that changes in the outcomes occurred prior to changes in the mediators. To establish a timeline with greater confidence, future research should assess mediators and outcomes at multiple time points during treatment, and/or at times when changes in the mediators are deemed more likely to occur (Kazdin, 2007; Laurenceau, Hayes, & Feldman, 2007).

We investigated RNT and resilience as mediators of the gratitude intervention's effect on symptoms of depression and anxiety. We did not assess more proximal mediators explaining the gratitude intervention's effect on these mediators. Even if it seems plausible that the gratitude intervention exerts its effect by increasing the emotion of gratitude, this may not be the case and the effect of the gratitude intervention might also be explained by other mechanisms such as more general positive affect (Wood et al., 2010). Future research should assess and test even more proximal mediators to further understand how the gratitude intervention works.

#### 4. Conclusions

Notwithstanding the above-listed limitations, the present study is among the first to show that an internet- and app-based gratitude intervention can reduce transdiagnostic RNT. It also reduces other mental health outcomes, like anxiety, depression and insomnia, both short- and long-term. Subgroup analyses of clinically distressed individuals suggest that the gratitude intervention might also be helpful for clinical samples. Furthermore, mediational analyses suggest that the gratitude intervention works by reducing RNT, as a transdiagnostic risk factor. Analyses regarding the mediating role of resilience, as a transdiagnostic protection factor, were inconsistent and require future research.

#### Conflicts of interest

DL and DDE are stakeholders in the 'Institute for Online Health Training', which aims to transfer scientific knowledge related to the present research into routine health care. HH and HF do not have any conflicts of interest.

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## Additional analyses

### Above threshold depressive symptoms

Table M3 shows the proportion of participants with a value  $< 23$  or  $\geq 23$  on the Center for Epidemiological Studies Depression Scale. At T2 and 3-MFU significantly more participants in the IG, as compared to the WLG, scored under the clinical cut-off for depression. The proportions correspond to an NNT of 5.3 at T2. At the same time 23% of the IG, after having received the intervention, scored above the cut-off for clinical depression.

Table M3: Proportion of participants with depressive symptoms  $\geq$  clinical cut-off vs.  $<$  clinical cut-off.

	IG				WLG				<i>p</i>	NNT [95% CI]
	$< 23$		$\geq 23$		$< 23$		$\geq 23$			
	n	%	n	%	n	%	n	%		
T1	78	59	54	41	68	52	62	48		
T2	101	77	31	23	75	58	55	42	**	5.3 [3.3; 13.0]
3-MFU	99	75	33	25	72	55	58	45	**	5.1 [3.2; 12.0]
6-MFU	114	86	18	14						

Note. Depression was measured with the Center for Epidemiological Studies Depression Scale (CES-D). A value  $\geq 23$  indicates clinically significant levels of depression.

IG = intervention group; WLG = waitlist control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

### Clinically relevant change in depressive symptoms

Table M4 shows the proportion of participants with and without a clinically relevant change in depressive symptoms from baseline. At T2 and 3-MFU significantly more participants in the IG, as compared to the WLG, reported a clinically relevant change in depressive symptoms. While

Table M4: Proportion of participants with a change in depressive symptoms  $< 33$  vs.  $\geq 33\%$  from baseline.

	IG				WLG				<i>p</i>	NNT [95% CI]
	$< 33\%$		$\geq 33\%$		$< 33\%$		$\geq 33\%$			
	n	%	n	%	n	%	n	%		
T2	75	57	57	43	104	80	26	20	***	4.3 [2.9; 8.1]
3-MFU	73	55	59	45	98	75	32	25	**	4.9 [3.2; 11.3]
6-MFU	68	52	64	48						

Note. IG = intervention group; WLG = waitlist control group; T1 = baseline; T2 = post-intervention; 3-MFU = 3-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

at T2 43% in the IG reported a clinically relevant change, only 20% in the WLG reported a clinically relevant change. This equals an NNT of 4.3 at T2. At the same time 57% of the IG at T2 did not

experience a clinically relevant change despite having received access to the intervention.

**Reliable deterioration**

From T1 to T2  $n = 7$  (5%) in the IG, as compared to  $n = 8$  (6%) in the WLG, reported a reliable deterioration ( $p > 0.05$ ). From T1 to 3-MFU  $n = 8$  (6%) in the IG, as compared to  $n = 14$  (11%) in the WLG, reported a reliable deterioration ( $p > 0.05$ ).

**Chapter 4 – Internet-based intervention during the COVID-19 pandemic**

**Published Paper – Effectiveness of an Internet-Based Self-Help Intervention versus Public Mental Health Advice to Reduce Worry during the COVID-19 Pandemic: A Pragmatic, Parallel-Group, Randomized Controlled Trial**

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# Effectiveness of an Internet-Based Self-Help Intervention versus Public Mental Health Advice to Reduce Worry during the COVID-19 Pandemic: A Pragmatic, Parallel-Group, Randomized Controlled Trial

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## Keywords

COVID-19 · Worry · Internet-based intervention · Self-help · Randomized controlled trial

## Abstract

**Introduction:** The mental health burden for the general population due to the COVID-19 pandemic has been highlighted. Evidence on effective, easily accessible public health interventions to reduce worry, a major transdiagnostic risk-factor for, e.g., anxiety and depression, is scarce. **Objective:** In a pragmatic randomized controlled trial, we aimed to assess whether an internet cognitive-behavioral self-help intervention could reduce worry more than public mental health advice in the general population. **Methods:** Eligible internet users above the age of 18 were recruited from the German general population and randomly assigned, to either get.calm-move.on (GCMO), a 10-day unguided, internet-based self-help intervention, or mental health advice waiting group (MHA-W, receiving officially endorsed mental health recommendations). The primary outcome was level of worry, using the Penn State Worry Questionnaire (PSWQ), 2 weeks after randomization. Baseline assessment and

2-month and 6-month follow-ups were conducted. The trial was registered at the German Clinical Trials Registry (DRKS00021153). **Results:** Between April 7, 2020 and December 11, 2020, we randomly assigned 351 individuals to receive either GCMO ( $n = 175$ ) or MHA-W ( $n = 176$ ). Participants receiving GCMO (PSWQ = 46.6; change  $-10.3$ ) reported significantly less worrying at post-intervention ( $F_{1,219} = 12.9$ ;  $p < 0.001$ ;  $d = 0.38$ ) than MHA-W controls (PSWQ = 51.6; change  $-5.1$ ). Improvements were also seen on most secondary outcomes, including symptoms of anxiety and depression, general well-being, resiliency, and emotion regulation skills. Improvements made from baseline were stable until the 6-month follow-up. **Conclusions:** This internet-based self-help intervention providing cognitive-behavioral techniques to cope with the threatening pandemic situation is effective in reducing worry in the general population and should complement existing and potentially effective mental health recommendations.

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## Introduction

Societies worldwide have felt threatened by the SARS-CoV-2 virus pandemic, with COVID-19 morbidity and mortality being the most salient health consequences. Studies on prior virus outbreaks highlight the adverse influence of pandemics on mental health as well [1]. There is evidence, from several observational studies, that similar negative effects on mental health should be expected with the current pandemic [2–5]: a “quiet” consequence of the pandemic. However, evidence from prior epidemics or pandemics from well-designed interventional studies on successful strategies to prevent adverse mental health outcomes is limited [6].

From a psychological perspective, pandemics can be characterized as highly volatile, mainly controlled by external factors with an uncertain future, in which the potential for several negative outcomes exists. In general, such characteristics are likely to elicit worry, symptoms of anxiety, and depression. This can be exacerbated by self-isolation and quarantine measures, physical distancing, and working remotely. COVID-related medical worries include the fear of infection, fear of the healthcare system being overloaded, and fear that either oneself or close others who contract COVID-19 syndrome will have a severe, chronic, or potentially fatal COVID-19 course [7–9]. Non-medical worries include negative repetitive thoughts about one’s general life situation, as well as psychosocial and socioeconomic consequences of the crisis [7–9].

Worrying as a form of future-oriented negative thinking is characterized by repetitive thoughts and images that are negative affect-laden, perceived as difficult to disengage from, and focused on negative content [10, 11]. Negative repetitive thoughts about the future are a transdiagnostic risk factor for the development and maintenance of depression and anxiety disorders [12], and partly explain their comorbidity [13]. Therefore, interventions targeting worrying might reduce psychological distress and positively affect symptoms of depression and anxiety. Moreover, transdiagnostic interventions are one way to reach the broader population [14].

From a public mental health perspective, it is important to reach the broader population with low-threshold, easily accessible interventions that can be delivered on a large scale and by keeping physical distance. Accordingly, early in the pandemic, the World Health Organization (WHO) published educational material for mental health protection on the internet, including advice for individuals to, for example, limit worry and focus on self-efficacy

in the face of adversity [15]. There is meta-analytic evidence supporting the premise that psychoeducation is effective at reducing psychological distress and depression [16]. Internet-based self-help interventions also have the potential to reach a large group of distressed individuals. Other meta-analytic evidence suggests that internet-based self-help interventions reduce distress both in the general population [17] and in subclinical settings [18]. As such, this approach has the potential to provide help for the general population to cope with worries in the pandemic [19]. However, in these meta-analyses a high degree of heterogeneity was identified, revealing beneficial effects for only some interventions [17].

For the current pandemic, Wahlund et al. developed a self-help internet intervention targeting medical and non-medical COVID-19 worries [20]. In a population with excessive COVID-19-related worries and already existent losses in psychosocial function, these investigators detected greater reductions in the symptoms of generalized anxiety disorder (GAD) in the intervention as compared to a non-active waitlist control group. Conversely, in a general population sample, a digitally delivered expressive writing exercise led to increased psychological distress [21]. Taken together, while the first study supports the notion that self-help internet interventions might be effective, the second study suggests that interventions proven effective in other settings might not in the current pandemic, implying that careful adaptation offering a variety of exercises and using multiple behavioral change techniques [22] may be needed.

Our research group has developed several cognitive-behavioral internet interventions over the last decade, serving as a construction kit for rapid new development. Building upon these interventions [23–25] and newly developed components, the intervention *get.calm* and *move.on* (GCMO) was created. GCMO is a cognitive-behavioral unguided self-help internet intervention with ten daily lessons. The aim of the current study was to evaluate the effectiveness of this novel program in reducing worry in the general population relative to internet-delivered psychoeducation.

## Materials and Methods

### *Study Design*

The current study was conducted as a two-arm, parallel, randomized controlled trial (RCT) at the Leuphana University of Lüneburg, Germany. The study was approved by the Ethics Committee of the University of Lüneburg, Germany and the protocol registered at the German Clinical Trials Registry (DRKS), the pri-

mary German WHO registry (reference number: DRKS00021153). The study is reported in accordance to the CONSORT statement for nonpharmacological treatment trials.

### *Participants*

Eligibility criteria were: (a) age 18 years or older, (b) no reported acute suicidal tendencies, and (c) no history of psychotic or dissociative symptoms. Participants were recruited mainly via reports in different media and social networks. No further inclusion or exclusion criteria were employed to facilitate access to the intervention for all interested individuals in the general population.

### *Randomization and Masking*

Individuals were randomly assigned, using a computer-generated randomization list with a ratio of 1:1 and block size of two, to receive either GCMO, a cognitive-behavioral self-help internet intervention developed to reduce worries during the COVID-19 pandemic (intervention group), or internet-delivered psychoeducational advice on how to protect one's mental health (control group, mental health advice waiting group: MHA-W). Group allocation was conducted anonymously, with no personal contact between study personnel and participants. Blinding of participants was infeasible.

Participants in the GCMO group received immediate access to the intervention. Individuals in the MHA-W group were referred to a mental health advice website but granted access to the GCMO program after the 2-week follow-up assessment.

### *Procedures*

Participants expressing their interest on the program's landing page (<https://geton-training.de/get-calm-and-move-on/>) were directed to a baseline questionnaire. Data collection was conducted online and occurred at baseline (T1) and after the intervention was completed (2 weeks after randomization, T2). Following the T2 assessment, the MHA-W group received access to the intervention. To assess the stability of the effects, we conducted a 2-month follow-up (T3) and a 6-month follow-up (T4) in both groups. Prior to completing the baseline questionnaire, participants were provided further information regarding the conditions of their participation, as well as details about the processing and handling of personal data. After individuals gave their written consent, inclusion criteria, demographic variables, and other outcome measures were assessed.

The GCMO program consists of ten daily sessions, each averaging 30–45 minutes in duration. The sessions include psychoeducational and cognitive-behavioral exercises that focus on maintaining daily structure, values-based behavioral activation, strategies to mentally disengage from worries, problem solving, relaxation, sleep hygiene, acceptance of unpleasant emotions, self-care, and the activation of personal strengths and resources. The intervention was conceptualized and newly developed against the background of the pandemic in March 2020. We have made extensive adaptations to the COVID-19 pandemic (see online suppl. Table 2; see [www.karger.com/doi/10.1159/000521302](http://www.karger.com/doi/10.1159/000521302) for all online suppl. material). The intervention was designed to be an interactive self-help program, incorporating instructional videos, audio-guided imagination exercises, reading and writing sections, individualized feedback, and virtual companions (persona) to serve as role models for coping with problems related to the pandemic. The intervention did not include any guidance or human support. In

order to enable replication [26], the components of the treatments are described in more detail in online supplementary Table 1.

The MHA-W group received official mental health recommendations on how to cope mentally with the pandemic from the German Society for Psychiatry and Psychotherapy, Psychosomatics and Neurology (see online suppl. Table 3). These recommendations (around 600 words and 3 minutes reading time) inform about the importance of a daily structure, social contact, acceptance of negative emotions and strengthening of positive emotions, and stimulus control to assimilate COVID-19-related news. The advice covers topics comparable to the WHO recommendations provided in "Coping with stress during the 2019-CoV outbreak," but in a more detailed manner. Those in the MHA-W group were informed that they would receive access to the same intervention that the GCMO group received after T2. The GCMO group did not receive the information that was provided to the MHA-W group. Both interventions advised individuals to contact physicians or psychotherapists and seek usual care if symptom deterioration occurred or if the low-threshold intervention was perceived to be unsatisfactory. The GCMO intervention made use of 19 different behavioral change techniques [22] as compared to two in the information given to the MHA-W group (see online suppl. Table 4). Therefore we expected that participants in the GCMO group were more likely to actually implement techniques and thus more likely for greater improvement on mental health outcomes.

### *Outcomes*

The pre-specified primary outcome was level of worry, measured using the German version of the Penn State Worry Questionnaire (PSWQ) [27]. This scale consists of 15 items (e.g., "My worries overwhelmed me.") and has a total score that ranges from 0 to 90. Scores  $\geq 32.3$  can be regarded as moderate-high worry, scores  $\geq 53.4$  as high worry [28] (for details see online suppl. Tables 5 and 6).

Secondary outcomes included generalized anxiety severity, measured using the seven-item version of the Generalized Anxiety Disorder (GAD-7) scale, which has a total score that ranges from 0 to 28 [29]. A score  $\geq 10$  indicates moderate or severe levels of anxiety. Depression severity was measured with the eight-item version of the Patient Health Questionnaire (PHQ-8) depression scale [30], with a total score ranging from 0 to 24. A total score  $\geq 10$  indicates clinically significant levels of depression. Resiliency was measured with the Brief Resilience Scale (BRS) [31], consisting of six items, with a total score from 6 to 30. Well-being was measured with the WHO-5 well-being index [32], consisting of five items, with a total score between 0 and 25. Self-efficacy was measured with the General Self-Efficacy Short Scale (GSES) [33], consisting of three items, with a total score ranging from 3 to 15. To measure emotion regulation skills, the 27-item Emotion Regulations Skills Questionnaire (ERSQ) was used [34], for which total scores range from 0 to 108. Bivariate correlations of outcome variables to assess incremental validity [35] at T1 are depicted in online supplementary Table 7. To measure clients' satisfaction with the intervention, a validated version of the Client Satisfaction Questionnaire, adapted to the online context, was used (CSQ-I) [36]. The CSQ-I consists of eight items, with a total score ranging from 0 to 32, with higher values corresponding to greater satisfaction. Demographic variables and COVID-19 infection status were collected at baseline.



### Statistical Analysis

For our sample size calculation, we followed DELTA guideline recommendations and specified the target difference between groups by considering both the practical importance of the effect and how realistic these effects are, based on meta-analytic evidence on the effects of online self-help interventions on anxiety for universal prevention [17]. Assuming that a difference of 3 points in the primary outcome is a meaningful and realistic effect, with a standard deviation of 10 points [27], we hypothesized a minimal clinically important difference between groups of  $d = 0.30$  at post-intervention. Under these assumptions, a total (2-group) sample size of  $N = 352$  individuals was deemed necessary to detect the assumed effect with 80% power and a two-tailed significance level of 5%.

Data analysis was performed using the statistical software program R (Version 1.3.959). A two-tailed significance level of  $p \leq 0.05$  was used for all inferential tests. Data were analyzed employing the intention-to-treat (ITT) principle. Missing data were estimated with multiple imputations, with 20 estimates calculated for each missing value. Imputed data sets were analyzed separately and the parameter estimates and hypothesis tests ultimately pooled. Existing data on the primary and secondary outcomes, as well as the grouping variable and sociodemographic variables, were used in the imputation model.

Considering analysis strategy, simulation studies demonstrated that analyses of covariance (ANCOVA) modeling would be more effective than either analysis of variance (ANOVA) or linear mixed modelling [37]. Accordingly, ANCOVA was employed to evaluate between-group differences at T2, including participant's baseline values as a covariate. To control for pandemic effects, each participant's and their significant other's COVID-19 infection status and the participant's time of registration for the intervention also were included as covariates. Between-group Cohen's  $d$  values were calculated using pooled estimated marginal means and standard deviations.

For endpoints related to the two mental disorders of interest, using the GAD-7 anxiety and PHQ-8 depression scales, we calculated the number of participants reporting clinically relevant levels of symptoms, levels defined as scores equal to or above the clinical thresholds of 10 for the GAD-7 and 10 for the PHQ-8 at T2. Additionally, we calculated the number of participants reporting a 50% reduction in their symptoms of generalized anxiety and depression at T2. Numbers needed to treat (NNT) to achieve one clinical response in anxiety and in depression were then derived for both interventions.

To measure adverse effects, clinically significant deterioration was measured following a recently conducted individual participant meta-analysis on the side effects of internet interventions [26, 38]. Accordingly, deteriorations from T1 to T2 of  $\geq 20.71$  points on the PSWQ,  $\geq 5.36$  points on the PHQ-8, and  $\geq 5.25$  on the GAD-7 were defined as adverse effects.

Exploratory moderation analysis was conducted to assess if baseline scores moderated the intervention's effect. Additionally, the Johnson-Neyman procedure was used to identify regions of significance.

The medium- and long-term effects were analyzed in a descriptive manner. Means, standard deviations, within-group change to baseline, and between-group Cohen's  $d$ s were calculated.

### Results

The trial flow is depicted in Figure 1. The first participant enrolled on April 7, 2020 and the last participant on December 10, 2020. Of the 610 individuals who applied for participation, 372 filled out both the baseline and screening questionnaires. Of these, 352 were randomized to either the GCMO ( $n = 175$ ) or MHA-W ( $n = 176$ ) group. The last participant was randomized on December 11, 2020. The last participant out was on July 11, 2021. Due to an administrative error, one participant was randomized despite an age below the minimum 18 years required for study inclusion and was later excluded from the study.

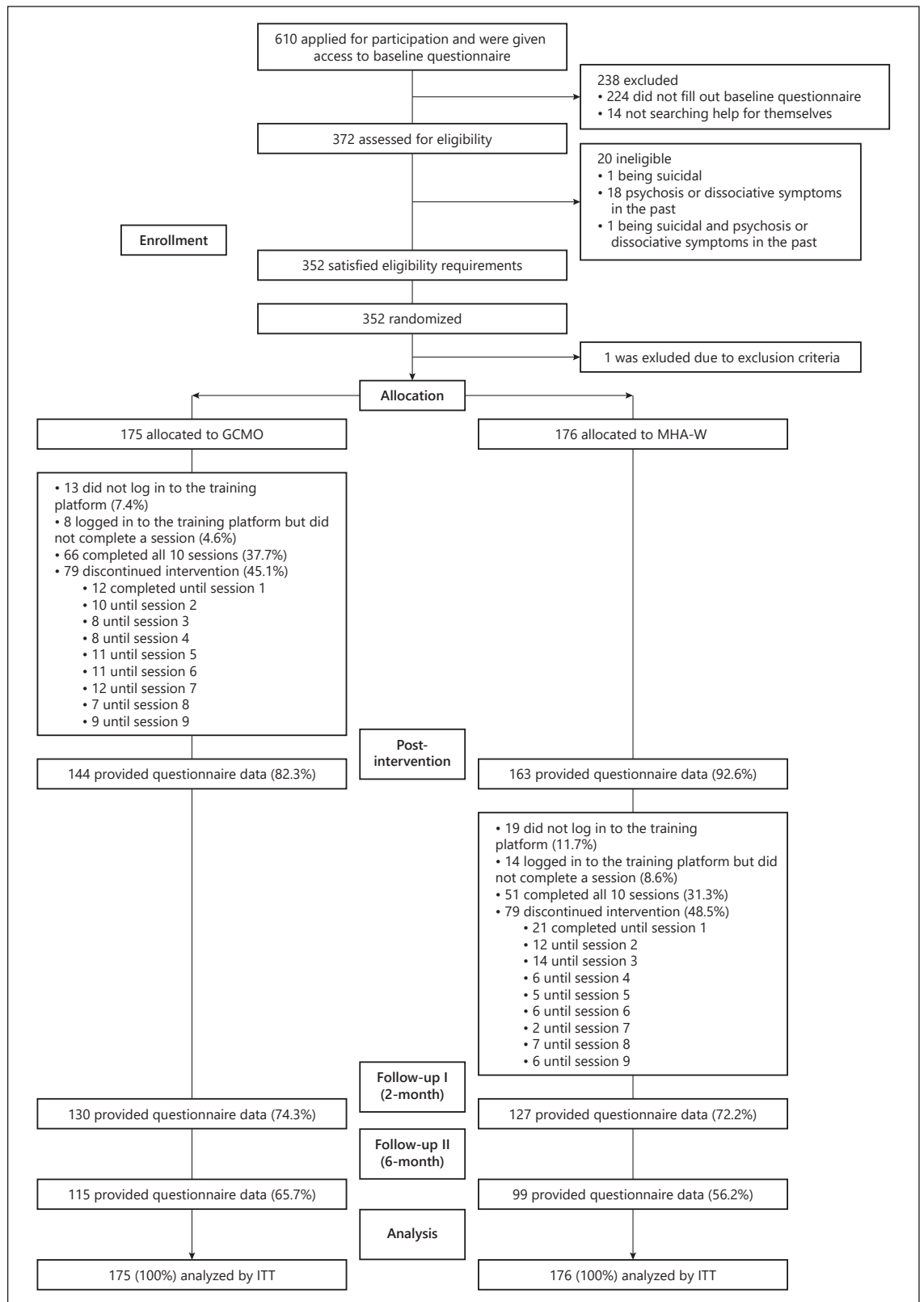
Table 1 summarizes the sample's baseline characteristics. On average, 6.2 (61.5%) of the ten GCMO sessions were completed ( $SD = 3.9$ ). Roughly 15% of the study participants reported actual infection with SARS-CoV-2 among close personal contacts, while 84% reported worrying about the possibility of infection among loved ones, 55% about themselves becoming infected, 43% about financial issues, and 31% about job insecurity caused by the pandemic. Further COVID-19-related worries at baseline and T2 are presented in online supplementary Table 8.

Overall, data were missing for the primary outcome for 12.5% of all participants at T2 (GCMO: 17.7%; MHA-W: 7.4%). At T2, individuals in the GCMO group reported significantly less worry than those in the MHA-W group ( $F_{1,219} = 12.9$ ;  $p < 0.001$ ;  $\Delta = 5.0$  points;  $d = 0.38$ ; see Table 2). Moderation analysis revealed a significant group-by-baseline interaction for PSWQ baseline scores (est =  $-0.29$ ; SE = 0.08;  $t$  value<sub>279,6</sub> =  $-3.3$ ;  $p < 0.001$ ). Probing this effect with the Johnson-Neyman procedure revealed a baseline PSWQ score of 49.4 (95% CI 48.9; 50.0), as the point of transition between a statistically nonsignificant and significant effect of GCMO, relative to MHA-W, on the PSWQ score at T2. This means that a significant between-group difference was identified for participants scoring 49.4 or greater on the baseline PSWQ score. This corresponds to 73.8% ( $n = 259$ ) of all study participants.

Per-protocol analysis, restricting analysis to participants who completed nine or more of the ten sessions (number of participants analyzed: GCMO:  $N = 75$ ; MHA-W:  $N = 176$ ) supported the results obtained with ITT analysis, but generated slightly larger effect sizes at T2 ( $F_{1,241} = 19.9$ ;  $p < 0.001$ ;  $d = 0.43$ ).

Significant between-group differences also were identified for all secondary outcomes, except for self-efficacy. Specifically, generalized anxiety ( $d = 0.48$ ) and depressive





**Fig. 1.** Flow of participants. GCMO, get.calm and move.on, intervention group; MHA-W, mental health advice waiting group.

**Table 1.** Baseline characteristics of the sample

		Total (N = 351)		GCMO (n = 175)		MHA-W (n = 176)	
		N	%	n	%	n	%
Age (M/SD)		42.6	14.3	43.0	14.1	42.2	14.4
Sex	Men	60	17.1	30	17.1	30	17.0
	Women	289	82.3	144	82.3	145	82.4
	Other	2	0.6	1	0.6	1	0.6
Relationship	Single	90	25.6	42	24.0	48	27.3
	In partnership or married	232	66.1	125	71.4	107	60.8
	Divorced or separated	24	6.8	6	3.4	18	10.2
	Widowed	5	1.4	2	1.1	3	1.7
Having children	Yes, living in same household	84	23.9	40	22.9	44	25.0
	Yes, living in other household	60	17.1	26	14.9	34	19.3
	No	207	59.0	109	62.3	98	55.7
Educational degree	None yet	37	10.5	19	10.9	18	10.2
	Apprenticeship training	41	11.7	19	10.9	22	12.5
	Technical college	27	7.7	14	8.0	13	7.4
	University (of applied sciences)	246	70.0	123	70.3	123	69.9
Employment status	Full-time working	167	47.6	76	43.4	91	51.7
	Part-time working	74	21.1	41	23.4	33	18.8
	On sick leave	8	2.3	2	1.1	6	3.4
	Nonworking	34	9.7	20	11.4	14	8.0
	Unemployed/seeking work	17	4.8	9	5.1	8	4.5
	Student	51	14.5	27	15.4	24	13.6
Experience with psychotherapy	Yes, in the past	168	47.9	88	50.3	80	45.5
	Yes, currently in therapy	40	11.4	20	11.4	20	11.4
	No, never	135	38.5	64	36.6	71	40.3
	No, but on the waiting list	8	2.3	3	1.7	5	2.8
COVID-19 infection status	Yes, infection confirmed by test	2	0.6	–	–	2	1.1
	Yes, but not confirmed by test	10	2.8	5	2.9	5	2.8
	No, not infected	339	96.6	170	97.1	169	96.0
People close to me had COVID-19	Yes	52	14.8	22	12.6	30	17.0
	No	299	85.2	153	87.4	146	83.0
PSWQ scores	PSWQ <32.3	28	8.0	13	7.4	15	8.5
	PSWQ ≥32.3	97	27.6	50	28.6	47	26.7
	PSWQ ≥53.4	226	64.4	112	64.0	114	64.8
PHQ-8 scores	PHQ-8 <10	142	40.5	70	40.0	72	40.9
	PHQ-8 ≥10	209	59.5	105	60.0	104	59.1
GAD-7 scores	GAD-7 <10	143	40.7	75	42.9	68	38.6
	GAD-7 ≥10	208	59.3	100	57.1	108	61.4

PHQ-8, Patient Health Questionnaire; GAD-7, Generalized Anxiety Disorder; GCMO, intervention group; MHA-W, mental health advice waiting group. Symptoms of worrying based on PSWQ-scores: moderate-high worry ≥32.3; high worry ≥53.4 Classification has been calculated by transformation of cut-off scores derived from Korte et al. [28], for details see online supplementary Tables 7 and 8. Symptoms of depression based on PHQ-8 scores: no or mild depressive symptoms <10, moderate or severe depressive symptoms ≥10. Symptoms of depression based on PHQ-8 scores: no or mild depressive symptoms <10, moderate or severe depressive symptoms ≥10. Levels of anxiety symptoms based on GAD-7 scores: no or mild anxiety symptoms <10, moderate or severe anxiety symptoms ≥10. For more detailed classification of PHQ-8 and GAD-7 scores please see online supplementary Table 9.

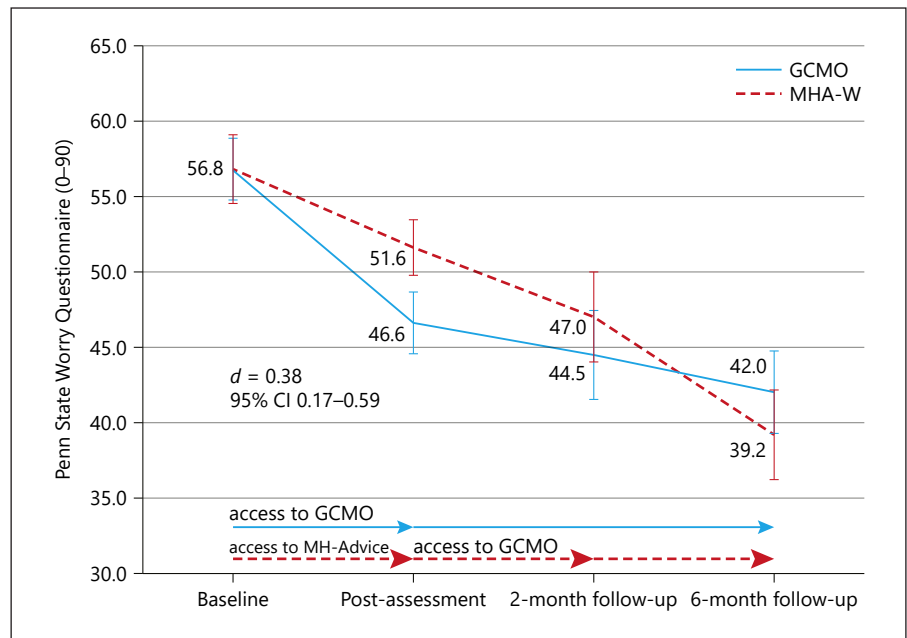
**Table 2.** Means and standard deviations of the outcomes, results of ANCOVAs, and Cohen's *ds* for primary and secondary outcomes – intention to treat sample

		GCMO		MHA-W		ANCOVA		Effect size
		Mean (SD)	Δ T1	Mean (SD)	Δ T1	<i>F</i> <sub>(df)</sub>	<i>p</i>	<i>d</i> (95% CI)
PSWQ	T1	57.2 (13.9)		56.3 (15.4)		12.9 <sub>(1,219)</sub>	<0.001	0.38 (0.17–0.59)
	T2	46.6 (13.8)	–10.3	51.6 (12.4)	–5.1			
	T3 <sup>a</sup>	44.5 (20.0)	–12.5	47.0 (20.0)	–9.4			
	T4 <sup>a</sup>	42.0 (18.5)	–15.0	39.2 (20.0)	–17.4			
GAD-7	T1	11.2 (4.5)		11.4 (4.7)		19.9 <sub>(1,200)</sub>	<0.001	0.48 (0.26–0.69)
	T2	7.9 (4.0)	–3.3	9.8 (3.7)	–1.6			
	T3 <sup>a</sup>	8.3 (5.8)	–2.9	8.8 (6.0)	–2.6			
	T4 <sup>a</sup>	7.1 (6.0)	–4.1	7.5 (6.4)	–3.8			
PHQ-8	T1	10.8 (5.0)		10.9 (4.7)		18.3 <sub>(1,141)</sub>	<0.001	0.47 (0.26–0.68)
	T2	8.0 (4.3)	–2.8	10.0 (3.8)	–0.9			
	T3 <sup>a</sup>	8.5 (6.4)	–2.4	8.8 (6.6)	–2.1			
	T4 <sup>a</sup>	7.7 (6.7)	–3.2	7.8 (6.8)	–3.1			
BRS <sup>b</sup>	T1	15.9 (4.2)		16.8 (4.8)		4.4 <sub>(1,250)</sub>	0.037	0.22 (0.01–0.43)
	T2	18.0 (3.3)	1.7	17.3 (3.1)	0.7			
	T3 <sup>a</sup>	17.7 (5.1)	1.5	17.9 (4.9)	1.4			
	T4 <sup>a</sup>	18.4 (5.1)	2.2	18.4 (4.8)	1.9			
GSES <sup>b</sup>	T1	10.1 (2.3)		10.3 (2.4)		0.4 <sub>(1,167)</sub>	0.522	
	T2	10.7 (1.9)	0.6	10.8 (1.8)	0.6			
	T3 <sup>a</sup>	10.5 (2.7)	0.3	11.0 (2.6)	0.7			
	T4 <sup>a</sup>	11.2 (2.7)	1.1	11.7 (2.4)	1.4			
WHO-5 <sup>b</sup>	T1	7.7 (4.0)		7.9 (4.7)		14.9 <sub>(1,156)</sub>	<0.001	0.40 (0.61–0.19)
	T2	10.7 (4.8)	2.9	8.9 (4.1)	1.1			
	T3 <sup>a</sup>	10.5 (6.2)	2.7	10.4 (6.6)	2.5			
	T4 <sup>a</sup>	11.0 (7.1)	3.2	12.1 (7.7)	4.3			
ERSQ <sup>b</sup>	T1	53.5 (15.8)		55.3 (17.5)		23.8 <sub>(1,190)</sub>	<0.001	0.52 (0.74–0.31)
	T2	65.1 (14.4)	10.8	57.8 (13.5)	3.2			
	T3 <sup>a</sup>	64.0 (21.4)	10.0	63.8 (20.6)	9.1			
	T4 <sup>a</sup>	67.4 (22.0)	13.3	67.6 (23.3)	12.9			

PSWQ, Penn State Worry Questionnaire; PHQ-8, Patient Health Questionnaire; GAD-7, Generalized Anxiety Disorder Scale; BRS, Brief Resilience Scale; GSES, General Self-Efficacy Short Scale; WHO-5, WHO-5 well-being index; ERSQ, Emotion Regulations Skills Questionnaire; GCMO, intervention group; MHA-W, mental health advice waiting group; T1, baseline; T2, post-intervention (2 weeks); T3, follow-up I (2 months); T4, follow-up II (6 months). Reported data is from the intention-to-treat sample. Therefore missing data was imputed by multiple imputations. Pooled estimated marginal means are reported. Scores for differences to baseline (Δ T1) refer to imputed, but unadjusted means at T1, T2 or T3. <sup>a</sup>The MHA-W group received the GCMO intervention after T2. For T3 and T4 no between-group differences were expected. <sup>b</sup>Higher values represent better outcomes.

symptoms ( $d = 0.47$ ) were reduced more at T2 in the GCMO than MHA-W group. The distribution of participants into the different categories of symptom severity for worry, depression, and anxiety at all measurement points is depicted in online supplementary Tables 5 and 9. Emotional regulation skills ( $d = 0.52$ ), general well-being ( $d = 0.40$ ), and resiliency ( $d = 0.22$ ) also were increased at T2 in the GCMO versus MHA-W group. At T2, 74.7% of the participants assigned to the GCMO program reported no

clinically relevant generalized anxiety symptoms ( $n = 130.8$ ), versus 47.4% ( $n = 83.4$ ) among their MHA-W counterparts, a difference that was highly significant ( $\chi^2(1) = 24.1$ ;  $p < 0.001$ ). This corresponded to a NNT of 3.7 (95% CI 2.7; 5.7) for one additional participant to experience a reduction in their GAD-7 score at T2 to non-clinically relevant status. At T2, 69.1% of GCMO group subjects reported no clinically relevant symptoms of depression ( $n = 120.9$ ), versus 45.3% ( $n = 79.7$ ) in the MHA-



**Fig. 2.** Estimated means with 95% confidence intervals on the primary outcome measure (intention-to-treat;  $N = 351$ ). The MHA-W group received the GCMO intervention after T2. For T3 and T4 no between-group differences were expected. Penn State Worry Questionnaire (scale 0–90).

W group. This between-group difference in clinically relevant symptoms of depression also was significant ( $\chi^2(1) = 17.3$ ;  $p < 0.001$ ). This corresponds to a NNT of 4.2 (95% CI 3.0; 7.3) for one additional participant to achieve a reduction in their PHQ-8 score at T2 to non-clinically relevant status. Proportions of participants experiencing at least a 50% reduction in their symptoms relative to baseline are listed in online supplementary Table 10. Corresponding NNTs were 5.8 (95% CI 3.9; 10.9) for generalized anxiety disorder and 4.7 (95% CI 3.4; 7.5) for depression.

The client satisfaction questionnaire was completed by 76.0% of those allocated to the GCMO ( $n = 133$ ). Overall satisfaction with the intervention was comparable to that reported for other, previously studied interventions ( $M = 26.6$ ,  $SD = 5.3$ , range = 8–32) [36]. In an “overall, general sense,” 56.4% ( $n = 75$ ) were very and 34.6% ( $n = 46$ ) mostly satisfied with the intervention they received, while 5.3% ( $n = 7$ ) were mildly and 3.8% ( $n = 7$ ) quite dissatisfied. The majority of the participants rated the sessions as rather or completely helpful with no clear preference for a particular session and about 85 to 95% reported to have actually conducted the exercises offered in the particular sessions (see online suppl. Tables 12 and 13). The majority (82.7%) stated that they would have preferred a longer interval between sessions than the recommended one session per day. This preference was also expressed in the analysis of open text fields, in which participants were asked about possible improvements (see online suppl. Table 14). The

majority (67.7%) indicated that it would have been optimal for them to have one session every 3 to 4 days. With regard to implementation to daily life, participants most frequently (43%) planned to continue using some form of gratitude exercise in the final session for their future (see online suppl. Table 15). The majority (85.7%) of the GCMO group at T2 claimed to have applied the exercises they had learned in the program in the past week, with 51.1% reporting using the exercises on occasional days, 21.1% on more than half of the days, and 13.5% almost every day.

A clinically significant deterioration at T2 in worrying was observed in 2 (1.2%), in anxiety symptoms in 3 (1.5%), and in depressive symptoms in 4 individuals (2.5%) in the GCMO group, versus 1 (0.6%), 4 (2.2%), and 8 (4.7%), respectively, in the MHA-W group. For respective numbers at T3 and T4, please see online supplementary Table 11.

With regards to mid- and long-term effects, Table 2 shows that the improvements made until T2 were maintained or extended until the 2-month (PSWQ = 44.5; change  $-12.5$ ) and 6-month follow-ups (PSWQ = 42.3; change  $-14.7$ ) for the GCMO group. After the MHA-W group had received the GCMO intervention following T2, the intensity of worry further decreased at 2-month (PSWQ = 47.0; change  $-9.4$ ) and 6-month follow-up (PSWQ = 40.7; change  $-15.8$ ). Differences between groups at 2-month ( $d = 0.12$ ) and 6-month follow-up ( $d = -0.07$ ) did not exceed the predefined minimal clinically important difference of  $d = 0.30$ .

Also see Figure 2 for the development of PSWQ scores over time. At T3 and T4 usage of the exercises did not differ between groups. 69.7% of the participants at T3 (59.1% at T4) claimed to have applied the exercises they had learned in the program in the past week, with 56.2% (48.3% at T4) reporting using the exercises on occasional days, 8.0% (5.7% at T4) on more than half of the days, and 5% (5.1% at T4) almost every day.

## Discussion

We found that the internet-based self-help intervention get.calm and move.on (GCMO), tailored to the COVID-19 pandemic, was effective at reducing worry to a larger extent compared to controls receiving officially endorsed internet-delivered advice to protect mental health during the pandemic and delayed access to GCMO. Additionally, we observed superior effectiveness of the GCMO program, in terms of reducing the symptoms of anxiety and depression, and the number of individuals who fell below the threshold of clinically significant symptoms for both mental conditions. Moreover, effects could be maintained up to 6 months. Other beneficial effects observed were enhanced emotional competency coping with stress, and increased resilience and well-being, though no effect on self-efficacy was apparent. Despite the program's rapid and low-budget development, over 90% of the participants assigned to the GCMO program were satisfied with the intervention's quality.

To our knowledge, this study is the first to investigate an internet-based self-help intervention, accessible to the general population, developed to reduce worry during the COVID-19 pandemic. Results demonstrated rapid, clinically meaningful, and greater-than-expected relief in psychological distress in a most challenging situation. The study was designed from a public health and prevention perspective. As such, we focused primarily on worry reduction as an important risk factor and considered any psychopathology that might result from it [12], like depression and generalized anxiety disorder, as secondary outcomes, while the study reported by Wahlund and colleagues [20] focused on psychopathology. Given its different focus, the present study minimized inclusion criteria to mimic a universal prevention approach targeting the general population, contrary to Wahlund et al., who employed more restrictive eligibility criteria to assess a more indicated prevention strategy [20], excluding individuals with lower levels of wor-

ry. While the effects were slightly higher for generalized anxiety disorder (GAD) symptoms in the latter study ( $d = 0.74$  vs.  $d = 0.48$  for GCMO), the effects were more similar for depressive symptoms ( $d = 0.38$  vs.  $d = 0.47$  GCMO). The latter study's greater effect on anxiety might be explained by both the higher level of GAD symptoms in the selected sample and, more importantly, the study's use of a non-active control group [39]. A strength of the present study was its inclusion of internet-delivered mental health advice in the waiting condition, covering topics similar to WHO recommendations, provided by the leading national association for psychiatry and psychotherapy. Descriptive data demonstrated a reduction of 5.1 points in worry from pre to post amongst controls in the MHA-W group. This is consistent with meta-analytic evidence suggesting beneficial effects of psychoeducation on depressive and stress-related symptoms [16], and might indicate the effectiveness of providing mental health advice from trusted and credible sources (i.e., national medical associations or the WHO) to the general population. Putting the effects of GCMO into the context of meta-analytic evidence for internet interventions targeting the general population in non-pandemic settings, the present effect sizes compare favorably for both anxiety ( $d = 0.31$ ) and depression ( $d = 0.25$ ) [17]. Likewise, the antidepressant effects of GCMO were slightly greater than those calculated in an individual-participant meta-analysis of self-help and therapist-guided internet interventions designed to target subclinical depression ( $g = 0.39$ ) [18], and self-help interventions providing treatment to patients suffering from depression ( $d = 0.33$ ) [40]. The number of individuals that must be treated to observe an additional clinically significant effect (NNT) of either a 50% reduction in depression symptoms or scoring below the clinical threshold for symptoms, also was superior for GCMO than the programs assessed in the aforementioned meta-analyses [18]. One reason for GCMO's superior beneficial effects might be its adherence to the recommendation for tailored information [41] and the variety of exercises and behavioral change techniques [22] offered. Accordingly, the intervention was adapted carefully to meet participants' needs in the current pandemic situation (see online suppl. Table 2). The importance of such adaptation was previously highlighted by Vukčević and colleagues [21], who found unexpected adverse effects in a stand-alone expressive writing exercise during the COVID-19 pandemic. They attributed these adverse effects to neglecting that COVID-19-related stressors were constantly present during the inter-



vention and expressive writing usually focusses on past stressors. Additionally, more comprehensive digital interventions comprising various exercises like the program of Wahlund and colleagues [20] or GCMO might be more effective as they allow greater personalization compared to offering a single exercise [42]. In accordance with the literature, we defined adverse effects as clinically significant deteriorations in the symptoms of depression and generalized anxiety [38], and both were infrequently observed in either treatment condition. Even amongst the controls, the proportion of individuals with adverse effects did not exceed the rate of adverse effects observed among active intervention groups (5.8%) in a recent individual-participant meta-analysis on the potential harmful effects of self-help internet interventions [38]. Notably, the same meta-analysis detected adverse effects in more than 9% of non-treated controls, highlighting the importance of providing at least a minimal level of intervention to participants in control groups.

Another strength of the present study is the assessment of mid- and long-term effects. The rapid and clinically meaningful relief after 2 weeks was maintained until the 2- and 6-month follow-up with a tendency of further improvement over time. Likewise, after the control group completed the GCMO intervention at T3 the effects were maintained at T4. It also appears noteworthy that nearly 60% of all participants at the 6-month follow-up reported to have used the strategies learned in the intervention in the last week. The stability of effects is in line with meta-analytic results for internet interventions for subthreshold depression [18] and may indicate that participants were able to successfully implement the strategies learned in this self-help intervention into everyday life. Our results suggest that gratitude exercises seem particularly popular with regard to implementation in daily life and may have contributed to the sustainable symptom reductions in worrying [25]. Since we designed the GCMO intervention to be accessible to anyone in the general population, it is itself of interest who elected to enroll in our study. First, the sociodemographic characteristics of our sample were similar to the sample population studied by Wahlund et al. [20]. Prior meta-analyses on internet interventions failed to consistently identify evidence to implicate subject gender, age, employment status, level of education, or past experience with psychotherapy as moderating variables [18, 40]. Second, the medical (i.e., fear of infection) and non-medical (i.e., fear of financial worsening) COVID-related worries reported by our participants confirm results from observational studies re-

porting psychological distress due to insecure life situations [7–9], and indicate that it was possible for us to access our intended target group with GCMO. Third, the high proportion of individuals with a history of psychotherapy and elevated symptoms of depression and anxiety indicates that the intervention reached a population with increased vulnerability. Finally, consistent with prior research involving non-clinical samples, higher levels of symptom severity at baseline predicted stronger effects of the internet interventions [18]. One advantage of the Johnson-Neyman technique we employed in our present analysis is that it specifies a threshold defining when an intervention has achieved a significant beneficial effect. Accordingly, individuals with PSWQ scores of 50 or more are likely to benefit more from the more intensive GCMO intervention than from mental health advice. This is an important finding, as it suggests that internet-delivered mental health advice is useful for those with lower levels of mental health complaints. However, public health strategies for mental health protection during a major pandemic should not be limited to recommendations, but be complemented with evidence-based self-help interventions for individuals with elevated levels of worry. Get.calm and move.on is, due to its self-help nature, a highly scalable internet-based intervention for the general population. It could be implemented at low costs as a preventive routine program, making an evidence-based intervention accessible for low- and middle-income countries, where resources are limited. As other public health interventions during the pandemic, such as vaccination or testing, are often disseminated by national or international health authorities, it seems worthwhile to augment these actions with public mental health measures, including interventions such as GCMO. However, recent meta-analyses suggest that internet-based interventions, when offered as part of routine care, show smaller effectiveness, which is partly due to reduced adherence [43, 44]. To prevent the loss of adherence future research should therefore investigate whether additional motivational features [42] or the provision of human support increases the effectiveness in real-world settings.

Several limitations of our study must be considered. First, we did not include a third, non-treatment condition. Therefore, convincing conclusions about the effectiveness of the mental health advice that was offered are impossible, despite positive effects being observed from pre- to post-intervention. Based on existing evidence on psychoeducation and the perceived urgency for psychological support, we considered a non-treatment condition ethically inappropriate. Second, we conducted the

post-intervention assessment very short-term, just 2 weeks after randomization. This was driven by ethical considerations and our aim to keep the waiting time for the control group as short as possible, since we expected that GCMO would most likely be of benefit to the participants. The majority of the participants stated that they were hardly able to adhere to the protocol of one session per day and preferred to practice the proposed strategies to cope with worry over a longer period of time. As a consequence of this short interval, the GCMO program's effects might have not become fully manifest, potentially underestimating the intervention's effectiveness. On the other hand, other researchers have found that effects develop rapidly within the first phase of an intervention [45]. Third, the levels of threat and hardship posed by the pandemic changed significantly over time, and moderating effects of the pandemic's various phases on GCMO's effectiveness cannot be excluded. However, statistically controlling for time and the infection status of both participants and their close contacts revealed no indication of such an effect. Fourth, replication is needed to further support these findings.

## Conclusion

The current study's results suggest that a carefully adapted internet-based self-help intervention can be effective, even in extraordinary circumstances like a major pandemic. It sheds light on the heterogeneous findings on the effectiveness of internet-based self-help in general [40] and particularly on the previous mixed findings for interventions targeting mental health in the pandemic [20, 21]. Interventions delivered over the internet are particularly helpful when physical distancing is mandated, a characteristic that may be especially important among those who fear face-to-face contact due to the heightened risk of infection. GCMO also provides fast and meaningful relief from worry, while simultaneously reducing the symptoms of generalized anxiety disorder and depression, thereby potentially preventing various forms of psychopathology from becoming compounded or chronic. It seems especially encouraging that participants were able to use the intervention in a way that led to stable reduction in worry up to 6 months after the intervention. Whilst mental health advice seems to be beneficial for those with average levels of worry, GCMO appears to be effective in those with more elevated levels of worry and is readily accessible to the general population at large.

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## Statement of Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. This study protocol was reviewed and approved by the Ethics Committee of the University of Lüneburg, Germany, approval number [EB-Antrag\_202003\_12\_Lehr\_getcalm]. Written informed consent was obtained from participants to participate in the study prior to baseline assessment.

## Conflict of Interest Statement

H.H., D.L., and L.B. declare no competing interests.

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Leuphana University of Lüneburg informed about the study in a press release and had no further role in study design; data collection, analysis, or interpretation; or writing of the report. There was no external funding source for this study.

## Author Contributions

H.H. initiated the study, developed and programmed the intervention, conceptualized the study, contributed to the literature search, was responsible for designing and programming the study and instruments, was the trial manager, prepared, analyzed, and interpreted the data, wrote the first draft, and critically reviewed and edited the manuscript. D.L. developed and programmed the intervention, conceptualized the study, contributed to the literature search, was responsible for designing the study and its instruments, supervised the trial manager, communicated with the ethics committee, interpreted the data, wrote the first draft, and critically reviewed and edited the manuscript. L.B. conducted setup and maintenance of the technical platform, contributed to the literature search, accessed, verified, analyzed, and interpreted the data, and critically reviewed the manuscript.

## Data Availability Statement

Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and online suppl. material) will be made available upon request with researchers who provide a methodologically sound proposal.

## Intervention Sharing Statement

Researchers, public health agencies, and other non-profit organizations that intend to implement the intervention are encouraged to contact Dirk Lehr (lehr@leuphana.de) for permission to provide GCMO in any country worldwide on a free-of-charge basis.

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**Online Supplementary Material – Effectiveness of an Internet-Based Self-Help Intervention versus Public Mental Health Advice to Reduce Worry during the COVID-19 Pandemic: A Pragmatic, Parallel-Group, Randomized Controlled Trial**

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## Online Supplementary Material

Table 1

*Session content of get.calm and move.on (GCMO)*

The intervention was designed to be an interactive self-help program, incorporating instructional videos, audio-guided imagination exercises, reading and writing sections, individualized feedback, and virtual companions (persona) to serve as role models for coping with problems related to the pandemic. The intervention did not include any guidance or human support. Each session of the training was built according to a uniform structure. At the beginning of each session, participants are welcomed by an expert (HH and DL) in a video and the rationale of the session is explained. At the beginning of session 1, the virtual companions are introduced and then integrated into each new exercise in all subsequent sessions. At the beginning of each session (from session 2 onwards), participants are asked to take a “look back” at the exercises of the previous session. Here, the participants reflect on how the implementation of the exercises worked out for them, what obstacles came across and what could help in the future. This is followed by the main topics of the individual sessions which are described in the table below. The end of each session follows the same pattern. Participants can write down helpful strategies that they would like to remember in their “strategy kit”. They can view the exercises they have planned in past sessions and adapt them if necessary. They receive a preview of the content of the next session and have the opportunity to set a date when they would like to complete the next session. In a video, an expert says goodbye to the participants and optional information for further support services is offered.

Session	Description
1. Introduction and day structure	Participants are welcomed by the experts (the first authors HH and DL) in a video, the rationale and the structure of the intervention/session is explained*. Participants get to know the virtual companions that accompany the participants throughout the whole intervention and demonstrate ways to perform the exercises*. Information on positive emotional consequences of a daily structure and how to establish it is provided and participants are asked to plan their daily structure in exercises; including getting up and going to bed times, a morning routine, regular meals, fixed working times, exercising and social times. Participants are asked to plan obstacles for implementing the daily structure and collect possible solutions to overcome these. In order to facilitate the transfer of what had been learned into everyday life, at the end of each session, participants are asked to write down helpful strategies in their “strategy kit”*. They can view the exercises they have planned in past sessions and adapt them if necessary*. They are given a preview of the content of the next session and have the opportunity to set a date when they would like to complete the next session*. An expert says goodbye to the participants and praises them for engaging in the intervention and optional information for further support services is offered*.
2. Values and COVID-19-conform, value-oriented activities	At the beginning, exercises planned in the previous session are evaluated with the “looking back” exercise. Participants are asked to reflect how practising the exercises went for them and what could be helpful in continuing practicing these in the future. The “looking back”-exercise can be found at the beginning of each of the following sessions*. Information on values is given, the difference between values and goals and why values could be helpful is explained. Participants are asked to identify their most important values using checkboxes. In the checkboxes, 42 values are proposed (e.g. in the area of family relations: familiar contact in one’s own family). In addition, participants can also add their own values. After identifying one’s most important values, participants are asked to derive and plan COVID-19-conform, value-oriented activities. Participants can view the exercises they have planned in past sessions and adapt them if necessary*.

### 3. Dealing with worries

Participants receive information on the nature of worries, their association with health, the difference between worrying and problem-solving and a helpful technique to differentiate thinking and worrying (2-minute-rule). Four different techniques to deal with worries are introduced and participants are invited to try them out: Writing down worries, setting worry times, locking away worries in imagination, establishing times to check news regarding COVID-19.

### 4. Problem-solving

Worries that were written down in session 3 are displayed again and participants are asked to find labels for their worries and to distinguish them in controllable and non-controllable problems. Information on a 4-step problem-solving strategy to deal with controllable problems is given (1. acceptance of the problem, 2. breathing 5-times, 3. collecting multiple possible solutions, 4. getting started with the best solution). Participants are asked to work on one of their identified problems following the problem-solving strategy.

### 5. Regeneration and restful sleep

Information on the stress reaction and how muscle- and breathing relaxation can help with stress is given. In a quiz, participants are invited to test their knowledge on stress and are invited to train muscle- and breathing relaxation with an audio-file (that is also provided as download). Participants' experiences with the exercise are reflected. Two further relaxation techniques are offered. In the "feel-good place" imagery participants are asked to create a place in their imagination where they feel comfortable and safe and to imagine it using all their senses. In the "5-4-3-2-1-exercise", participants are asked to be aware of what they currently perceive visually, acoustically and tactilely by naming 5 (then 4, 3, 2, 1) perceptions for every sense.

Information on stress, worrying and restful sleep is given for participants reporting difficulties sleeping. In a quiz, participants' sleeping habits/sleep hygiene is assessed and information on sleep hygiene is given depending on the answers. After the provision of sleeping hygiene rules, participants are asked to develop their own solutions in order to make their bed a place of rest again. Information on the course of tension and relaxation and the helpfulness of an evening ritual is given. Participants are asked to develop their own evening ritual. Information on pressure for sleep is given and sleep restriction is explained. Exercises from the other sessions that also help with sleeping problems are repeated. At the end of the session, participants are asked to plan exercises to relax and unwind every now and then.

### 6. Coping with difficult feelings I

Information on emotions is given and different emotions are introduced. Participants are asked to identify their difficult emotions using checkboxes. In the checkboxes, 28 different terms describing emotions in different intensity are differentiated and categorized under 8 basic emotions (e.g. for fear: apprehension, jitters, being yellow, fear, panic). Participants are asked to identify and describe the emotion that currently is the most difficult and reflect where in their body they feel it and which impulse for action is associated with it. Information on the functionality of unpleasant emotions is given. Participants have the opportunity to reflect on what they think which function the basic emotions have and receive information about each of the basic emotions' function. They are then asked to think about what function the emotion has which was previously identified as the most difficult one. Information on mindful handling of thoughts is given and three different audio exercises to train detached mindfulness are provided (thoughts as clouds, thoughts as cars, thoughts as waves). Participants plan how they want to deal with emotions at that day.

### 7. Coping with difficult feelings II

The idea of temporary acceptance of unpleasant emotions is introduced and it is explained why fighting with one's unpleasant emotions could make them worse and why acceptance could be helpful in dealing with unpleasant emotions. In an expert video, a 5-step acceptance-plan is introduced and explained (1. set acceptance as a goal, 2. strengthen the goal through justification, 3. see emotions as allies, 4. becoming aware of one's own resilience, 5. becoming aware of the impermanence of emotions). Participants are asked to use the 5-step acceptance-plan for one of their difficult emotions and to summarise the plan in one sentence of

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<p>acceptance. With an audio exercise, participants first repeat the muscle- and breathing exercise (from session 5) and combine it with the acceptance exercise. The audio file is downloadable. Participants are asked to plan how to train acceptance and to set a training goal.</p> <p>8. Supporting myself</p> <p>Information on self-support and its importance is given. Participants are asked to reflect on how they support others and to then evaluate how self-support could look like. They are offered two more exercises to foster self-support. In the first exercise “focusing on one’s own helpful skills and strengths”, participants are guided to vividly recall skills that they think of as helpful in dealing with a current stressful situation. In the second audio exercise, participants are guided in four steps to develop inner imaginary helpers that could support them in dealing with the current stressful situation.</p> <p>9. Strengthening resources Keeping positive things in mind</p> <p>Information on human perception of negative and positive information is given. Participants have the opportunity to test their selective attention in perceptual experiments. Information on gratitude and its positive impacts is given. Areas where one could detect positive aspects are listed. The gratitude app is introduced, as well as a gratitude diary, a gratitude letter, a resource diary and the idea to use peas in order to become more aware of positive moments. Participants are asked to choose and plan how they want to become more aware of grateful moments.</p> <p>10. Packing my strategy kit for the future</p> <p>The content of the past 9 sessions is reviewed and the strategy kits from the last 9 sessions, where participants wrote down the exercises and techniques they want to remember, are displayed. The names of all exercises of the intervention are shown in a word cloud and participants are asked to plan at least one exercise/strategy that they want to continue using in the next weeks. Participants are asked to set a date when they want to login again to evaluate on their plan.</p>	<p>acceptance. With an audio exercise, participants first repeat the muscle- and breathing exercise (from session 5) and combine it with the acceptance exercise. The audio file is downloadable. Participants are asked to plan how to train acceptance and to set a training goal.</p> <p>Information on self-support and its importance is given. Participants are asked to reflect on how they support others and to then evaluate how self-support could look like. They are offered two more exercises to foster self-support. In the first exercise “focusing on one’s own helpful skills and strengths”, participants are guided to vividly recall skills that they think of as helpful in dealing with a current stressful situation. In the second audio exercise, participants are guided in four steps to develop inner imaginary helpers that could support them in dealing with the current stressful situation.</p> <p>Information on human perception of negative and positive information is given. Participants have the opportunity to test their selective attention in perceptual experiments. Information on gratitude and its positive impacts is given. Areas where one could detect positive aspects are listed. The gratitude app is introduced, as well as a gratitude diary, a gratitude letter, a resource diary and the idea to use peas in order to become more aware of positive moments. Participants are asked to choose and plan how they want to become more aware of grateful moments.</p> <p>The content of the past 9 sessions is reviewed and the strategy kits from the last 9 sessions, where participants wrote down the exercises and techniques they want to remember, are displayed. The names of all exercises of the intervention are shown in a word cloud and participants are asked to plan at least one exercise/strategy that they want to continue using in the next weeks. Participants are asked to set a date when they want to login again to evaluate on their plan.</p>
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*Note.* \* The elements can be found in every session and are not listed further below.

Table 2  
Adaptions made to the COVID-19 pandemic

The intervention was newly developed against the background of the pandemic in March 2020. Therefore, we first brainstormed the difficulties and needs that may arise for individuals with the pandemic (e.g. through reports from patients, in newspaper articles, first scientific studies). After identifying changes and difficulties individuals may experience within the pandemic (e.g. lockdown, short work, unemployment, loneliness, diverse medical and non-medical worries), we conceptualized the components needed in order to face those. Therefore, we developed new individual components (e.g. day structure, values-oriented activities) and further developed, integrated and extensively adapted already existing content (e.g. dealing with difficult feelings, gratitude) by taking the changes in everyday life due to the pandemic into account. Further adaptations were threefold: through 1. videos, 2. texts, 3. virtual companions.





Example – Look inside GCMO	Area of adaption
<p data-bbox="178 719 376 745"><b>Herzlich willkommen!</b></p> <p data-bbox="178 748 646 781">Klasse, dass Sie sich zu Einheit 2 angemeldet haben. Lassen Sie sich in diesem Video begrüßen und erfahren Sie, worum es heute gehen soll.</p>  <p data-bbox="178 1046 316 1066">+ Skript zum Video</p>  <p data-bbox="178 1247 300 1265"><b>Werte und die Krise</b></p> <p data-bbox="178 1267 646 1388">Im Krisenstadium des Alltags kann es leicht passieren sich von dem zu entfernen, was uns eigentlich wichtig ist. Den harten Schnitt einer Krise nehmen viele Menschen zum Anlass die Frage nach dem, was im Leben wichtig ist, anzustellen. Sie denken darüber nach oder sprechen mit Vertrauten darüber. Das ist eine lohnende Idee. Denn wenn die Werte wie ein Leuchtturm sind, dann helfen sie auch bei stürmischer See – wie zum Beispiel in der aktuellen Krise – Orientierung zu geben. Sie können insbesondere diese Einheit dafür nutzen, um über Ihre Werte nachzudenken.</p> <p data-bbox="178 1391 646 1406">Diese Einheit möchte Sie dabei unterstützen, Ihre „Leuchttürme“ noch einmal bewusst zu benennen. Das ist der Ausgangspunkt, um im zweiten Schritt zu überlegen, was Ihre wertvollen Aktivitäten für die kommenden Tage sein können. Eine wertvolle Aktivität ist alles, was Sie in Kontakt mit Ihren Werten bringt, was Sie Ihren Werten näher bringt und alles was Ihre Werte stärkt.</p> <p data-bbox="178 1435 446 1451"><b>Stefan, 47, Leiter eines IT-Unternehmens, verheiratet, 2 Kinder</b></p>  <p data-bbox="400 1453 662 1601">Aktuell arbeitet Stefan teils im Homeoffice und teilweise wieder im Büro. Die Mitarbeiter haben zunehmend schlechte Stimmung wegen der Hygienemaßnahmen und es gibt dicke Luft unter den Mitarbeitern. Belastend für ihn ist auch, dass seine Frau Anja als Pflegekraft im Krankenhaus arbeitet. Durch den hohen Krankenstand dort sowie die Zunahme der Corona-Fälle im Krankenhaus, ist sie oft ziemlich gestresst und ständig in Hektik-Stellung, da die Corona-Lage schnell unkontrollierbar werden kann. Auch die beiden Töchter Mia und Elina machen ihm zunehmend Sorgen. Die Familie einer Schulfreundin von Elisa hatte Corona und der Großvater des Mädchens ist daran gestorben. Nun</p> <p data-bbox="178 1603 662 1653">haben die Kinder große Angst, dass auch jemand aus ihrer Familie sterben könnte. Sie haben immer wieder Angst in die Schule zu gehen oder mit dem Bus zu fahren und fast jeden Morgen gibt es Diskussionen. Teilweise muss er die Kinder in die Schule fahren und abholen, weil sie sich weigern in den Bus zu steigen. Das alles auf einmal zu bewältigen und für so viele Menschen verantwortlich zu sein, setzt ihn ziemlich unter Druck.</p> <p data-bbox="178 1659 446 1675"><b>Maria, 43, gelernte Hotelfachfrau, aktuell arbeitslos, alleinstehend</b></p>  <p data-bbox="400 1677 662 1825">Marias Arbeitgeber hat aufgrund der Corona-Krise Insolvenz anmelden müssen und sie ist nun arbeitslos. Maria hat große Sorgen keinen Job zu finden, da schließlich die ganze Branche in Schwierigkeiten steckt. Ihre Horrorvorstellung ist, dass sie Hartz 4 beantragen muss. Schon mit dem Arbeitslosengeld ist es knapp. Sie kann sich gar nicht vorstellen, wie sie mit noch weniger Geld zurecht kommen soll. Maria ist alleinstehend und hat niemanden, der sie im Notfall auffängt. Sie hat Sorge vor einem sozialen Abstieg. Die Dinge, die sie normalerweise beruhigen, ihre Kraft und positive Energie geben, wie die Treffen mit der Walking Gruppe oder der Austausch mit den Kollegen bei der Arbeit, fehlen ihr sehr.</p> <p data-bbox="178 1827 662 1848">Auch finden weniger Aktivitäten statt, die sie ablenken könnten. Aktuell hat sie Sorge Weihnachten und Silvester allein sein zu müssen. Sie möchte ihre Mutter aber auch nicht in Gefahr bringen. Sie wünscht sich Klarheit, wie alles weitergehen soll.</p>	<p data-bbox="703 707 826 741"><b>1. Videos:</b></p> <p data-bbox="703 743 1396 1012">At the beginning of each session, expert videos serve to embed the intervention in the COVID-19-pandemic. The videos were newly produced in March 2020. Throughout the videos, the experts address the changes and possible difficulties caused by the pandemic, explain the rationale of the whole intervention, the training’s components and individual exercises against the background of the pandemic.</p> <p data-bbox="703 1111 807 1144"><b>2. Texts:</b></p> <p data-bbox="703 1146 1396 1348">Newly developed texts explain the connection between the pandemic and psychological problems (e.g. worry, problems with sleeping, feeling stressed and tensed). Furthermore, suitable metaphors, displaying the connection with the pandemic, are used (e.g. values as a lighthouse in stormy seas).</p> <p data-bbox="703 1440 983 1473"><b>3. Virtual Companions:</b></p> <p data-bbox="703 1476 1396 2072">Furthermore, multiple virtual companions (VCs) are introduced in the first session. The VCs describe the changes they are experiencing due to the COVID-19-pandemic and their difficulties and concerns with it (e.g. Maria, 43 years old; she feels alone since she is single and lost most of her social contacts with the pandemic, she worries about her job as a hotel manager, and about her mother who is living in a retirement home where visiting is difficult). The VCs serve as identification figures and role models, they normalize experiencing difficulties due to the pandemic, strengthen a sense of community and foster the feeling of not being alone. The VCs are integrated into all exercises throughout the intervention. By describing their ideas on how to do the exercises, their difficulties and obstacles with them in times of the pandemic as well as their successes with the exercises, they serve to further adapt the exercises to the pandemic-context.</p>

Table 3

*Content of mental health advice in the MHA-W group (596 words – 3 minutes reading time)*

The MHA-W group received official mental health recommendations on how to cope mentally with the pandemic, published by the German Society for Psychiatry and Psychotherapy, Psychosomatics and Neurology. These recommendations counted around 600 words and included information on the importance of a daily structure, social contact, acceptance of negative emotions and strengthening of positive emotions, and stimulus control to assimilate COVID-19-related news.

Recommendation	Description
1. Stay informed - but do it right	Advice to lower worry and stress by functional information seeking behaviour was given, including usage of trustworthy sources. (59 words)
2. Organize your daily routine in a positive way	The importance structuring daily routines to maintain mental health was highlighted especially in situations where existing routines and social contacts are no longer feasible. (125 words)
3. Share concerns and care for each other	People were instructed to share worries with significant others for relieve. Likewise, staying in contact with each other was recommended to prevent loneliness and to support others in order to strengthen relationships and experience positive emotions resulting from helping. (157 words)
4. Acknowledging negative feelings, strengthening positive emotions	It was acknowledged that worries and distress are normal reactions to exceptional circumstances. Acceptance of negative feelings was recommended and people were encouraged to engage in pleasant activities. (88 words)
5. If you are doing very badly: seek professional help	In case people get overwhelmed by worries and distress they were advised to seek help from professionals e.g. psychiatrist or psychotherapists. (83 words)

*Note.* Recommendations were translated by the authors. Available in German on <https://www.dgppn.de/presse/pressemitteilungen/pressemitteilungen-2020/corona-psyche.html> (accessed on 20.03.2020). MHA-W = mental-health advice waiting group.



Table 4

*Usage of behavioral change techniques within GCMO and MHA-W group*

GCMO is a complex intervention that involves many interacting components and made use of multiple behavioral change techniques in order to facilitate behavior change [1]. The information given to the MHA-W group does only provide short recommendations (around 600 words) with limited information on how to perform a specific behavior (e.g. “accept negative emotions”, without explaining how exactly this could work). GCMO integrated 19 different behavioral change techniques vs. two that were used in MHA-W.

Technique	GCMO	MHA-W
4.1 Instruction on how to perform a behavior.	xxx	x
5.6 Information about emotional consequences	xxx	x
1.1 Goal setting (behavior)	xxx	
1.4 Action planning	xxx	
1.5 Review behavior goal(s)	xxx	
6.1. Demonstration of the behavior	xxx	
8.1 Behavioral practice/rehearsal	xxx	
8.3 Habit formation	xxx	
9.1 Credible source	xxx	
10.4 Social reward	xxx	
1.2 Problem solving	xx	
11.3 Conserving mental resources	xx	
5.4 Monitoring of emotional consequences	xx	
5.1 Information about health consequences	xx	
10.3 Non-specific reward	x	
13.4 Valued self-identity	x	
5.3 Information about social and environmental consequences	x	
15.3 Focus on past success	x	
15.4 Self-talk	x	

*Note.* Interventions were coded regarding the usage and intensity of usage of behavioral change techniques according to Michie et al. [1]. Intensive usage =xxx, moderate usage=xx, minimal usage = x. GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group.

Table 5  
*Proportion of participants scoring in each PSWQ category at all measurement points in the ITT-sample*

	Low worry			Moderate-high worry			High worry					
	GCMO		MHA-W	GCMO		MHA-W	GCMO		MHA-W			
	n	%	n	%	n	%	n	%	n	%		
T1	13	7.4	15	8.5	50	28.6	47	26.7	112	64.0	114	64.8
T2	30	17.1	30	17.0	90	51.4	56	31.8	54	30.9	89	50.6
T3	44	25.1	37	21.0	78	44.6	73	41.5	53	30.3	66	37.5
T4	51	29.1	60	34.1	70	40.0	70	39.8	55	31.4	46	26.1

*Note.* We have used a German adaption of the PSWQ [6] that differs from the original PSWQ in item number (1 item less) and the range of the scale (16-80 vs. 0-90). Korte et al. [7] have derived classes for the original PSWQ: a cut-score of 39 for classifying individuals in the low worry vs. moderate-high worry class and a cut-score of 54 for classifying individuals in the high vs. moderate-high class. In order to derive corresponding categories for the German-PSWQ, we have transformed the values of the two versions into each other. We did this by dividing the range of the German-PSWQ (90) with the range of the original PSWQ (80-16 = 64). The quotient is 1.41. This means that every item of the German-PSWQ corresponds with a value of 1.41 on the original PSWQ. Please see Table 9 below. Thus, a score above 32.3 was taken as a proxy for moderate-to high and above 53.4 for high worry. However, these transformed cut-scores are exploratory estimates and have to be interpreted carefully. GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group ; PSWQ = Penn State Worry Questionnaire.

Table 6  
*Original PSWQ-score and corresponding PSWQ-score in German version*

Original PSWQ	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48
German PSWQ	0.0	1.4	2.8	4.2	5.6	7.0	8.4	9.8	11.3	12.7	14.1	15.5	16.9	18.3	19.7	21.1	22.5	23.9	25.3	26.7	28.1	29.5	30.9	32.3	33.8	35.2	36.6	38.0	39.4	40.8	42.2	43.6	45.0
Original PSWQ	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	
German PSWQ	46.4	47.8	49.2	50.6	52.0	53.4	54.8	56.3	57.7	59.1	60.5	61.9	63.3	64.7	66.1	67.5	68.9	70.3	71.7	73.1	74.5	75.9	77.3	78.8	80.2	81.6	83.0	84.4	85.8	87.2	88.6	90.0	

*Note.* PSWQ = Penn State Worry Questionnaire.

Table 7  
Correlations of outcome variables at T1

	PSWQ	GAD-7	PHQ-8	BRS	GSES	WHO-5	ERSQ
PSWQ	1.00	0.75	0.59	-0.35	-0.43	-0.60	-0.48
GAD-7		1.00	0.72	-0.30	-0.43	-0.56	-0.46
PHQ-8			1.00	-0.33	-0.47	-0.61	-0.45
BRS				1.00	0.47	0.33	0.34
GSES					1.00	0.43	0.46
WHO-5						1.00	0.57
ERSQ							1.00

Note. PSWQ = Penn State Worry Questionnaire; GAD-7 = Generalized Anxiety Disorder Scale; PHQ-8 = Patient Health Questionnaire; BRS = Brief Resilience Scale; GSES = General Self-Efficacy Short Scale; WHO-5 = WHO-5 well-being index; ERSQ = Emotion Regulations Skills Questionnaire; T1 = Baseline assessment.

Table 8  
Overview of COVID-19 related worries of the sample at T1 and T2

	T1				T2				p-value*
	GCMO		MHA-W		GCMO		MHA-W		
	n	%	n	%	n	%	n	%	
1. I am very afraid of infecting others with the Corona virus.									
Not true at all	34	20.0	39	23.1	25	19.1	34	22.1	0.87
Rather not true	60	35.3	59	34.9	56	42.7	57	37.0	
Rather true	48	28.2	50	29.6	31	23.7	45	29.2	
Completely true	28	16.5	21	12.4	19	14.5	18	11.7	
2. I am afraid of getting infected with the Corona virus.									0.37
Not true at all	19	11.2	8	4.7	14	10.7	16	10.4	
Rather not true	57	33.5	67	39.6	53	40.5	58	37.7	
Rather true	55	32.4	66	39.1	49	37.4	52	33.8	
Completely true	39	22.9	28	16.6	15	11.5	28	18.2	
3. I am very worried about people close to me getting infected.									0.98
Not true at all	4	2.4	6	3.6	3	2.3	8	5.2	
Rather not true	20	11.8	24	14.2	25	19.1	25	16.2	
Rather true	66	38.8	71	42.0	61	46.6	70	45.5	
Completely true	80	47.1	68	40.2	42	32.1	51	33.1	
4. I feel well informed about how to protect myself from infection.									0.86
Not true at all	0	0.0	2	1.2	1	0.8	4	2.6	
Rather not true	15	8.8	14	8.3	7	5.3	11	7.1	
Rather true	90	52.9	77	45.6	72	55.0	77	50.0	
Completely true	65	38.2	76	45.0	51	38.9	62	40.3	
5. I am confident that I will receive adequate medical treatment if I become infected.									0.81
Not true at all	2	1.2	5	3.0	4	3.1	3	1.9	
Rather not true	29	17.1	35	20.7	17	13.0	17	11.0	
Rather true	97	57.1	82	48.5	69	52.7	87	56.5	
Completely true	42	24.7	47	27.8	41	31.3	47	30.5	
6. My job has become insecure because of the crisis.									0.80
Not true at all	80	45.7	83	47.2	68	51.1	82	51.9	
Rather not true	42	24.0	36	20.5	34	25.6	40	25.3	
Rather true	27	15.4	33	18.8	17	12.8	25	15.8	

Completely true	26	14.9	24	13.6	14	10.5	11	7.0	0.40
7. I will / or have lost my job due to the crisis.	131	74.9	137	77.8	107	80.5	133	84.2	
Not true at all	18	10.3	20	11.4	11	8.3	9	5.7	
Rather not true	20	11.4	17	9.7	11	8.3	15	9.5	
Rather true	6	3.4	2	1.1	4	3.0	1	0.6	
Completely true	58	33.1	51	29.0	53	39.8	53	33.5	0.83
8. Because of the crisis, I am increasingly worried about my financial situation	42	24.0	47	26.7	32	24.1	53	33.5	
Not true at all	53	30.3	54	30.7	35	26.3	41	25.9	
Rather not true	22	12.6	24	13.6	13	9.8	11	7.0	
Rather true	27	15.4	37	21.0	27	20.3	42	26.6	
Completely true	60	34.3	56	31.8	60	45.1	53	33.5	
9. Conflicts with people close to me have increased (e.g. because of home offices, closed daycare centers or schools).	63	36.0	57	32.4	35	26.3	48	30.4	
Not true at all	25	14.3	26	14.8	11	8.3	15	9.5	
Rather not true	16	9.1	22	12.5	16	12.0	32	20.3	0.42
Rather true	58	33.1	50	28.4	73	54.9	52	32.9	
Completely true	72	41.1	79	44.9	34	25.6	64	40.5	
10. Because of the crisis, I feel increasingly alone and without help.	29	16.6	25	14.2	10	7.5	10	6.3	
Not true at all	20	11.4	23	13.1	38	28.6	39	24.7	0.26
Rather not true	75	42.9	82	46.6	66	49.6	75	47.5	
Rather true	57	32.6	53	30.1	24	18.0	38	24.1	
Completely true	23	13.1	18	10.2	5	3.8	6	3.8	
11. I invest a lot of my free time on it, to inform myself about everything around the Corona virus or the COVID-19 disease.									

*Note:* p-value was calculated for difference between groups at T2 with Wilcoxon rank sum test and was non-significant for all items. We also calculated exploratory sum scores (COVID-19-Health-worries: consisting of item 1-5 and COVID-19-related-socio-economic-worries: consisting of item 6-10). COVID-19-Health-worries at T1: GCMO (M=7.04, SD = 2.54) vs. MHA-W (M=6.82, SD=2.74); COVID-19-Health-worries at T2: GCMO (M=6.47, SD = 2.44) vs. MHA-W (M=6.53, SD=2.54). COVID-19-socio-economic-worries at T1: GCMO (M=5.79, SD = 3.22) vs. MHA-W (M=5.64, SD=3.00); COVID-19-socio-economic-worries at T2: GCMO (M=4.74, SD = 3.07) vs. MHA-W (M=4.66, SD=2.89). A t-test comparing both groups at T2 on COVID-19-health-worries was non-significant (p=0.64) as well as a t-test for COVID-19-socio-economic-worries (p=0.84). T-tests for dependent samples over both groups however showed significant reduction from T1 to T2 on COVID-19-health (t=2.77, p=0.003) and COVID-19-socio-economic-worries (t= 2.77, p=0.003). GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group; T1 = baseline assessment; T2 = post-intervention.

Table 9  
*Proportion of participants in each PHQ-8 and GAD-7 category at all measurement points in the ITT-sample*

	No symptoms (0-4)		Mild symptoms (5-9)		Moderate symptoms (10-14)		Moderately severe (≥15)									
	MHA-W		MHA-W		MHA-W		MHA-W									
	n	%	n	%	n	%	n	%								
<b>GAD-7</b>																
T1	9	5.1	14	8.0	66	37.7	54	30.7	59	33.7	57	32.4	41	23.4	51	29.0
T2	30	17.1	25	14.2	101	57.7	58	33.0	30	17.1	61	34.7	14	8.0	32	18.2
T3	45	25.7	46	26.1	68	38.9	57	32.4	42	24.0	50	28.4	19	10.9	23	13.1
T4	48	27.4	51	29.0	88	50.3	73	41.5	30	17.1	40	22.7	10	5.7	12	6.8
<b>PHQ-8</b>																
T1	14	8.0	15	8.5	56	32.0	57	32.4	69	39.4	62	35.2	36	20.6	42	23.9
T2	44	25.1	27	15.3	77	44.0	52	29.5	36	20.6	68	28.6	18	10.3	29	16.5
T3	49	28.0	43	24.4	64	36.6	60	34.1	39	22.3	51	29.0	23	13.1	22	12.5
T4	38	21.7	47	26.7	86	49.1	76	43.2	40	22.9	42	23.9	10	5.7	11	6.3

*Note.* GAD-7 = Generalized Anxiety Disorder Scale; PHQ-8 = Patient Health Questionnaire; GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group; T1 = baseline; T2 = post-intervention (2 weeks); T3 = Follow-up I (2 months); T4 = Follow-up II (6 months).

Table 10

*Proportion of participants with at least 50% reduction of their respective baseline value at T2*

	GCMO				MHA-W				GCMO vs. MHA-W	
	Yes <sup>1</sup>		No <sup>2</sup>		Yes <sup>1</sup>		No <sup>2</sup>		NNT	95%-CI
	n	%	n	%	n	%	n	%		
PSWQ	14	7.7	161	92.3	5	3.0	171	97.0	21.7	10.8-10 <sup>6</sup>
GAD-7	49	28.2	126	71.8	19	11.0	157	89.0	5.8	3.9-10.9
PHQ-8	53	30.1	122	70.0	16	8.9	160	91.1	4.7	3.4-7.5

*Note.* <sup>1</sup>T2-value  $\leq 0.5$ \*T1-value at participant level. <sup>2</sup>T2-value  $> 0.5$ \*T1-value. NNT = Number needed to treat; PSWQ = Penn State Worry Questionnaire; GAD-7 = Generalized Anxiety Disorder Scale; PHQ-8 = Patient Health Questionnaire; GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group; T2 = post-intervention (2 weeks).

Table 11

*Proportion of participants experiencing deterioration in the ITT-sample*

	GCMO				MHA-W			
	Yes		No		Yes		No	
	n	%	n	%	n	%	n	%
<b>PSWQ</b>								
T1-T2	2	1.2	173	98.8	1	0.6	175	99.4
T1-T3	5	2.8	170	97.2	9	5.0	167	95.0
T1-T4	2	1.1	173	98.9	1	0.3	175	99.7
<b>GAD</b>								
T1-T2	3	1.5	172	98.5	4	2.2	172	97.8
T1-T3	8	4.7	167	95.3	11	6.3	165	93.8
T1-T4	3	1.5	172	98.5	5	2.8	171	97.2
<b>PHQ-8</b>								
T1-T2	4	2.5	171	97.5	8	4.7	168	95.3
T1-T3	7	4.0	168	96.0	12	7.0	164	93.0
T1-T4	4	2.3	171	97.7	6	3.6	170	96.4

*Note.* Missing values were imputed with multiple imputation. Reliable deterioration was calculated according to a recently conducted meta-analysis [2]. For the PSWQ = Penn State Worry Questionnaire a retest-reliability of 0.74 [3] and the standard deviation at baseline of (14.65) was used and resulted in a cut-off for reliable deterioration of 20.71. For the PHQ-8 = Patient Health Questionnaire a retest-reliability of 0.84 [4] and the baseline's standard deviation of 4.84 was used and resulted in a cut-off for reliable deterioration of 5.36. For the GAD-7 = Generalized Anxiety Disorder Scale a retest reliability of 0.83 [5] and a standard deviation of 4.60 was used and resulted in a cut-off for reliable deterioration of 5.25. Deterioration from T1 to T2 (T3 and T4 resp.) greater than the defined cut-off values were coded as clinically significant deterioration. ITT = intention-to-treat; PSWQ = Penn State Worry Questionnaire; GAD-7 = Generalized Anxiety Disorder Scale; PHQ-8 = Patient Health Questionnaire; GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group; T1 = baseline; T2 = post-intervention (2 weeks); T3 = Follow-up I (2 months); T4 = Follow-up II (6 months).

Table 12

*Rated helpfulness of each session (GCMO and MHA-W group)*

Session	Not at all		Rather not		Moderately		Rather yes		Yes completely		N
	n	%	n	%	n	%	n	%	n	%	
	Session 1	3	1.3	25	10.5	70	29.3	115	48.1	26	
Session 2	6	2.7	11	4.9	48	21.3	113	50.2	47	20.9	225
Session 3	-	0.0	2	1.0	31	15.4	87	43.3	81	40.3	201
Session 4	1	0.6	14	7.7	25	13.8	83	45.9	58	32.0	181
Session 5	-	0.0	7	4.3	22	13.5	69	42.3	65	39.9	163
Session 6	-	0.0	3	2.1	20	14.0	70	49.0	50	35.0	143
Session 7	1	0.8	3	2.3	17	12.8	57	42.9	55	41.4	133
Session 8	1	0.8	6	4.8	21	16.8	54	43.2	43	34.4	125
Session 9	-	0.0	2	1.7	8	7.0	54	47.0	51	44.3	115
Session 10	-	0.0	5	4.9	17	16.7	46	45.1	34	33.3	102

*Note.* Participants at the end of each session were asked to rate the following question on a 0-5 Likert scale: Was this session helpful to you? Feedback of participants from the GCMO and the MHA-W group, that received delayed access to GCMO, is depicted. Overall helpfulness was high. On average 78.9% of participants providing feedback rated the sessions as rather or completely helpful. Session 1 was most often rated as rather not or not helpful (n=28, 11.7%), followed by session 4 (n=15, 8.3%). Session 3 (n=168, 91.3%) was most often rated as rather or completely helpful, followed by Session 9 (n=105, 84.2%) and session 6 (n=120, 83.9%). GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group.



Table 13

*Numbers and proportion of participants reporting to have conducted the exercises offered in a particular session (GCMO and MHA-W)*

	Not this time		yes		N
	n	%	n	%	
Session 1	32	13.5	205	86.5	237
Session 2	28	12.7	192	87.3	220
Session 3	7	3.5	191	96.5	198
Session 4	24	13.6	152	86.4	176
Session 5	13	8.0	150	92.0	163
Session 6	7	4.9	136	95.1	143
Session 7	13	10.1	116	89.9	129
Session 8	13	10.8	107	89.2	120
Session 9	6	5.4	106	94.6	112
Session 10	29	30.2	67	69.8	96

*Note.* Participants at the end of each session were asked to indicate if they have tried out one or more of the exercises from the session directly or have made a firm commitment to try out the exercises. Feedback of participants from the GCMO and the MHA-W group, that received delayed access to GCMO, is depicted. Overall, behavioral practice was high, with  $\geq 86.4\%$  of participants indicating behavioral practice. Behavioral practice was highest in session 3 (n=191, 96.5%) followed by session 6 (n=136, 95.6%) and session 9 (n=106, 94.6%). GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group.

Table 14

*Problems reported in open text field from participants of GCMO*

Problem	N	
	(n = 133)	%
Too little time, too much time pressure for the sessions (1 session per day)	19	14.3
Printable summary would be helpful	7	5.3
Reminder mail to log in would be helpful	4	3.0
Further adaption to other life situations (seniors, student) would be helpful	3	2.3
Professional support from coach or psychologist would be helpful	3	2.3
Problems with App-usage	2	1.5
Desire for more interpersonal exchange	2	1.5

*Note.* We conducted a qualitative analysis, derived categories and counted how many times participants mentioned this problem in an open text asking participants for further feedback. GCMO = get.calm and move.on, intervention group.

Table 15

*Exercises that participants (GCMO and MHA-W) planned to continue using in session 10*

Exercise/ element	N	%
	(n = 93)	
Gratitude journal / Gratitude App	40	43.0
Relaxation	22	23.7
Emotion-focused techniques	21	22.6
Acceptance-focused techniques	14	15.1
Locking away worries in imagination	14	15.1
AALL – problem-solving	11	11.8
Day structure	9	9.7
Peas exercise	8	8.6
Values-based activities	7	7.5

*Note.* In session 10 we asked participants to plan which exercises/strategies they want to continue using in the next weeks. We conducted a qualitative analysis and counted to which exercises the participants referred. Responses of participants from the GCMO and the MHA-W group, that received delayed access to GCMO, is depicted. GCMO = get.calm and move.on, intervention group; MHA-W = mental-health advice waiting group.

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## Additional analyses

### Above threshold depressive symptoms

Table M5 shows the proportion of participants with a value  $< 10$  or  $\geq 10$  on the Patient Health Questionnaire (PHQ-8). At T2 significantly more participants in the IG, as compared to the MHA-W, scored under the clinical cut-off for depression. The proportions correspond to an NNT of 4.2 at T2. At the same time 38% of the IG, after having received the intervention, scored above the cut-off for clinical depression.

Table M5: Proportion of participants with depressive symptoms  $\geq$  clinical cut-off vs.  $<$  clinical cut-off.

	IG				MHA-W				<i>p</i>	NNT [95% CI]
	$< 10$		$\geq 10$		$< 10$		$\geq 10$			
	n	%	n	%	n	%	n	%		
T1	70	40	105	60	72	41	104	59		
T2	121	69	54	38	80	45	96	55	***	4.2 [3.0; 7.3]
2-MFU	113	65	62	35	103	59	73	41	n.s.	
6-MFU	124	71	50	29	123	70	53	30	n.s.	

Note. Depression was measured with the PHQ-8. A value  $\geq 10$  indicates clinically significant levels of depression. The MHA-W group received access to the intervention following the T2-assessment. Therefore for 2-MFU and 6-MFU no difference between groups was expected.

IG = intervention group; MHA-W = mental health advice waiting group; T1 = baseline; T2 = post-intervention; 2-MFU = 2-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

### Clinically relevant change in depressive symptoms

Table M6 shows the proportion of participants with and without a clinically relevant change in depressive symptoms from baseline. At T2 significantly more participants in the IG, as compared to the MHA-W, reported a clinically relevant change in depressive symptoms. While at T2 50% in the IG

Table M6: Proportion of participants with a change in depressive symptoms  $< 33$  vs.  $\geq 33\%$  from baseline.

	IG				MHA-W				<i>p</i>	NNT [95% CI]
	$< 33\%$		$\geq 33\%$		$< 33\%$		$\geq 33\%$			
	n	%	n	%	n	%	n	%		
T2	88	50	87	50	138	78	38	22	***	3.6 [2.7; 5.4]
2-MFU	91	52	84	48	107	61	69	39	n.s.	
6-MFU	93	53	82	47	90	51	86	49	n.s.	

Note. The MHA-W group received access to the intervention following the T2-assessment. Therefore for 2-MFU and 6-MFU no difference between groups was expected.

IG = intervention group; MHA-W = mental health advice waiting group; T1 = baseline; T2 = post-intervention; 2-MFU = 2-month follow-up; 6-MFU = 6-month follow-up; NNT = numbers needed to treat.

n.s. = non-significant; \*  $p \leq 0.05$ ; \*\*  $p \leq 0.01$ ; \*\*\*  $p \leq 0.001$ .

report a clinically relevant change, only 22% in the MHA-W reported a clinically relevant change. This equals an NNT of 3.6 at T2. At the same time 50% of the IG at T2 did not experience a clinically relevant change despite having received access to the intervention.

### Reliable deterioration

From T1 to T2  $n = 5$  (3%) in the IG, as compared to  $n = 8$  (5%) in the WLG, reported a reliable deterioration ( $p > 0.05$ ). From T1 to 2-MFU  $n = 7$  (4%) in the IG reported a reliable deterioration.

### Mediation analysis

As shown in Figure M2, worry at two-week post randomization,  $a_1b_1 = -0.51$ , 95% CI [-0.85, -0.18], significantly mediated the effect of the intervention on depression at two-week post randomization. The direct effect of the intervention reducing depression remained significant after the mediator was incorporated into the model,  $c' = -1.49$ , 95% CI [-2.28, -0.7].

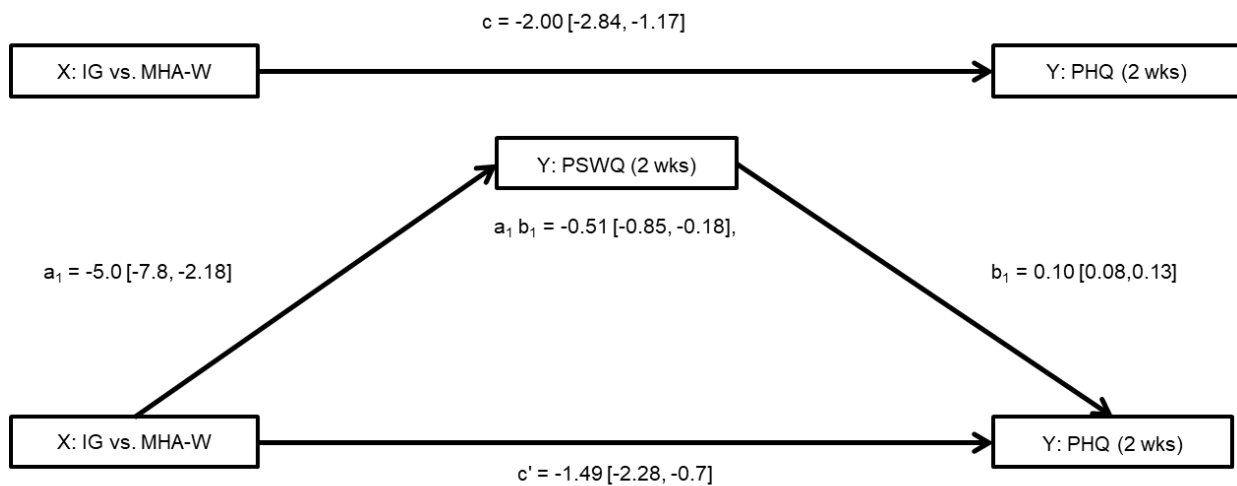


Fig. M2: Simple mediation model with 3-month follow-up depression scores as the outcome variable, posttreatment worry scores as mediators and baseline values of mediators and outcome as covariates. Treatment is coded 0 = Mental health advice waiting group, 1 = intervention group. Path diagrams representing statistically significant mediated effects. Unstandardized beta coefficients are shown, with 95% confidence intervals in brackets. IG = intervention group; MHA-W = mental health advice waiting group; PSWQ = Penn State Worry Questionnaire; PHQ-8 = Patient Health Questionnaire; 2 wks = post-intervention at two weeks post randomization.

**Chapter 5 – Main findings and general discussion**

Depression is a highly prevalent and impairing disorder that is associated with a high burden of disease for individuals and societies (e.g. Arias-de la Torre et al., 2021; GBD 2019 Mental Disorders Collaborators, 2022).

IMIs for the treatment and prevention of depression have been promised to overcome many of the barriers to traditional mental health care (e.g. Christensen & Griffiths, 2002; Cuijpers et al., 2008; Ritterband et al., 2003) and have been shown to be effective meta-analytically (e.g. Deady et al., 2017; Karyotaki et al., 2021; Königbauer et al., 2017; Reins et al., 2020).

However, despite evidence-based and effective IMIs being available for the reduction of depression, uptake is suggested to be low (e.g. Batterham et al., 2008, 2021; Batterham & Callear, 2017; Cuijpers, 2021b; Musiat et al., 2014). The stigma associated with depression is proposed as one major factor explaining the reluctance to use IMIs for depression – despite the anonymity of the Internet (Batterham & Callear, 2017; Crisp & Griffiths, 2014; Cuijpers, 2021b).

To solve this problem, indirect interventions for the reduction of depression have been suggested as a valuable approach (Cuijpers, 2021b). Such interventions indirectly address depression, by directly focusing on other – less stigmatized – but related psychological problems (Cuijpers, 2021b).

Due to the high comorbidity of depression with other mental disorders such as anxiety disorders (e.g. Kessler et al., 2015; Plana-Ripoll et al., 2019; ter Meulen et al., 2021) common transdiagnostic risk factors seem particularly valuable to target in indirect interventions for depression. RNT and stress are such risk factors (e.g. A. G. Harvey et al., 2004; S. B. Harvey et al., 2017; Madsen et al., 2017; Watkins, 2008). Primarily targeting these in indirect interventions might be an acceptable and effective approach to indirectly reduce depression.

The aims of this dissertation were divided into overarching and study-specific goals.

The overarching aim of this dissertation was to (a) develop and assess the efficacy of three different indirect IMIs for depression that primarily focus on the reduction of common transdiagnostic risk factors (stress and RNT) and (b) to investigate whether the reduction in these risk factors mediate the reduction in depression.

In addition to these overarching aims, this dissertation had several study-specific aims that arose from the specific interventions studied. After presenting the main findings, answering the study-specific goals, the main findings regarding the overarching research question will be summarized and discussed. In doing so, the overarching results on uptake and acceptance of the interventions are summarized and briefly discussed in one section. Then, the overarching results regarding efficacy and mechanisms of change are presented and will be discussed separately.

### **Main findings regarding the study-specific research questions**

#### **Main findings from Study I – Internet-based stress- and classroom management for beginning teachers (GetWell.Started)**

One goal of Study I was to tailor an iSMI for beginning teachers and to complement it with a newly developed work-related skills training. For this purpose, in addition to studying the scientific literature



on beginning teachers, interviews were conducted with beginning teachers and Internet-forums of beginning teachers were researched. In this way, typical problems and difficulties of beginning teachers were identified, and based on this, three example individuals were developed that were themselves beginning teachers. These were integrated into the exercises of an existing iSMI (Heber et al., 2016) throughout the whole intervention. Furthermore, based on the above mentioned sources of information on typical difficulties of beginning teachers, problems in classroom management emerged as one major stressor of beginning teachers (Aldrup et al., 2018; Harmsen et al., 2018; Schmidt et al., 2017). For this reason an internet-based classroom management intervention, consisting of seven sessions, was developed to complement the iSMI. Since, the intervention was provided with guidance, an e-Coaching manual was developed and e-Coaches were trained and supervised.

Further goals of Study I were to assess the efficacy of this intervention and to study the mechanisms of change in distressed beginning teachers. For this purpose a registered RCT (German Clinical Trials Registry: reference number: DRKS00013880) was conducted that compared the intervention – consisting of an iSMI and an optional internet-based classroom management intervention (GetWell.Started) – to a WLG. Assessments were conducted at post-intervention (T2), three-month follow-up (3-MFU) and for the intervention group (IG) at an extended six-month follow-up (6-MFU). Overall, 200 beginning teachers with elevated perceived stress were randomized.

Regarding the primary outcome the IG reported significantly less perceived stress (measured with the Perceived Stress Scale, PSS; S. Cohen et al., 1983) as compared to the WLG with a moderate between-group effect size at T2, adjusted PSS-means- $\Delta_{\text{WLG-IG}} = 3.5$ ,  $d = 0.52$ , 95% CI [0.24, 0.80], and at 3-MFU,  $d = 0.49$ , 95% CI [0.21, 0.77]. Furthermore, results of an extended 6-MFU suggest that the improvements made from baseline could be sustained, baseline to 6-MFU within-group Cohen's  $d = 1.58$ , 95% CI [1.16, 1.95]. The NNT for reliable improvement of perceived stress from baseline to T2 was 3.70, 95% CI [2.51, 7.05].

Furthermore, the results of the study show that it was feasible to tailor and complement the iSMI to the stressors and needs of the target group by complementing it with a newly developed internet-based classroom management training and significant differences between groups in classroom management self-efficacy suggest the efficacy thereof.

The IG also reported significant improvements on depression (also see the findings regarding the overarching research question) and most further mental health and work-related health outcomes and showed significantly higher coping skills and self-efficacy at T2 and 3-MFU, with sustained effects at 6-MFU.

Regarding mechanisms of change a parallel mediation analysis showed that the iSMI that was developed based on Lazarus and Folkman's transactional stress theory (1984) indeed exerted its effect on stress by increasing both emotion-focused,  $a_1b_1 = -0.97$ , 95% CI [-1.73, -0.22], and problem-focused coping skills,  $a_2b_2 = -0.77$ , 95% CI [-1.50, -0.04].

### **Main findings from Study II – Internet- and app-based gratitude intervention (Get.On Gratitude)**

The second study's specific goals were to assess the short- and longer-term efficacy of a complex internet-based gratitude intervention to reduce RNT as a primary and depression and further measures as secondary outcomes as compared to a WLG in an RCT and to investigate whether a reduction in RNT and improvements in resiliency both explain change in depression and anxiety symptoms.

For this purpose a registered RCT (German Clinical Trials Registry reference number: DRKS00011862) was conducted. Within this trial 262 individuals with elevated RNT were randomized to either the internet-based gratitude intervention or a WLG. Assessments were conducted at T2, 3-MFU, and for the IG at an extended 6-MFU. Individuals in the IG reported significantly reduced RNT (measured with the Perseverative Thinking Questionnaire, PTQ; Ehring et al., 2011) of moderate-to-large size at T2, adjusted PTQ-means- $\Delta_{\text{WLG-IG}} = 6.6$ ,  $d = 0.61$ , 95% CI [0.36, 0.86] and 3-MFU,  $d = 0.75$ , 95% CI [0.50, 1.00], as compared to the WLG. At an extended 6-MFU the IG reported sustained reductions, baseline to 6-MFU within-group effect  $d = 1.66$ , 95% CI [1.32, 1.98]. The NNT for one reliably improved participant regarding RNT at T2 was 3.0, 95% CI [2.3, 4.4].

The IG also reported mostly significant short- and longer-term improvements on depression and further mental health outcomes and significant higher values on gratitude. However, effects on resiliency, social support and optimism did not or not consistently show significant effects.

In a parallel mediation model, the hypothesis that the gratitude intervention enacts its effect on depression and anxiety via reducing RNT as a risk factor could be confirmed, with significant indirect effects on depression,  $a_1b_1 = -1.25$ , 95% CI [-2.42, -0.07], and anxiety,  $a_1b_1 = -0.64$ , 95% CI [-1.14, -0.13]. However, results regarding the hypothesis of a parallel resource-building pathway were inconsistent, since indirect effects via resiliency were not significant in the ITT-sample, but significant in the completer sample.

### **Main findings from Study III – Internet-based intervention during the COVID-19 pandemic (get.calm and move.on – GCMO)**

The third study's specific goals were to develop an IMI to reduce worries in the COVID-19 pandemic and assess its short-term efficacy in an RCT as compared to an active control group to reduce worry as a primary and depression and other measures as secondary outcomes and to investigate if the reduction in worrying mediates the intervention's effect on depression.

In following calls to rapidly develop interventions to support the general population's mental health during the COVID-19 pandemic (e.g. Gruber et al., 2020; Holmes et al., 2020; Xiang et al., 2020), get.calm and move.on was developed and consisted of 10 sessions.

The intervention was developed within two and a half weeks so that the first participant could be randomized on April 7, 2020. To the best of my knowledge this was the first registered RCT of an IMI to support the general population's mental health within the COVID-19 pandemic (German Clinical Trials Registry reference number: DRKS00021153).

In line with the idea of coping flexibility (e.g. Aldao et al., 2015; Bonanno & Burton, 2013) a wide range of psychotherapeutic interventions was included in the intervention.

The IG was compared to an active waiting list control group that received mental health recommendations on how to cope mentally with the pandemic from the German Society for Psychiatry and Psychotherapy, Psychosomatics and Neurology (MHA-W group).

Within this trial 352 individuals were randomized. The primary endpoint was at two-week post-randomization. For ethical reasons the MHA-W group was given access to the intervention thereafter and 2- and 6-MFUs were conducted in both groups to assess if the effects made within the IG were sustained over the longer-term and to monitor the development of outcomes within the MHA-W group after access to the intervention was given.

At T2 the IG reported significantly reduced levels of worry (measured with the Penn State Worry Questionnaire, PSWQ; Stöber & Bittencourt, 1998) as compared to the MHA-W group, adjusted  $PSWQ\text{-means-}\Delta_{MHA-W-IG} = 5.0$ ,  $d = 0.38$ , 95% CI [0.17, 0.59]. The extended follow-ups in the IG indicated that the improvements from baseline were sustained until the 2- and the 6-MFUs. The follow-ups within the MHA-W group suggest that this group also reduced their levels of worry after access to the intervention was given.

Significant short-term improvements were also reported for depression and further secondary outcomes, with an exception of self-efficacy.

### **Main findings regarding the overarching research question of this dissertation**

Three different IMIs that primarily focus on the reduction of common risk factors for depression were developed. Registered, randomized-controlled studies comparing the IGs with control groups were conducted. While the studies assessing GetWell.Started (Study I) and Get.On Gratitude (Study II) used three-month WLGs, the study assessing GCMO (Study III) used a two-week active control group. Table M7 gives an overview of the key characteristics of the three studies.

In order to get an idea of the uptake and acceptability of the interventions studied, the characteristics of the participants recruited and their satisfaction and adherence will be compared and discussed first. Secondly, the results regarding the efficacy to reduce depressive symptoms are compared and thirdly, the results of the mediation analyses assessing the targeted risk factors' role in the indirect reduction of depression will be summarized.

Following that, the results will be discussed and compared in the light of previous evidence, and the strengths, limitations and implications for future research and practice will be addressed.

### **Results and discussion of the uptake and acceptability of the interventions**

#### ***Characteristics of the participants recruited***

Overall, 813 participants were included in the trials. The majority of the participants in all three trials were female (ranging from 58.8% within the Get.On Gratitude study to 82.3% in the GCMO study, to 85.5% within the GetWell.Started study). The proportion of women within the Get.On Gratitude study

Table M7: Comparing key characteristics of the three studies of this dissertation.

Study	Target group	Primary outcome/ primary target risk factor	Inclusion criteria	Conditions	N	Format	Sessions/ Duration	Assessment- points	Instrument for measurement of Depression	Provided data at T2
Study I – GetWell.Started	Beginning teachers with elevated stress	Perceived stress	- being part of the German teacher induction phase - PSS > 21 - not being suicidal - no psychosis or dissociative symptoms in the past - not on waiting list or currently receiving PT - no changes in dosage of psychopharmacological treatment last 30 days	1. iSMI + iCRM 2. WLG	n1=100 n2=100	Guided	7 sessions/ ~ 7 weeks	T2: 8 weeks 3-MFU 6-MFU	CES-D (15 items)	1. 84% 2. 90%
Study II – Get.On Gratitude	Adults with elevated RNT	RNT	- PTQ > 33 - not being suicidal - no psychosis or dissociative symptoms in the past - not on waiting list or currently receiving PT - no changes in dosage of psychopharmacological treatment last 30 days	1. Get.On Gratitude 2. WLG	n1=132 n2=130	Feedback on demand	5 sessions/ ~ 5 weeks	T2: 6 weeks 3-MFU 6-MFU	CES-D (20 items)	1. 68% 2. 92%
Study III – GCMO	Adult general population	Worry	- not being suicidal - no psychosis or dissociative symptoms in the past psychopharmacological treatment last 30 days	1. iCBT 2. MHA-W	n1=175 n2=176	Unguided	10 daily sessions/ ~ 10 days	T2: 2 weeks 2-MFU 6-MFU	PHQ-8	1. 82% 2. 93%

Note. CES-D = Center for Epidemiological Studies Depression Scale; iCRM = internet-based classroom management intervention; iSMI = internet-based stress management intervention; MHA-W = mental health advice waiting group; PHQ-8 = Patient Health Questionnaire; PSS = Perceived Stress Scale; PT = Psychotherapy; PTQ = Perseverative Thinking Questionnaire; RNT = Repetitive negative thinking; T2 = post-intervention; WLG = waitlist control group; x-MFU = x-month follow-up.

seems to be comparable to the gender ratio found for depressive symptoms in Germany of 1.3 women : 1 men (as a proxy for the gender ratio for a possible target group) (Bretschneider et al., 2017).

Surprisingly, this might suggest that the Get.On Gratitude study might have been comparably acceptable within men and women (although there are a range of other explaining factors for this gender distribution, e.g. source of recruitment, male-gender of the person who presented the study).

The proportion of women within the GCMO study seems to go beyond what could be expected due to the higher prevalence rates of depressive symptoms in women in Germany (Bretschneider et al., 2017). However, this gender ratio, which was found before the pandemic, might not apply to the gender ratio of depressive symptoms within the pandemic. For example Santomauro et al. (2021) suggested a greater increase in MDD prevalence in women as compared to men during the pandemic which is explained by the greater social and economic consequences of the pandemic for women. The much higher proportion of women within the GCMO study, thus, might also reflect this pandemic-specific development.

For the GetWell.Started study the higher proportion of women that goes beyond the gender ratio of a possible target group can additionally be explained by the overall higher proportion of women in teaching occupations (German Federal Statistical Office, 2022c).

The higher proportion of women within the three studies of this dissertation is typical for IMIs for sub- and above threshold depression (e.g. Deady et al., 2017; Karyotaki et al., 2021; Reins et al., 2020) but also for other more general preventive/health oriented services in Germany (Robert Koch-Institut, 2014) and highlights that efforts must be made to reach more men.

The participants' age distribution is depicted in Figures M3 – M5. The GetWell.Started study aimed at beginning teachers and had an average age of 29 years (range: 23-48). In the Get.On Gratitude and GCMO studies the age ranged from 18 to 87 years with an average age of 42 years.

To obtain an estimate of the age distribution of a potential target population for depression interventions within the German general population, a combination of age-specific prevalence rates and population statistics is needed.

By combining prevalence rates for above threshold depressive symptoms for the different age groups from Bretschneider et al. (2017) with data on the age structure of the population in Germany from the German Federal Statistical Office (2022b) the following distributions of individuals with elevated depression can be estimated: Of all individuals with elevated depression within the German population, 20.6% can be estimated to be between 18-29 years, 23.5% between 30-44 years, 37.2% between 45-64 and 18.7% older than 65 years old (also see Table M8). A comparison of the studies' participants' age with this estimated age distribution in the general population with above threshold depressive symptoms (as a proxy for a possible target group) suggests that for the Get.On

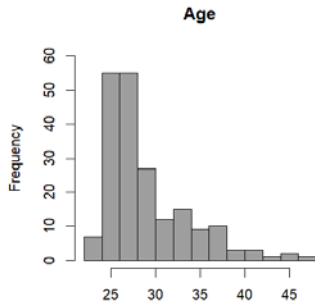


Fig. M3: Age distribution in Study I – GetWell.Started

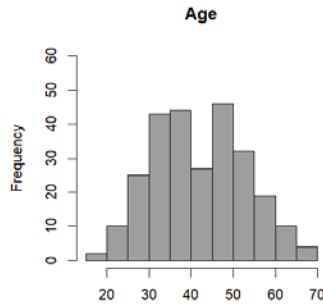


Fig. M4: Age distribution in Study II – Get.on Gratitude

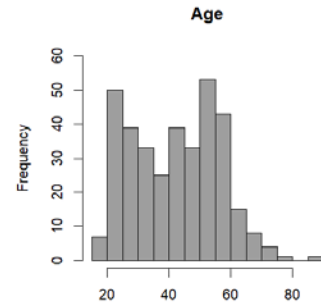


Fig M5: Age distribution in Study III – GCMO

Gratitude and the GCMO studies – that recruited within the general population – the age group of those > 65 years is underrepresented and within the Get.On Gratitude study the age group of those between 30-44 is rather overrepresented suggesting that a gratitude intervention might have been especially appealing to those. Overall, the GCMO study seemed to have attracted the widest age range, while the GetWell.Started study – in line with the idea of early intervention – succeeded in recruiting the youngest age group.

Table M8: Comparison of age distribution in possible target group of individuals with clinical symptoms of depression in the German general population with age distribution in studies.

Age group	Proportion within those with PHQ-8 ≥ 10*	Proportion in Study II	Proportion in Study III
18-29	20.6%	13.7%	24.8%
30-44	23.5%	43.1%	26.8%
45-64	37.2%	41.2%	42.7%
>65	18.7%	1.9%	5.7%
All	100%	100%	100%

Note. \*Of those with PHQ-8 ≥ 10 in German general population ≥ 18 years, % estimated within age group. Estimate of age distribution in possible target group in the German general population. By combining prevalence rates for above threshold depressive symptoms for the different age groups from Bretschneider et al. (2017) with data on the age structure of the population in Germany from the German Federal Statistical Office (2022b). The age distribution found within Study I is not depicted since the recruitment focused only on career starters.

The participants in all three studies were highly educated. Due to inclusion criteria all of the participants in the GetWell.Started study had at least a university degree. In the Get.On Gratitude study 76% and in the GCMO study 70% reported to have a university degree.

The proportion of individuals with a university degree within the German general population is estimated to be less than 20% (German Federal Statistical Office, 2022a) and evidence suggests that prevalence for depressive symptoms is even higher in less educated individuals (Bretschneider et al., 2017). This difference between the proportion of academics within the German general population and within the samples within the trials suggests that the studies conducted within this dissertation did not

succeed in recruiting a representative sample of the German population in terms of education. The high proportion of female and highly educated individuals and the average age of 42 (in studies II and III) are comparable to the gender, average age and education distribution found in other studies of IMIs for depression (Karyotaki, Ebert, et al., 2018; Köhnen et al., 2020; Königbauer et al., 2017; Reins et al., 2020) and suggests the acceptability of the interventions particularly within these groups. Similarly, it shows the difficulties to reach other groups with a potential need for help, particularly male individuals, those with less education and the elderly.

The participants' experience with psychotherapy prior to the study was different between studies. The majority of the participants in GetWell.Started reported no experience with psychotherapy before the study (82%) – also in line with the idea of early intervention. Less than half of the participants in the Get.On Gratitude (42%) and a majority in the GCMO study, reported experience with psychotherapy before the study (59%).

The proportion of participants reporting prior experience with psychotherapy in studies II and III is in line with the proportion of psychotherapy experience reported in the meta-analysis on IMIs for subthreshold depression from Reins et al. (2020) and suggests that the interventions might be acceptable also for individuals that might not have experienced a need or that might have been reluctant to use traditional mental health services before. At the same time it shows that IMIs might also be acceptable to those with experience from face-to-face psychotherapy.

In the sample of beginning teachers most had no prior experience with psychotherapy, but nearly half of those that reported to have experienced a need for professional mental health care stated that fear of negative consequences for their career was the main reason not to use it. This suggests that a tailored iSMI for career starters might be a feasible way to reach individuals early in life that are reluctant to use traditional health care due to a fear of stigmatization.

Overall the samples in all three studies were highly distressed. While participants in the GetWell.Started and Get.On Gratitude studies had to report elevated scores on the particular primary outcomes (i.e. stress and RNT, respectively), in order to be included in the study; in the GCMO trial no inclusion criteria regarding symptom severity were employed.

None of the three trials employed inclusion criteria regarding depression. Thus both, participants scoring below clinical cut-offs for depression as well as those scoring above clinical cut-offs were included in the trials. In all three studies a significant proportion of participants reported clinically relevant depression scores at baseline (GetWell.Started: 59%, Get.On Gratitude: 44%, GCMO: 60%). Similarly, most participants reported clinically relevant generalized anxiety scores (GetWell.Started: 59%, Get.On Gratitude: 41.2%, GCMO: 59%).

Around half of the participants in GetWell.Started (47%) and GCMO (49%) reported both; clinical depression and generalized anxiety levels (also see Figures M6 – M8). Within the Get.On Gratitude study 28% reported comorbid clinical depression and anxiety levels.

These high rates of comorbid above threshold depression and anxiety levels is in line with studies

showing that depression is a highly comorbid mental disorder, with a majority of those diagnosed with depression having a comorbid anxiety disorder (Kessler et al., 2015; ter Meulen et al., 2021). Further studies of IMIs for depression also suggest that comorbidity, particularly with anxiety disorders, is common among participants (Ebert et al., 2016; Karyotaki, Ebert, et al., 2018; Reins et al., 2020). This high comorbidity highlights the possible potential and need of transdiagnostic indirect interventions. Moreover, it shows that the samples that self-select in IMIs that would traditionally be categorized as preventive interventions, do not necessarily represent a preventive sample. It rather shows that the probability is high to have both types of individuals in self-selected samples within IMIs: individuals with subclinical symptoms of depression and those with clinical symptoms of depression or even comorbid mental disorders. This is an important finding with implications for the safety requirements of such interventions (e.g. the importance to ensure access to more intensive care).

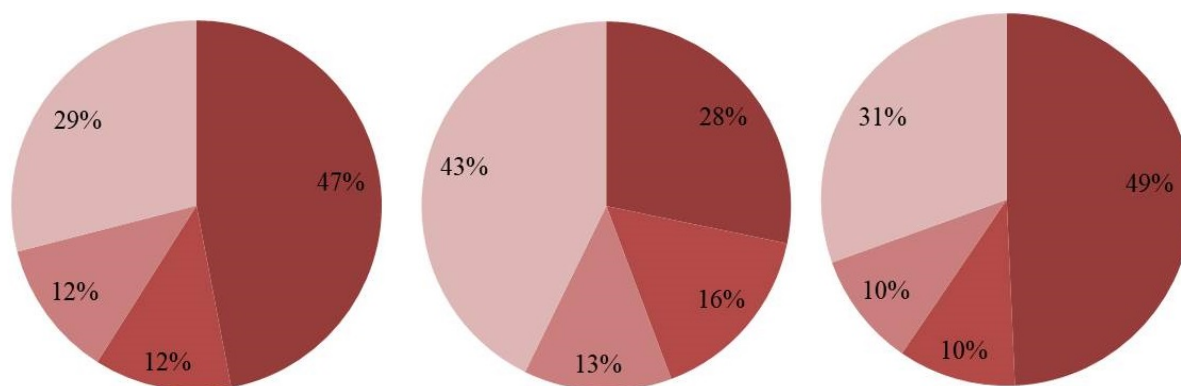


Fig. M6: Distribution of clinical depression and generalized anxiety levels in Study I

Fig. M7: Distribution of clinical depression and generalized anxiety levels in Study II

Fig. M8: Distribution of clinical depression and generalized anxiety levels in Study III

- clinical levels of depression and anxiety
- clinical levels of depression
- clinical levels of anxiety
- neither clinical levels of depression nor anxiety

### ***Adherence and satisfaction with the intervention***

Low adherence is a common problem in IMIs, especially when provided in a self-guided format (Beatty & Binnion, 2016; Christensen et al., 2009; van Ballegooijen et al., 2014; Zarski et al., 2016). The three interventions studied within this dissertation were offered with different amounts of guidance. While the GetWell.Started intervention was offered with full guidance, the Get.On Gratitude intervention was offered with adherence-focused guidance and the GCMO intervention was offered with no guidance at all.

Furthermore, the interventions varied in intensity. Of the 7 sessions offered within the GetWell.Started intervention participants conducted on average 4 sessions. Of the 5 sessions within the Get.On Gratitude intervention participants on average conducted 3.5 sessions and of the 10 sessions offered within the GCMO intervention participants averagely conducted 6.2 sessions (also see Figures M9 –



M11). This corresponds to adherence rates of 57% for GetWell.Started, 70.5% for Get.On Gratitude and 61.5% for the GCMO intervention.

While the adherence rate for GetWell.Started compares unfavourably to adherence rates of guided direct interventions for depression, the adherence rates for Get.On Gratitude compares favorably and the adherence rate for GCMO is comparable to adherence rates found for unguided direct interventions for depression (Karyotaki et al., 2021).

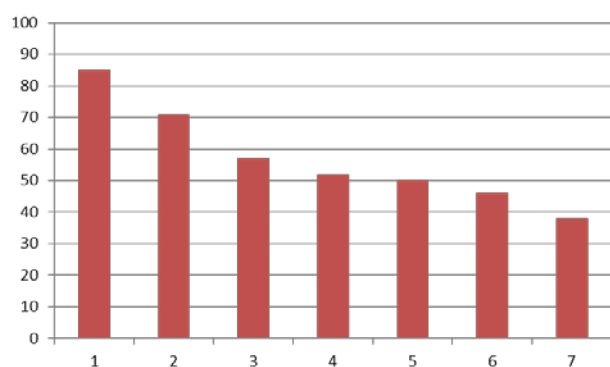


Fig. M9: Adherence to the sessions the intention to treat sample in Study I

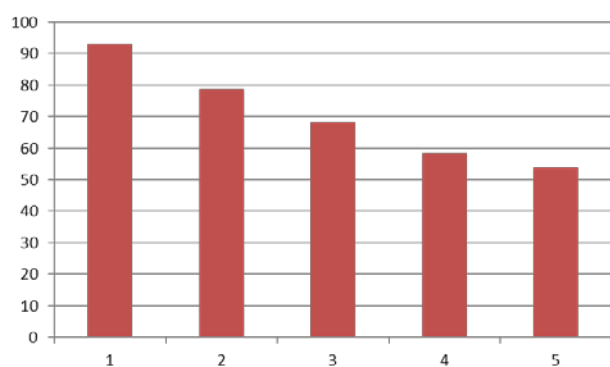


Fig. M10: Adherence to the sessions the intention to treat sample in Study II

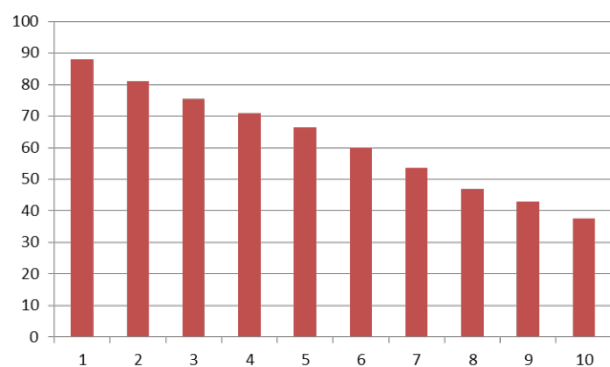


Fig. M11: Adherence to the sessions the intention to treat sample in Study III

With regard to GetWell.Started – although considerable effort was undertaken to increase adherence – the younger age (Karyotaki et al., 2015) and the restricted time due to the high occupational demands (Beatty & Binnion, 2016) of the target group, might explain the lower adherence.

The higher adherence to the Get.On Gratitude intervention is consistent with suggestions that gratitude interventions are easy to complete and enjoyable (Davis et al., 2016), as well as findings suggesting that adherence to gratitude interventions might be higher as compared to traditional CBT interventions (Geraghty et al., 2010b).

Besides adherence rates, ratings on satisfaction with the interventions are important indicators of an intervention's acceptance. Satisfaction with the particular interventions was measured with the Client Satisfaction Questionnaire adapted to IMIs (CSQ-I; Boß et al., 2016) in all three studies. Satisfaction was high and comparable between all three interventions with a CSQ-I mean ranging between 27.3 (GetWell.Started), to 26.6 (GCMO), to 25.7 (Get.On Gratitude). The satisfaction with the interventions in an overall, general sense is depicted in Figures M12 – M14. The vast majority of the participants stated to be very or mostly satisfied with the intervention they have received in an overall, general sense (GetWell.Started: 98%, Get.On Gratitude: 87%, GCMO: 91%).

There might be several reasons for the slightly higher satisfaction in the GetWell.Started study. It might be that the perceived fit to personal needs was higher in this trial due to extensive tailoring to the specific sample (e.g. Lehr et al., 2016), but the most intense human support provided within this trial might also be an explaining factor (e.g. Apolinário-Hagen et al., 2018). The overall satisfaction within the studies however is comparable to those reported in other interventions (Boß et al., 2016).

Overall, these results indicate that participants perceived the interventions as acceptable and suitable for their problems and needs.

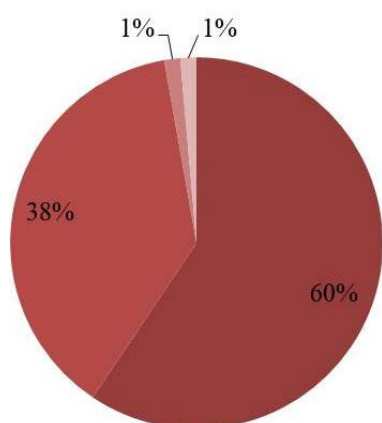


Fig. M12: Satisfaction with the intervention in an overall, general sense with the GetWell.Started Study

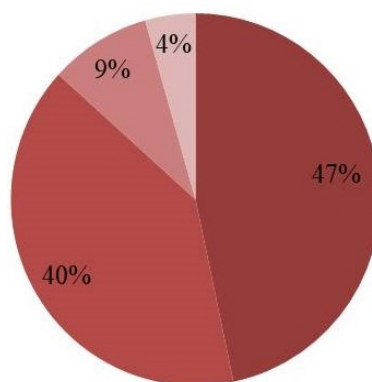


Fig. M13: Satisfaction with the intervention in an overall, general sense with the Get.On Gratitude intervention

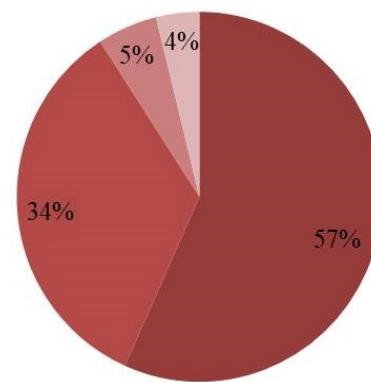
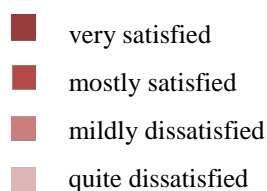


Fig. M14: Satisfaction with the intervention in an overall, general sense with the GCMO intervention



### Results on the efficacy to reduce depressive symptoms

All three studies significantly reduced depression as compared to the particular control groups at T2 (see Fig. M15) with a small effect ( $d = 0.38$ , 95% CI [0.13; 0.62]) within the Get.On Gratitude study and moderate effects within the GetWell.Started ( $d = 0.66$ , 95% CI [0.38; 0.94]) and GCMO ( $d = 0.47$ , 95% CI [0.26; 0.68]) studies. Overall, the three studies yielded a pooled effect on depressive symptoms at T2 of Hedges'  $g = 0.47$ , 95% CI [0.26; 0.68]. Pooled effects were calculated with Meta-

Essentials (Van Rhee et al., 2015).

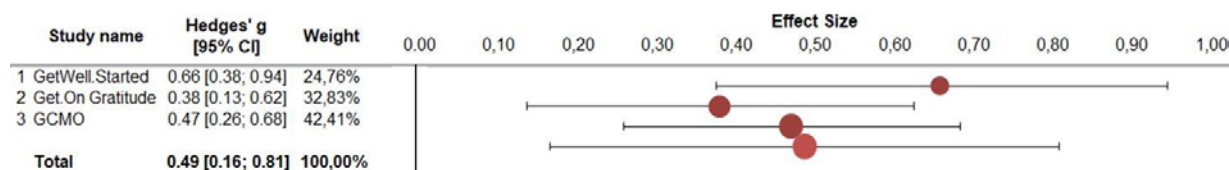


Fig. M15. The between-groups effects of the interventions studied within this dissertation on symptom severity of depression at T2. The time of post-intervention varied from two weeks (GCMO) to eight weeks (GetWell.Started). Heterogeneity:  $I^2 = 7.92\%$ .

In the GetWell.Started ( $d = 0.47$ ; 95% CI [0.19, 0.75]) and the Get.On Gratitude ( $d = 0.40$ ; 95% CI [0.15, 0.64]) studies, participants also reported significantly reduced depressive symptoms as compared to the WLGs at 3-MFU.

At 6-MFU in all three studies, participants reported significantly less depressive symptoms as compared to their baseline values with moderate to large within-group effect sizes (see Fig. M16), suggesting that the improvements made could be sustained up to six months. The overall pooled within-groups effect size for the 6-MFU was Hedges'  $g = 0.69$ , 95% CI [0.24; 1.13].

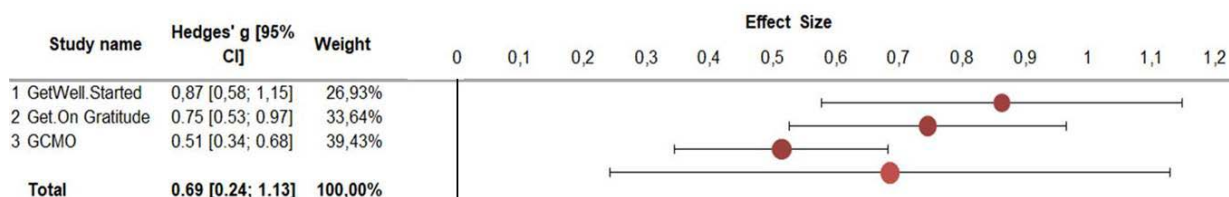


Fig. M16. The within-groups effects of the interventions studied within this dissertation on symptom severity of depression from baseline to 6-MFU. Heterogeneity:  $I^2 = 63.33\%$

While at baseline a significant proportion of participants reported clinically relevant depression scores (GetWell.Started: 59%, Get.On Gratitude: 44%, GCMO: 60%), rates were reduced in the IGs at T2. The participants who scored below the cut-off point for clinical significant levels of depression at T2 ranged across the three trials from 68% in the IG of the GetWell.Started trial, to 69% in the GCMO's IG, to 77% in the Get.On Gratitude's IG and from 44% in the GetWell.Started's WLG, to 45% in the GCMO's control group, to 58% in the Get.On Gratitude's WLG, with a significant difference between groups in all trials (all  $p$ 's < 0.01).

The corresponding NNTs ranged from 4.2 to 5.3 across studies. This means that in order for one additional participant – as compared to the control group – to be below the cut-off at T2 approximately five to six individuals had to be given access to one of the interventions.

At 3-MFU 68% in the IG of the GetWell.Started study and 75% in the IG of the Get.On Gratitude study scored below the cut-off point for clinical significant levels, as compared to 51% and 55%, respectively, in the WLGs. The difference between groups was also significant in both trials ( $p$ 's < 0.05).

The NNTs at 3-MFU for one additional participant below the cut-off were 5.9 and 5.1 for the

GetWell.Started and Get.On Gratitude study, respectively. In the GCMO study at 2-MFU 65% scored below the cut-off for clinical depression. This cannot be compared to the control group since the control group had access to the intervention prior to the 2-MFU.

However, a change of someone first scoring above a clinical cut-off to later scoring below a clinical cut-off might not represent a clinical meaningful change, since a difference of one point might be sufficient to change from clinically relevant to subthreshold symptoms. Therefore percentages for those with a minimal important clinical change were additionally calculated for each trial.

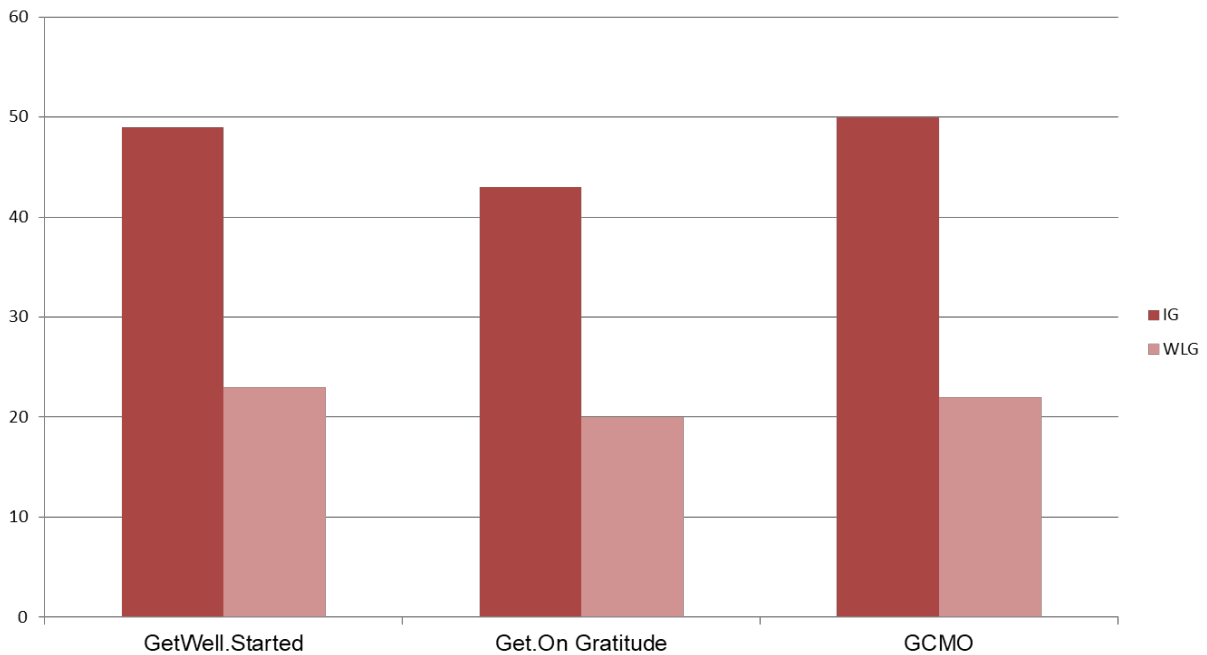


Fig. M17: Proportion of individuals in each study arm with a minimal important clinical improvement from baseline to post-intervention.

The participants that reported a minimal important clinical difference from baseline to T2 (also see Fig. M17) in the IGs ranged between 43% in the Get.On Gratitude trial, to 49% in the GetWell.Started, to 50% in the GCMO trial. In the control groups, participants with a minimal important clinical difference ranged from 20% in the Get.On Gratitude trial, to 22% in the GCMO, to 23% within the GetWell.Started trial.

The corresponding NNTs for one additional participant with minimal important clinical difference ranged between 3.6 and 4.3. This implies that four to five individuals need to partake in the studies in order for one to perceive a minimal important clinical reduction in depression.

From baseline to 3-MFU 53% in the GetWell.Started and 45% in the Get.On Gratitude study reported a minimal clinical important improvement as compared to 24% and 25% in the WLGs, respectively.

This corresponds to an NNT of 3.5 within the GetWell.Started study and an NNT of 4.9 within the Get.On Gratitude study. In the GCMO study 48% of the IG reported a minimal important clinical reduction of depression from baseline to 2-MFU.

Since using indirect interventions for depression reduction can be regarded as an off-label use of these interventions, it is important to also consider potential harmful effects. Therefore reliable deterioration

rates were calculated across trials.

Reliable deterioration was infrequently observed across all three trials with deterioration rates ranging from 3% to 5% in the IGs at T2 and from 5% to 12% in the control groups. The difference between groups was mostly non-significant (with an exception for the GetWell.Started study where the WLG at T2 had significantly higher deterioration rates than the IG). Reliable deterioration rates were slightly higher at the 3-MFU, with no significant differences between IGs ( $p > 0.05$ ) (8% GetWell.Started; 6% GetOn Gratitude) and WLGs (15% GetWell.Started; 11% GetOn Gratitude). At 2-MFU 4% of the IG's participants in the GCMO study reported a reliable deterioration.

### **Results on the mechanisms of change**

All three interventions studied within this dissertation can be interpreted as interventions for the indirect reduction of depressive symptoms, since they all primarily targeted a risk factor for depression (stress or RNT). It was hypothesized that the interventions all have indirect effects on depression by reducing the risk factors primarily targeted. The mediation analyses with the study-specific targeted risk factors as mediators and depression as outcome, all showed a significant indirect effect on depression.

In the GetWell.Started study the effect of the iSMI on depression at 3-MFU was significantly mediated by a reduction in stress at T2,  $a_1b_1 = -2.35$ , 95% CI [-3.66, -1.04].

In the Get.On Gratitude study in a parallel mediation model also including resilience, RNT at T2 significantly mediated the internet-based gratitude intervention's effect on depression at 3-MFU,  $a_1b_1 = -1.25$ , 95% CI [-2.42, -0.07]. The indirect effect through resilience was marginally significant,  $a_2b_2 = -0.56$  [-1.14, 0.02], within the ITT-sample, but was significant in an analysis within the completer sample. In both studies, the direct effect of the intervention was no longer significant after the hypothesized mechanisms of change (GetWell.Started: stress; Get.On Gratitude: RNT and resilience) were included in the model, GetWell.Started:  $c' = -2.30$ , 95% CI [-4.86, 0.26]; Get.On Gratitude:  $c' = -2.36$  [-4.92, 0.19].

In the GCMO study worry at T2 also mediated the effects of the intervention on depression (at T2),  $a_1b_1 = -0.51$ , 95% CI [-0.85, -0.18]. However, within this trial the direct effect remained significant,  $c' = -1.49$ , 95% CI [-2.28, -0.7].

### **Discussion of the significance of the results regarding efficacy and comparison to prior work**

The results of the trials of this dissertation show that interventions that primarily focus on risk factors for depression are also effective in the reduction of depression. In the following the results on depression will be first discussed in light of effects from comparable indirect interventions and second in light of the effects of direct IMIs for depression.

#### ***Internet-based Stress Management Interventions***

The results of GetWell.Started on depression are in line with meta-analytic evidence showing that iSMIs are effective in reducing depression in general (Heber et al., 2017), working (Phillips et al., 2019; Stratton et al., 2017) and student populations (Amanvermez et al., 2020) and add to the

knowledge that they are also effective for a group of highly distressed career starters – a population that has been under-investigated before.

The pooled effects meta-analytically found for iSMIs on depression range from  $d = 0.34$  to  $d = 0.63$  (Amanvermez et al., 2020; Heber et al., 2017; Stratton et al., 2017) with a wide heterogeneity regarding efficacy but also regarding important efficacy-moderating factors of the included participants (e.g. age, baseline severity; Reins et al., 2020) and the actual ingredients of the interventions.

Recently, an individual participant meta-analysis investigated the indirect effects of one particular iSMI (Harrer et al., under review). The iSMI investigated in this meta-analysis is the same as the one investigated in GetWell.Started, although the latter has been adapted and tailored to beginning teachers and complemented with a work-related skills training. The overall effect size of GetWell.Started on depression ( $d = 0.66$ ) is comparable with the overall effect found within this meta-analysis ( $d = 0.65$ ), but slightly smaller when comparing it with the pooled effect size of those studies with comparable amount of guidance ( $d = 0.82$ ).

The smaller effect might be explained by the younger age and the lower baseline severity of the participants within GetWell.Started which were found meta-analytically as moderators of efficacy (Reins et al., 2020) and adherence (for age: Karyotaki et al., 2015).

By complementing the iSMI with a work-related skills training within GetWell.Started a new paradigm for the development of occupational e-mental health interventions was developed, since it is the first to combine traditional elements of an iSMI with a work-related skills training for typical occupation-specific stressors. Combining an iSMI with an internet-based work-related skills training was found feasible, laying the foundation for the development of future occupational health interventions.

Although not directly tested within this dissertation, work-related skills trainings might also be valuable as indirect interventions and might have an additional indirect effect on depression (e.g. by increasing self-efficacy), but due to its tailoring might also be associated with increased acceptance and uptake.

### ***Gratitude Interventions***

In line with the results regarding Get.On Gratitude, meta-analytic evidence shows the efficacy of gratitude interventions on depression with pooled effect sizes between  $d = 0.13$  and  $d = 0.23$  (Cregg & Cheavens, 2021; Dickens, 2017). These effects are clearly below effects of direct internet-based self-help interventions for depression (Karyotaki et al., 2021; Reins et al., 2020), but a comparison is difficult since the samples in the gratitude interventions were mostly non-clinical samples with lower levels of depressive symptoms at baseline. Moreover, the gratitude interventions studied so far consisted mostly only of one exercise and are therefore not comparable in complexity to depression interventions.

As compared to the gratitude interventions investigated before – mostly containing only one gratitude

exercise – Get.On Gratitude contains a variety of strategies covering the complex psychological structure of gratitude. This might explain that the effect size found on depression for Get.On Gratitude is markedly higher ( $d = 0.38$ ) than that found in previous studies. Moreover, due to inclusion criteria participants were highly distressed at baseline leaving more room for improvement (Reins et al., 2020).

***Internet-based interventions for the general population’s mental health during the COVID-19 pandemic***

Regarding IMIs to tackle the general population’s health within the COVID-19 pandemic, evidence is still scarce to date. Only one study investigated an IMI comparable to GCMO. The effect of GCMO on depression ( $d = 0.47$ ) is comparable to the effect found within the study from Wahlund et al. ( $d = 0.38$ ). However, within the latter study a pure WLG was used, while in GCMO an active control group was used, thereby providing stronger evidence that an IMI is superior to inexpensive mental health advice provided over the Internet.

***Internet-based interventions directly targeting depression***

In the following the results regarding depression of the studies of this dissertation are compared to IMIs directly targeting depression. The average baseline depression values of all three studies within this dissertation are at the border between subclinical and mild depression.

Effects meta-analytically found for IMIs directly targeting depression within participants with comparable baseline severity are as follows: For subthreshold depression they range between  $d = 0.31$  for unguided IMIs against WL to  $d = 0.43$  for guided IMIs against WL. For mild depression they lie around  $d = 0.6$  against WL for both guided and unguided interventions (Karyotaki et al., 2021). The effects found for all three trials of this dissertation ( $d = 0.38$  to  $d = 0.66$ ) are thus comparable to these effects meta-analytically found for IMIs directly targeting depression within participants of comparable severity.

The response rates meta-analytically found for this subthreshold to mild participant group for IMIs directly targeting depression, lie around 20% for WL groups and around 46% for guided and around 37% for unguided IMIs (Karyotaki et al., 2021).

In contrast to the calculation of the response rate within the meta-analysis above – in line with recent recommendations (AWMF et al., 2022; J. A. Cook et al., 2019; Haase et al., 2022) – in this dissertation anchor-based response rates were calculated to determine the minimal important clinical difference. While traditionally used thresholds to classify treatment response are either based on statistical measures or randomly chosen thresholds, anchor-based methods are based on either patients’ or health professionals’ judgements of a minimal clinically important relevant effect.

Both, the response rates for the control groups of the three trials of this dissertation (range: 20–23%) and the response rates within the IGs (range: 45–50%) are comparable to the meta-analytically reported response rates, suggesting that participants benefitted to comparable extent from the indirect interventions.

Since previous trials on IMIs that could be framed as indirect interventions assessed depression only as a continuous secondary variable, the results of this dissertation additionally show the clinical and practical meaningfulness of indirect interventions on depression.

The deterioration rates for all three IGs assessed within this dissertation were low (range: 3–5%) and comparable to deterioration rates meta-analytically reported (range: 3–6%) for IGs within direct depression interventions (Ebert et al., 2016; Karyotaki, Kemmeren, et al., 2018), suggesting that indirect interventions are not associated with higher risk of deterioration than direct interventions for depression – at least in participants with averagely subthreshold to mild depression.

However, while there is an awareness to monitor and react to symptom deterioration in direct interventions for depression (Ebert et al., 2016), there might be insufficient awareness of the importance of similar safety procedures for indirect interventions although these seem equally important for indirect interventions.

### **Discussion of the significance of the results regarding mediators of change and comparison to prior work**

Besides efficacy of the indirect interventions for depression, within this dissertation, mediators of change of indirect interventions, primarily targeting transdiagnostic risk factors for depression, were investigated. This is important, since knowing why an intervention works might help in optimizing therapeutic interventions and therapeutic change (Kazdin, 2007; Lemmens et al., 2016).

In line with the idea of indirect interventions, the mediation analyses of all three studies showed that the transdiagnostic risk factors targeted primarily, mediated the interventions' effects on depression.

The research on mediators of change is under-investigated especially regarding IMIs for depression (Mogoşe et al., 2017) and has been identified as a key research area for the future (Holmes et al., 2018).

The results of RNT – or worry as a specific form of RNT – as a mediator of change is in line with previous evidence also suggesting that reductions in RNT mediate reductions in depression in traditional psychotherapeutic interventions (for a review: Lemmens et al., 2016) and IMIs (e.g. Cheng et al., 2020; Lamers et al., 2015; Newby et al., 2014; Warmerdam et al., 2010). Within the Get.On Gratitude study a dual pathway model via a risk-reduction and a resource-building pathway was examined. While RNT was significant, results on resiliency as a mediator were inconsistent: insignificant in the ITT-sample and significant in the completer sample. The finding that RNT mediated the intervention's effect on depression, while resiliency might not or to a lesser extent, might be explained by the greater conceptual proximity between RNT and depression and also by using RNT as an inclusion criterion, which led to a sample with greater room to improvement on RNT.

Regarding stress as a mediator of change in an iSMI's effect on depression, our results are in line with results from Nixon et al. (2021) that also found stress as a mediator in an iSMIs effect on depression.

These findings suggest that reducing transdiagnostic risk factors for depression might explain why indirect interventions might have an effect on depression, although the more proximal mediators of



change in the risk factor-depression relationship and the role of the therapeutic techniques used within the indirect interventions is still unclear.

The therapeutic techniques used within the indirect interventions were framed for the reduction of the primary outcomes, but are also used within direct interventions for the reduction of depression. For example within GetWell.Started and GCMO, (value-based) behavioral activation, problem solving and affect regulation exercises were used; within Get.On Gratitude the exercises were based on a CBT working-model that explained the interconnectedness of perception, thoughts, feelings and behavior and included exercises to change these aspects.

These methods have been used and been found effective in direct interventions for depression (Berking et al., 2019; Cuijpers et al., 2019). Thus the indirect interventions' effects on depression might also be explained by the comparable ingredients of the interventions that might have the same effect regardless of the concrete context in which they are framed.

Although the more concrete mechanisms of change of indirect interventions are not completely clear, the mediation analyses within this dissertation further support the evidence on indirect interventions for depression and highlight the potential value of targeting transdiagnostic risk factors.

### **Strengths**

*Gold standard of efficacy testing.* One major strength of the studies conducted within this dissertation is that they were conducted as RCTs according to the CONSORT guideline (e.g. a priori power analysis, specification of primary and secondary outcomes) and by employing state of the art measures to handle missing data. To avoid HARKing (Kerr, 1998) all studies were registered in one of the World Health Organization's primary registries. By these measures the highest scientific standards were ensured which strengthens the results on the efficacy of the interventions assessed within this dissertation.

*Active control group.* In the GCMO study an active control group was used, thereby showing that the IMI is more effective than inexpensive public mental health advice that was rapidly available at the beginning of the pandemic and could be considered standard care.

*New and innovative interventions.* All three internet-based interventions investigated within this dissertation were new in various aspects. First, the iSMI within the GetWell.Started study was the first internet-based intervention that combined an iSMI with a work-related skills training. For this purpose an internet-based classroom management intervention was newly developed, which, to the best of my knowledge, is also the first existing internet-based classroom management intervention.

Second, while prior studies on gratitude interventions only evaluated single exercises such as a gratitude diary, the gratitude intervention investigated in the Get.On Gratitude study was the first gratitude intervention that combined gratitude exercises in a complex intervention that is comparable in its complexity to other internet-based interventions.

Finally, the GCMO intervention was newly developed and registered as the first internet-based intervention for the general population's mental health during the COVID-19 pandemic.

*Mechanisms of change.* Although importance of studying mechanisms of change has long been agreed on (Lemmens et al., 2016; Mogoşe et al., 2017), research on mechanisms of change in internet-based interventions was long under-investigated. In all three studies of this dissertation in addition to examining efficacy, mediation analyses, testing how the interventions might work on depression, were conducted. Studying mechanisms of change may aid in optimizing therapeutic change and might inform refinement of intervention packages by including or fostering those elements that are crucial for change and excluding those that seem not to bring any change (Kazdin, 2007; Lemmens et al., 2016).

In two of the three studies by assessing the mediator and the outcome at different time points temporal precedence of the mediators was tried to be established, thereby providing stronger evidence on causality. By showing that the primarily targeted transdiagnostic risk factors, mediated the interventions' effect on depression the idea of indirect intervention for the reduction of depression is further corroborated.

*Assessing clinical and practical meaningfulness of the effects.* Research on IMIs that could be framed as indirect interventions for the reduction of depression have mostly only reported results regarding the efficacy on depression in terms of standardized mean differences between groups. Numbers of participants reporting above or subthreshold symptoms of depression at baseline and T2, as well as those with minimal important clinical change from baseline to T2 or reliable deterioration of depression have mostly not been reported (Cuijpers, 2021b). Within this dissertation additional analyses were conducted to also assess the clinical and practical meaningfulness of the indirect interventions. In line with recent recommendations (AWMF et al., 2022; J. A. Cook et al., 2019; Haase et al., 2022) an anchor-based approach was used to determine minimal clinical important change.

*Targeting transdiagnostic risk factors.* Depression is a highly comorbid disorder (ter Meulen et al., 2021). With stress and RNT two transdiagnostic risk factors were addressed. Thereby a wider range of disorders was targeted (A. G. Harvey et al., 2004; Schaeuffele et al., 2021). In addition to reductions on depression, all trials showed significant reductions on anxiety and two trials on insomnia symptoms. These finding further corroborate the idea of transdiagnostic risk factors.

*Tailoring interventions to participants' stressors and needs and combining internet interventions for mental health with a work-related skills training.* In line with recommendations made on personalizing and tailoring of IMIs (Holmes et al., 2018; Schaeuffele et al., 2021), with GetWell.Started and GCMO, two interventions were developed to fit participants' stressors and needs. With GetWell.Started, by combining an iSMI with a work-related skills training, a new avenue of tailoring interventions has been developed and shown to be feasible. This work-related skills training might have had synergistic effects on depression. In order to increase perceived fit of GCMO as a mental aid within the COVID-19 pandemic, exercises used were tailored to the stressors many individuals experienced during the COVID-19 pandemic.

*Showing the sustainability of the effects.* By employing extended six-month follow-ups within the IGs it could be shown that the effects of all three interventions regarding the primary outcomes as well as the secondary outcome depression were sustained up to six months. Before this dissertation, particularly evidence on the longer-term efficacy of gratitude interventions as well as on IMIs for mental health within the COVID-19 pandemic was non-existent and the results of this dissertation show that both were able to produce sustained effects up to six months.

### **Limitations**

*Open community recruitment strategy.* Participants within all three trials of this dissertation were recruited with an open recruitment strategy and self-selected to participate in the studies. This limits the generalizability of the results since individuals with certain moderating factors for efficacy and prognosis of depression might not be included in the studies. For example the proportion of participants with a university degree is higher than what would be expected if a representative sample could have been recruited. Thus it can also be hypothesized that socioeconomically disadvantaged individuals were rather underrepresented within the trials. Since, socioeconomically disadvantaged individuals were found meta-analytically to have a worse prognosis for depression (Buckman, Saunders, Stott, et al., 2022) the effect found within the trials of this dissertation should not be generalized to these subgroups.

*Important characteristics of the sample unknown.* Moreover, important clinical and biographical characteristics that were found to be associated with the prognosis for depression were not assessed (e.g. childhood adversity, family history of mental disorders, age at onset, duration and number of depressive episodes and comorbidities (for reviews: Burcusa & Iacono, 2007; Hölzel et al., 2011; D. N. Klein & Santiago, 2003; Kraus et al., 2019; Struijs et al., 2021)) and it is not known if the study's samples are representative with regard to these variables and thus if the results also generalize to individuals with these risk factors for prognosis or whether these variables are associated with non-response.

*No comparative efficacy studies.* All three interventions were assessed in separate RCTs. Therefore the comparison of the effects found is limited. Since different measures of depression were used for which no conversion algorithm exists (Wahl et al., 2014), direct comparisons of depression values are restricted. Moreover, the recruitment strategy as well as the differing application of inclusion criteria might have led to samples differing in important characteristics potentially moderating efficacy of the interventions (Lindner et al., 2015).

For example a comparison of the number of participants with above threshold depression and anxiety levels suggests that participants within the Get.On Gratitude study – despite all participants fulfilled inclusion criteria regarding elevated RNT – were less distressed as compared to the participants in GetWell.Started and GCMO. This might be explained by the positive psychological focus of the intervention, potentially addressing also individuals with less severe distress. Another explanation might lie in the differences in recruitment strategies, since for the Get.On Gratitude study a higher

proportion of individuals was recruited through a print magazine, which was found to lead to lower proportions of individuals with severe mental health problems as compared to recruitment strategies through the Internet (Lindner et al., 2015).

*No comparison with direct interventions.* Furthermore, although we compared the effects on depression with meta-analytical evidence from IMIs directly targeting depression, no direct comparison between indirect interventions for depression and direct interventions for depression was conducted within this dissertation. Future RCTs should compare preferences for, efficacy of and adherence to direct vs. indirect interventions for depression in head-to-head studies.

*Harmful effects.* Within all three studies of this dissertation reliable deterioration rates were assessed as one indicator for potential harmful effects. However, reliable deterioration as the only indicator has been argued to neglect a range of important harmful effects (J. P. Klein et al., 2021). Since recommendations should be guided by taking efficacy and harmful effects into account, future studies should assess harmful effects in a more comprehensive manner, e.g. experience of unpleasant memories, stigma or changes and strains in life areas (Herzog et al., 2019; Strauss et al., 2021).

*Depression as secondary outcome.* Depression within all three interventions of this dissertation was not the prespecified primary outcome and the results of the analyses on depression are thus of exploratory nature.

*Mechanisms of change.* Although the assessment of mediators of change is a major strength of this dissertation and the methodological approach already meets many important requirements for process research (Kazdin, 2007; Lemmens et al., 2016), it cannot be ruled out that change in the outcomes occurred prior to change in the mediators. Future studies should assess mediators and outcomes at multiple time points during treatment and should include multiple possible mediators. In addition to mediation analyses, such data could be used to investigate trajectories of change.

*Classification of effects found within this dissertation.* The classification of the effect sizes regarding efficacy that were referred to within this dissertation followed the conventional classification of Cohen (1988) (i.e. 0.2, 0.5 and 0.8 for small, medium and large effects, respectively). Solely classifying effects based on Cohen's definition, however, is difficult, since the same value of Cohen's  $d$  may be produced by different values of change (mean differences), depending on how heterogeneous the sample is ( $SD$ ). Furthermore Cohen's  $d$  does not make statements about the meaningfulness or practical importance of an effect (J. A. Cook et al., 2019; Cuijpers, 2021a). To address this limitation within this dissertation's interventions unstandardized mean differences between groups ( $\Delta_{WLG-IG}$ ) as well as binary outcomes (NNT) were additionally calculated.

### **Future research and implications for practice**

*Assessment of clinical moderators.* Depressive symptoms within this dissertation were solely measured with self-reported measures assessing depressive symptoms – in line with current diagnostic criteria – within the past two weeks. Solely with the help of this self-assessment measure, however, the different depressive disorder diagnoses – specified at the beginning of this dissertation – cannot be

clearly distinguished. Thus, two people who have comparable levels of depressive symptoms in the past two weeks count the same, regardless of whether those symptoms have been present for months or even years in one person – for example as part of chronic MDD or dysthymic disorder – and only for a few weeks in the other.

Similarly, other important clinical and biographical variables influencing treatment prognosis such as number of recurrences, family history of mental disorders or comorbidities – be it mental or physical diseases – have not been assessed, although it is known that they influence prognosis (for reviews: Burcusa & Iacono, 2007; Hölzel et al., 2011; D. N. Klein & Santiago, 2003; Kraus et al., 2019; Struijs et al., 2021).

To understand for whom indirect interventions for depression work, for whom they do not and for whom they might even be associated with a deterioration of symptoms or harmful effects, these potential moderating factors should be more rigorously examined in future studies.

*Examining change on the symptom level.* Furthermore, the efficacy within all three trials of this dissertation was based on aggregated symptom scores. Since IMIs for depression were shown to reduce only certain symptoms of depression, but not others (Kaiser et al., 2021), symptom specific effects should be evaluated in indirect interventions and compared to direct interventions.

This might help in identifying further mediators of change and moderators of efficacy in order to determine for whom such interventions might be helpful and for whom they might not be helpful.

Indirect and direct interventions for depression might differ in the symptom profile they are effective on. For example, in a meta-analysis, Torok et al. (2020) showed that only direct interventions targeting suicidal ideation reduced suicidal ideation but interventions targeting depression directly and suicidal ideation indirectly were not, although suicidal ideation is a symptom of depression.

*Prevention and treatment trials.* Within this dissertation, depression was not the prespecified primary outcome and no inclusion or exclusion criteria for depression were set up. Future studies should conduct both, prevention and treatment trials with depression as a prespecified primary outcome to further corroborate the findings of this dissertation.

Within treatment trials future research should particularly assess the efficacy in severely depressed individuals, since these were underrepresented within the current studies. In such trials the establishment of a monitoring system of symptom deterioration is particularly important. Moreover, the additive effect of a combined treatment including pharmacotherapy and internet-based (in-) direct interventions for depression should be assessed (e.g. Mantani et al., 2017), since a combination of pharmacotherapy with face-to-face psychotherapy has meta-analytically been found to be more effective than either treatment alone in severely depressed individuals (Cuijpers et al., 2020). Furthermore, future research should discuss practical meaningful target differences for prevention and treatment trials a priori with different stakeholder groups (J. A. Cook et al., 2019).

*Recruitment and tailoring to subgroups underinvestigated to date.* When examining important participant characteristics of the studies conducted within this dissertation, it becomes evident that

certain subgroups might not be reached as good as others.

Within the current trials men, the elderly and less educated individuals seem not to be reached as good, which is also typical for other IMIs for depression (Karyotaki, Ebert, et al., 2018; Köhnen et al., 2020; Königbauer et al., 2017; Reins et al., 2020).

This dissertation suggests that it is not necessary to target depression directly to reduce depression. This is an opportunity for future research to find and develop indirect interventions that might be appealing for those groups that are difficult to reach to date and to specifically tailor indirect IMIs for such groups.

For example, tailoring the iSMI for individuals transitioning from school to vocational training might be a valuable way to reach young, less educated individuals. Future research has to determine whether such tailored interventions are indeed associated with higher uptake in difficult-to-reach populations.

*Assessing the value of complementing IMIs with setting-specific skills training.* Within the GetWell.Started study the feasibility of complementing an iSMI with a work-related skills training was shown. Future research should assess the efficacy of complementing the iSMI with the work-related skills training. If proven to be of additive value, future research might develop further setting-specific skills trainings to complement IMIs (e.g. application training for unemployed individuals, debt counseling for debtors). This could be a valuable way to further tailor and personalize IMIs to the preferences, stressors and needs of individuals.

*Stigmatization and uptake associated with indirect interventions for depression.* The results of this dissertation suggest that indirect interventions are comparably effective to reduce depression than direct interventions. Indirect interventions were proposed to be perceived as less stigmatizing and might thereby lead to higher uptake of interventions that reduce depression (Cuijpers, 2021b).

However, future research needs to examine whether indirect interventions are actually perceived as less stigmatizing and whether individuals who are reluctant to use IMIs that directly target depression are more likely to use indirect interventions that avoid the term “depression”. Other factors potentially influencing the intention to use should also be considered. For example individuals’ perceived causes of their mental symptoms might moderate the performance expectancy of an intervention.

*Participants’ subjective disease models.* Self-selection in the particular IMIs might have been influenced by individuals’ beliefs about their causes of distress and a resulting preference for a particular intervention (Dunlop et al., 2012; Khalsa et al., 2011; Meyer & Garcia-Roberts, 2007) leading to a congruence between participants’ beliefs about the causes of distress and a theoretically consistent intervention they have self-selected to.

Self-selecting in a suitable, preferred and acceptable treatment is suggested to be a moderator of treatment satisfaction, adherence and efficacy (e.g. Addis & Jacobson, 1996; Hamilton & Dobson, 2002; Kocsis et al., 2009; for a review: Lindhiem et al., 2014; for a review: Swift & Callahan, 2009; Williams et al., 2016) and future research should investigate the moderating role of the fit between individuals’ subjective disease models with the program theory of an intervention on acceptance and

efficacy.

*Dissemination and implementation of indirect interventions.* This dissertation shows that indirect interventions that primarily address “common mental health factors”, can reduce symptoms of depression to a comparable extent as IMIs that directly target depression.

If future research replicates and extends the findings of this dissertation in head-to-head studies, indirect interventions could broaden the range of effective intervention options for the prevention and treatment of depression.

Thus, in addition to IMIs for depression, an internet-based gratitude intervention, an IMI to reduce worry, or an iSMI could be offered for the reduction of depression and could be equally recommended – depending on the individual’s preferences. Indirect interventions might not only be valuable to individuals that are reluctant to use interventions that directly target depression, due to a fear of stigmatization. By offering a broader range of effective intervention options the preferences and needs of individuals might be better addressed. By this means, indirect interventions might increase the overall uptake of effective interventions for the reduction of depression.

More specifically in Germany with regard to prevention, the results of this dissertation strengthen the use of indirect interventions for depression by statutory health insurance companies in accordance with § 20 Abs. 2 SGB, to prevent and sustainably treat depressive disorders.

Regarding treatment of depression, indirect interventions might complement direct digital health applications (DIGAs) for depression and thereby extend the range of interventions to choose from.

DIGAs in Germany may be prescribed by physicians and psychotherapists. If an internet- and mobile based treatment is considered for the treatment of depression, physicians and psychotherapists together with their patients could – in a shared decision making process – choose an appropriate intervention out of a range of effective interventions by taking into account the patient’s perceived causes of depressive symptoms, their concerns and preferences. Offering multiple direct and indirect internet-based treatment options for depression and deciding on that in a shared decision making process might increase uptake, adherence and possibly even effectiveness.

## **Conclusion**

This dissertation assessed the efficacy of three different IMIs that could be framed as indirect interventions for the reduction of depression. The indirect interventions studied within this dissertation primarily target transdiagnostic risk factors that are suggested to be perceived as less stigmatizing as compared to “depression”. Within three RCT studies the efficacy to reduce depression as compared to (active) waitlist control groups was shown, as well as the clinical relevance of these effects. The effect sizes found for the indirect IMIs are comparable to those found within studies that directly target depression in individuals with less severe depression and deterioration rates also seem comparable.

In addition, three mediation analyses suggest that the interventions exerted their effect on depression by reductions of the risk factors primarily targeted.

Should future research corroborate the findings of this dissertation in head-to-head studies comparing direct interventions with indirect interventions for depression, the latter might extend the range of effective interventions for depression, potentially increasing the uptake of such services and thereby reducing the burden of depression.



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## **About the author**

Hanna Heckendorf studied psychology in Lüneburg, Hagen and Cologne, Germany. She has longstanding expertise in researching the efficacy and implementation of internet-based mental health interventions and has also worked in companies that implement such interventions in routine care. In 2017, she started her PhD research at the Leuphana University in Lüneburg, Germany, on the topic of internet-based interventions for the indirect reduction of depression. During this time she has developed several internet-based interventions and evaluated their efficacy. Parallel to her academic career, she worked as a therapist in an inpatient clinic. Currently she works in outpatient care, on her way to become a licensed CBT-psychotherapist.



## **Über die Autorin**

Hanna Heckendorf studierte Psychologie in Lüneburg, Hagen und Köln. Sie verfügt über langjährige Erfahrung in der Forschung zur Wirksamkeit und Implementierung von internetbasierten Interventionen für die psychische Gesundheit und hat auch in Unternehmen gearbeitet, die solche Interventionen in die Routineversorgung implementieren. Im Jahr 2017 begann sie ihre Promotion an der Leuphana Universität Lüneburg zum Thema internetbasierte Interventionen zur indirekten Reduktion von Depressionen. In dieser Zeit hat sie mehrere internetbasierte Interventionen entwickelt und deren Wirksamkeit evaluiert. Parallel zu ihrer akademischen Laufbahn arbeitete sie als Therapeutin in einer psychosomatischen Klinik. Aktuell arbeitet sie in der ambulanten Versorgung, auf dem Weg zur Approbation als VT-Psychotherapeutin.