LEUPHANA
UNIVERSITÄT LÜNEBURG

# Digital Stress Management Interventions:

# Promoting Mental Health in the Workplace

Von der Fakultät Nachhaltigkeit

der Leuphana Universität Lüneburg zur Erlangung des Grades

Doktorin der Naturwissenschaften

- Dr. rer. nat. -

genehmigte Dissertation von

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geboren am 12.01.1989 in Düsseldorf

Eingereicht am: 06.12.2024

Mündliche Verteidigung (Disputation) am: 27.06.2025

Erstbetreuer und Erstgutachter: Prof. Dr. Dirk Lehr, Leuphana Universität Lüneburg

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Drittgutachter: Prof. Dr. Christian Warneke, HAW Hamburg

Die einzelnen Beiträge des kumulativen Dissertationsvorhabens sind wie folgt veröffentlicht:

Nixon, P., Boß, L., Heber, E., Ebert, D. D., & Lehr, D. (2021). A three-armed randomised controlled trial investigating the comparative impact of guidance on the efficacy of a web-based stress management intervention and health impairing and promoting mechanisms of prevention. *BMC Public Health,* 21(1), 1-18. doi: 10.1186/s12889-021-11504-2.

Nixon, P., Ebert, D. D., Boß, L., Angerer, P., Dragano, N., & Lehr, D. (2022). The Efficacy of a Web-Based Stress Management Intervention for Employees Experiencing Adverse Working Conditions and Occupational Self-efficacy as a Mediator: Randomized Controlled Trial. *Journal of Medical Internet Research*, 24(10):e40488. doi: 10.2196/40488.

Harrer, M., Nixon, P., Sprenger, A. A., Heber, E., Boß, L., Heckendorf, H., Buntrock, C., Ebert, D. D., Lehr, D. (2024). Are Web-Based Stress Management Interventions Effective As An Indirect Treatment For Depression? An Individual Participant Data Meta-Analysis of Six Randomized Trials. *BMJ Mental Health,* 27: 1-8. doi: 10.1136/bmjment-2023-300846.

Veröffentlichungsjahr: 2025

*"We shall be made truly wise if we be made content;*
*content, too, not only with what we can understand,*
*but content with what we do not understand."*

– Charles Kingsley (1819-1875)

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# List of Abbreviations

| | |
|---|---|
| AFG | Adherence-focused guidance |
| ANCOVA | Analysis of covariance |
| CBT | Cognitive Behavioral Therapy |
| CD-RISC | Connor-Davidson Resilience Scale |
| CES-D | Center for Epidemiologic Studies Depression Scale |
| CI | Confidence interval |
| CrI | Credibility interval |
| d | Effect size |
| ERI | Effort-reward imbalance |
| IG | Intervention group |
| IPD | Individual participant data |
| M | Mean |
| NNT | Number needed to treat |
| OR | Odds ratio |
| OSS-SF | Occupational Self-Efficacy Scale-Short Form |
| PSS-10 | Perceived Stress Scale-10 |
| RCT | Randomised controlled trial |
| SD | Standard deviation |
| SH | Self-help |
| SMI | Stress management intervention |
| $T_n$ | Time points of assessment |
| WLC | Waitlist control |

# Abstract

Stress can have numerous adverse effects on both physical and mental health. In recent decades, the development of digital interventions has rapidly increased, accompanied by a growing body of research in this field. Meta-analyses have demonstrated that digital stress management interventions (SMIs) can effectively and sustainably reduce stress, resulting in improved health outcomes. However, questions remain about the practical application of these interventions, particularly regarding the resources required, such as the extent of guidance and the mechanisms through which positive effects are achieved. Employees facing high strain and adverse working conditions may be a target group that could especially benefit from digital SMIs; however, no research has yet examined whether a digital SMI can effectively reduce stress in this population. Furthermore, a novel paradigm proposes the utilisation of digital SMIs as an indirect treatment for depression. Despite this promising framework, systematic evidence supporting this approach remains unavailable. This dissertation aims to evaluate the efficacy of a digital SMI in employees through three distinct studies covering the following key aspects: (Study 1) guidance formats and mechanisms of prevention, (Study 2) adverse working conditions, and (Study 3) depression.

In Study 1 ($N$=404), a three-armed randomised controlled trial (RCT) was conducted to compare the efficacy of the investigated SMI for two different intervention conditions, adherence-focused guidance (AFG) and self-help (SH), to a waitlist control group (WLC). The primary outcome was perceived stress. Secondary outcomes were health- and work-related measures. In both intervention groups, stress levels were significantly reduced after participation. Analyses of covariance (ANCOVA) revealed significant group effects at post-intervention (T2), $F_{2,400}$=36.08, $P$<.001 and at a six-month follow-up (T3), $F_{2,400}$=37.04, $P$<.001, with large effect sizes for both AFG at T2, $d$=0.83, 95% $CI$ [0.58, 1.08], Δ5.46 and T3, $d$=0.85, 95% $CI$ [0.60, 1.10], Δ5.78, and SH at T2, $d$=0.88, 95% $CI$ [0.63, 1.13], Δ5.15, and T3, $d$=0.91, 95% $CI$ [0.66, 1.16], Δ5.41. Significant effects were also observed for the secondary outcomes in both intervention groups compared to the controls, including depression. The efficacy between intervention groups (AFG vs. SH) did not significantly differ from each other for any outcome. The positive effect of the intervention on depression was mediated by perceived stress, $a_1b_1$=−0.77, 95% $CI$ [−1.26, −0.34], and resilience, $a_2b_2$=−0.62, 95% $CI$ [−1.05, −0.26].

For Study 2 ($N$=262), a second RCT was conducted to compare the efficacy of the SMI for employees with elevated stress levels and an effort-reward imbalance (ERI) to a WLC.

ANCOVAs demonstrated significantly higher stress reductions for the intervention group compared to the controls at T2, $F_{259,1}$=46.14, $P$<.001, $d$=0.87, 95% *CI* [0.61, 1.12], Δ5.00 and T3, $F_{259,1}$=24.82, $P$<.001, $d$=0.65, 95% *CI* [0.41, 0.90], Δ4.19. Additionally, occupational self-efficacy significantly mediated the intervention's effect on perceived stress, $b$=–0.44, $t_{258}$=–6.87, $P$<.001. Further mediation analyses revealed a significant indirect effect of occupational self-efficacy on perceived stress via rewards received at work, $b$=0.18, $t_{259}$=4.52, $P$<.001, but not via efforts expended, $b$=0.01, $t_{259}$=0.27, $P$>.05.

Finally, in Study 3 ($N$=1235), the first systematic evaluation of the efficacy of a digital SMI on depression was conducted through an individual participant data (IPD) meta-analysis based on $K$=6 RCTs, including only participants with clinically relevant depression. The results demonstrated positive effects on depressive symptom severity at post-intervention (T2), $d$=–0.65, 95% *CrI* [–0.84, –0.48], and at follow-up (T3), $d$=–0.74, 95% *CrI* [–1.01, –0.48]. Furthermore, a linear relationship between depressive symptom severity and the number of completed intervention modules was found, with effects in favor of guided formats over unguided ones.

Overall, the utilised digital SMI was effective in sustainably reducing elevated stress levels in employees, including those exposed to adverse work conditions. Positive effects were also observed across various health- and work-related measures, including depression. The SMI was effective in both conditions, AFG and SH. Notably, occupational self-efficacy mediated the efficacy of the intervention, highlighting the importance of enhancing personal resources, particularly when adverse factors at work cannot be directly changed. First systematic evidence was obtained showing that SMIs may serve as a feasible approach for reducing depression. Additionally, a dual pathway was identified for this effect, demonstrating that both resilience and perceived stress directly impacted the relationship between the intervention and depression.

In conclusion, it can be assumed that the investigated digital SMI is effective (1) when offered with the guidance formats AFG or SH, (2) in reducing stress in employees, even those facing adverse working conditions, and (3) in reducing depression.

# Zusammenfassung

Stress kann zahlreiche negative Auswirkungen auf die körperliche und mentale Gesundheit haben. In den letzten Jahrzehnten hat die Entwicklung digitaler Interventionen rapide zugenommen, ebenso wie die Forschung auf diesem Gebiet. Meta-Analysen haben gezeigt, dass digitale Stressbewältigungsinterventionen (SMIs) Stress effektiv und nachhaltig reduzieren und sich damit positiv auf die Gesundheit auswirken können. Es gibt jedoch offene Fragen zur praktischen Anwendung solcher Interventionen, insbesondere hinsichtlich der benötigten Ressourcen und des Umfangs der persönlichen Unterstützung, die für positive Effekte benötigt werden. Insbesondere Berufstätige, die hohen Belastungen und ungünstigen Arbeitsbedingungen ausgesetzt sind, könnten von einer digitalen SMI profitieren; jedoch wurde bislang noch nicht untersucht, ob eine digitale SMI in dieser Zielgruppe effektiv Stress reduzieren und sich damit positiv auf die Gesundheit auswirken kann. Darüber hinaus postuliert ein neuartiges Paradigma den Einsatz digitaler SMIs zur indirekten Behandlung von Depressionen. Zu diesem vielversprechenden Ansatz liegt allerdings bislang keine systematische Evidenz vor. Die vorliegende Dissertation zielt darauf ab, die Wirksamkeit einer digitalen SMI bei Berufstätigen mittels drei verschiedener Studien zu evaluieren, die die folgenden Kernthemen abdecken: (Studie 1) Formate der persönlichen Begleitung und Präventionsmechanismen, (Studie 2) ungünstige Arbeitsbedingungen und (Studie 3) Depression.

In Studie 1 ($N$ = 404) wurde eine dreiarmige randomisierte kontrollierte Studie (RCT) durchgeführt, um die Wirksamkeit der untersuchten SMI in zwei verschiedenen Interventionsbedingungen, Adhärenz-fokussierte Unterstützung (AFG) und Selbsthilfe (SH), im Vergleich zu einer Wartelistenkontrollgruppe (WLC) zu untersuchen. Der primäre Endpunkt war wahrgenommener Stress, sekundäre Endpunkte waren gesundheits- und arbeitsbezogene Parameter. In beiden Interventionsgruppen, AFG und SH, waren die Stressniveaus nach der Teilnahme signifikant reduziert. Kovarianzanalysen (ANCOVA) ergaben signifikante Effekte zwischen den Gruppen nach der Intervention (T2), $F_{2,400}$ = 36,08, $P$<0,001 sowie nach sechs Monaten (T3), $F_{2,400}$ = 37,04, $P$ < 0,001, mit großen Effektstärken sowohl für AFG zu T2, $d$ = 0,83, 95 % $CI$ [0,58, 1,08], Δ 5.46 und T3, $d$ = 0,85, 95 % $CI$ [0,60, 1,10], Δ 5.78, als auch für SH zu T2, $d$ = 0,88, 95 % $CI$ [0,63, 1,13], Δ 5.15 und T3, $d$ = 0,91, 95 % $CI$ [0,66, 1,16], Δ 5.41. Signifikante Effekte wurden auch für die sekundären Endpunkte in beiden Interventionsgruppen im Vergleich zur Kontrollgruppe beobachtet, einschließlich für Depression. Die Wirksamkeit zwischen den Interventionsgruppen (AFG vs. SH) unterschied

sich für keinen Endpunkt signifikant voneinander. Der positive Effekt der Intervention auf Depression wurde durch wahrgenommenen Stress, $a_1b_1 = -0.77$, 95% *CI* [−1.26, −0.34], und Resilienz, $a_2b_2 = -0.62$, 95% *CI* [−1.05, −0.26], mediiert.

In Studie 2 ($N = 262$) wurde eine zweite RCT durchgeführt, um die Wirksamkeit der SMI für Berufstätige mit erhöhtem Stressniveau und einem Ungleichgewicht von Anforderungen und Gratifikationen (engl. effort-reward imbalance, ERI) im Vergleich zu einer WLC zu untersuchen. ANCOVAs zeigten signifikant höhere Stressreduktionen in der Interventionsgruppe im Vergleich zur Kontrollgruppe zu T2, $F_{259,1} = 46{,}14$, $P < ,001$, $d = 0{,}87$, 95% *CI* [0,61, 1,12], Δ 5.00) sowie zu T3, $F_{259,1} = 24{,}82$, $P < ,001$, $d = 0{,}65$, 95% *CI* [0,41, 0,90], Δ 4,19. Zudem mediierte berufliche Selbstwirksamkeit signifikant den Effekt der Intervention auf wahrgenommenen Stress, $b = –0{,}44$, $t_{258} = –6{,}87$, $P < ,001$. Weitere Mediationsanalysen zeigten einen signifikanten indirekten Effekt der beruflichen Selbstwirksamkeit auf Stress über Gratifikationen, jedoch nicht über Anforderungen, $b = 0{,}18$, $t_{259} = 4{,}52$, $P < ,001$.

Schließlich wurde in Studie 3 ($N = 1235$) mittels einer Meta-Analyse basierend auf individuellen Teilnehmendendaten (IPD) aus $K = 6$ RCTs die erste systematische Evaluation der Wirksamkeit einer SMI auf Depression durchgeführt, wobei nur Personen mit klinisch relevanter Depression eingeschlossen wurden. Die Ergebnisse zeigten positive Effekte auf die Schwere der depressiven Symptome nach der Intervention (T2), $d = –0{,}65$, 95 % *CrI* [–0,84, –0,48] sowie nach drei Monaten (T3), $d = –0{,}74$, 95 % *CrI* [–1,01, –0,48]. Darüber hinaus wurde ein linearer Zusammenhang zwischen der Schwere der depressiven Symptome und der Anzahl der absolvierten Interventionsmodule festgestellt, wobei die Effekte zugunsten Formaten mit persönlicher Begleitung gegenüber jenen ohne Unterstützung ausfielen.

Insgesamt war die untersuchte digitale SMI wirksam, um das erhöhte Stressniveau bei Berufstätigen nachhaltig zu reduzieren, einschließlich derjenigen, die unter ungünstigen Arbeitsbedingungen tätig waren. Darüber hinaus wurden positive Effekte für weitere gesundheits- und arbeitsbezogene Maße, einschließlich depressiver Symptome, gefunden. Die SMI war mit beiden angebotenen Formaten der persönlichen Unterstützung, AFG und SH, wirksam. Die Wirksamkeit der Intervention wurde durch berufliche Selbstwirksamkeit mediiert, was auf die Bedeutung der Förderung persönlicher Ressourcen hinweist. Diese könnten insbesondere dann eine wichtige Rolle spielen, wenn ein direktes Einwirken auf ungünstige Arbeitsbedingungen nicht möglich ist. Es konnten erste systematische Hinweise darauf gefunden werden, dass SMIs eine praktikable Methode zur Reduktion depressiver

Symptome sein könnten. Als Wirkmechanismus der SMI auf depressive Symptome wurde ein Doppelpfad identifiziert, der zeigt, dass sowohl Resilienz als auch wahrgenommener Stress einen direkten Einfluss auf den Zusammenhang zwischen der Intervention und Depression haben.

Abschließend kann angenommen werden, dass die untersuchte digitale SMI wirksam ist, (1) wenn die persönliche Begleitung in Form von AFG oder SH angeboten wird, (2) um Stress bei Berufstätigen zu reduzieren, auch wenn sie unter ungünstigen Arbeitsbedingungen tätig sind, und (3) um Depression zu reduzieren.

# Chapter 1: Introduction

In the first chapter of this dissertation, the underlying objectives of this work are presented, along with background information and evidence. Furthermore, the structure of this dissertation is outlined.

## 1.1 Impact of Stress

Stress is a global, multifaceted phenomenon with profound implications for both individual well-being and societal health. As such, the World Health Organization classified stress as a major risk factor for the 21st century (World Health Organization, 2008). Psychological stress is a known risk factor for cardiovascular morbidity and related mortality (Steptoe & Kivimäki, 2013), cardiovascular heart disease, and increased associated inflammation (Wirtz & von Känel, 2017). It is also associated with depression (Köhler et al., 2018). The workplace, in particular, can be a source of stress that has been extensively researched, with meta-analytic evidence demonstrating adverse effects on immune function (Segerstrom & Miller, 2004), blood pressure (M. Y. Liu et al., 2017), sleep (Linton et al., 2015), and cardiovascular (Dragano et al., 2017; Kivimäki et al., 2012), metabolic (Kuo et al., 2019), and musculoskeletal systems (Da Costa et al., 2015; Hauke et al., 2011; Lang et al., 2012). Work stress has also been linked to increased mortality (Russ et al., 2012; Taouk et al., 2020). In addition to physical well-being, negative effects were also observed for mental health outcomes, including anxiety and depressive disorders (Madsen et al., 2017; Rugulies et al., 2017; Siegrist & Wege, 2020; Stansfeld & Candy, 2006), and suicidality (Milner et al., 2018).

Since it was first recorded, work-related stress has steadily increased, particularly affecting individuals in low-skilled positions (Hassard et al., 2018; Rigó et al., 2021). This rise poses challenges not only for individuals but also for society as a whole, leading to economic consequences such as increased healthcare costs and a lack of resources (Hassard et al., 2018; Kalia, 2002). Work-related stress substantially impacts both healthcare systems and workplaces that must cope with higher rates of sick leave, particularly due to mental disorders (Duchaine et al., 2020), absenteeism (Taibi et al., 2021), reduced productivity (Hassard et al., 2018), and premature labour market exits (Juvani et al., 2014; Mäcken, 2019). As a result, in addition to demographic changes and a growing shortage of skilled workers, managing work-related stress presents a pressing societal and economic challenge that demands sustainable solutions (Hassard et al., 2018).

### 1.2 Digital Stress Management Interventions

Stress management interventions (SMIs) have been shown to be effective and sustainable solutions for addressing the increasing need to reduce perceived stress in employees, leading to improved health and work performance (Bhui et al., 2012; Carolan et al., 2017; Richardson & Rothstein, 2008). The primary aim of SMIs is to reduce stress levels, often achieved through methods originating from theoretical frameworks such as Cognitive Behavioural Therapy (CBT). Digital SMIs offer considerable advantages over traditional on-site interventions, especially for rural or shift workers, by allowing participants to engage at their own pace, free from temporal and spatial constraints, and at a low cost for both users and providers (Griffiths et al., 2006; Junge et al., 2015; Van der Klink et al., 2001). Additionally, the low threshold and higher degree of anonymity provided by digital SMIs may alleviate fears of stigmatisation, which has been reported as a barrier to seeking help for some individuals (Corrigan, 2004; Rüsch et al., 2005). Most importantly, digital SMIs have been shown to effectively and sustainably reduce stress and associated health consequences within general (Heber et al., 2017) and working (Zarski et al., 2016) populations. However, meta-analytic evidence demonstrated high levels of heterogeneity across studies on occupational digital SMIs (Phillips et al., 2019), indicating the need for further research, particularly in work settings, to strengthen the evidence base.

Despite the increasing number of individuals experiencing stress and growing evidence for the efficacy of digital SMIs, critical gaps remain in the research on key aspects of their design and implementation (Ebert et al., 2014). One such aspect is the type of guidance provided throughout participation, which can vary in intensity, whether automated or involving human support (e.g., an e-coach) (Ebert et al., 2014; Heber et al., 2017; Zarski et al., 2016). Other factors include the mode of contact (e.g., e-mail or text messages), communication (synchronous or asynchronous), presence (in-person, online, or hybrid), and the overall aim of the provided guidance (e.g., improving adherence). While intensive support involves proactive engagement by an e-coach, who initiates contact without solicitation, less intensive formats are client-driven, relying on participants taking initiative when in need of support. To date, the following guidance formats have been established and researched in the utilisation of digital SMIs (Zarski et al., 2016): intensive support including written personalised feedback on completed or planned sessions (referred to as ‘full guidance’ in this dissertation), support aimed at ensuring adherence to the intervention protocol, including personal support upon request (referred to as ‘adherence-focused guidance’, AFG), or administrative guidance only (referred to as ‘self-help’, SH).

In addition to directly influencing the resources needed, the choice of guidance might also impact participants' acceptance and adherence (Apolinário-Hagen et al., 2017; Lin et al., 2018; Scheutzow et al., 2022), with research showing that guided formats tend to be more effective compared to less intensive types of guidance (Baumeister et al., 2014; Carolan et al., 2017; Heber et al., 2017). Despite the advantages of guided formats, interventions providing less intensive guidance might still yield beneficial effects on a large scale, potentially reaching more individuals at lower costs (Ebert et al., 2014). Before this dissertation, however, there was no data available on the comparative efficacy of different guidance formats within digital SMIs.

Digital SMIs are typically utilised as person-focused interventions, aiming to educate and support users in acquiring stress management skills to enhance their well-being, as exemplified by GET.ON "Fit im Stress" (see Chapter 2.1 for a detailed description). Given that employees are particularly vulnerable to stress, it is vital to assess the efficacy of a digital SMI in the context of adverse working conditions. Prior to this dissertation, no studies have explored whether and to what extent a digital SMI can be effective in the face of adverse working environments. Additionally, there was a lack of data on the potential mediating effects of personal resources and workplace environmental factors on the efficacy of a digital SMI under these conditions.

### 1.3 Stress and Depression

Experiencing stress, particularly in an adverse work environment, significantly increases the risk of subsequent onset of depression (Aronsson et al., 2017; Madsen et al., 2017; Rugulies et al., 2017; Siegrist & Wege, 2020). Depression is a major public health concern and leading cause of disability (Abbafati et al., 2020; Ferrari et al., 2013), and associated with morbidity (Momen et al., 2020; Plana-Ripoll et al., 2019), mortality (Cuijpers et al., 2014), and substantial economic costs (König et al., 2019), which considerably contributes to the overall burden of disease in society (Mathers & Loncar, 2006). Worldwide, incident cases of depression increased by 49.68% from 1990 to 2017 (Q. Liu et al., 2020), yet only one third of affected individuals receive any treatment at all, of which at best only 40% is minimally adequate (Chisholm et al., 2016a; Mekonen et al., 2021; Thornicroft et al., 2017). In addition to structural challenges in responding to the ever-increasing demand for treatment, fear of stigmatisation (Barney et al., 2006; Boerema et al., 2016; Clement et al., 2015) and attitudinal factors (Andrade et al., 2014) have been identified as major barriers to the uptake of treatment that seem particularly hindering for individuals suffering from depression (Mohr et al., 2010; Pyne et al., 2004).

In addressing the global key challenge of managing depression, digital interventions that target related issues have gained increasing attention and have been found to be effective in numerous systematic reviews and meta-analyses with guided and non-guided formats (Etzelmueller et al., 2020; Karyotaki et al., 2018, 2021; Königbauer et al., 2017). Despite this, the uptake rates of such interventions have repeatedly been reported as low (Batterham et al., 2021; Chisholm et al., 2016b; Musiat et al., 2014; Woodford et al., 2011), with attitudinal barriers being described as one of the main reasons for this undertreatment (Crisp & Griffiths, 2014; Thornicroft et al., 2017).

Against this background, the utilisation of so-called indirect interventions has been proposed as an emerging paradigm for the prevention and treatment of depression (Cuijpers, 2021). This alternative method suggests offering interventions that focus on issues associated with depression rather than directly on the condition (Cuijpers & Reynolds, 2022). Based on this paradigm, an innovative strategy could be the dissemination of digital SMIs for the prevention and treatment of depression for several reasons. First, individuals might find it easier and more appealing to participate in a less stigmatised intervention labelled 'stress management' opposed to 'depression', which could potentially increase the uptake of health interventions (Cuijpers, 2021). Second, compelling evidence demonstrated positive and sustainable effects for digital SMIs on depression in numerous studies (Deady et al., 2017; Heber et al., 2017; Stratton et al., 2017; Tan et al., 2014), including adolescent (Chi et al., 2018), general (Heber et al., 2017), working (Zarski et al., 2016), and even severely burdened populations with clinically relevant symptom severity (Weisel et al., 2018). Third, stress, particularly in the workplace, has been reported as commonly believed cause for depression (Hansson et al., 2010). Thus, offering relief through an intervention that targets the believed cause might lead to improved help-seeking behaviours. Fourth, the low threshold in digital SMIs seems to be appealing to individuals, as a vast amount are first-time help-seekers (Ebert, Heber, et al., 2016; Harrer et al., 2018, 2021). And, finally, stress and depression are closely related (Cohen et al., 2007; Madsen et al., 2017), and interventions or therapies share similar approaches, originating, for example, from CBT.

Stress and depression are directly associated, and compelling evidence supporting the potential use of digital SMIs for alleviating depression is accumulating. However, the existing evidence is characterised by high heterogeneity (Heber et al., 2017; Stratton et al., 2017), and before this dissertation there was no systematic evaluation of the efficacy of a digital SMI on depression published. Additionally, beyond investigating whether a digital SMI can reduce depression, understanding the 'how' is equally crucial. Nevertheless, data on mechanisms of change is

limited and no study had explored such potential pathways before this work. Given the relevance of guidance formats in digital interventions, it is essential to examine if they influence the efficacy of digital SMIs on depression differently. Yet, no evidence in this regard was available before the commencement of this dissertation.

### 1.4 Dissertation Objectives and Research Questions

This dissertation aims to investigate the efficacy of a digital SMI in reducing perceived stress in employees with elevated stress levels compared to waitlist controls (WLC). For this purpose, three distinct studies focus on the following key aspects: (1) different guidance formats, specifically adherence-focused (AFG) and self-help (SH), (2) exposure to adverse working conditions, and (3) impact on depression.

To address these objectives, three studies were conducted, covering the following seven research questions:

1. Does the efficacy of a digital stress management intervention in reducing stress differ between adherence-focused guidance and self-help, and how do adherence and acceptability compare?
2. Do perceived stress and resilience mediate the effects of a digital stress management intervention on depression?
3. Is a digital stress management intervention effective in reducing stress in employees facing adverse working conditions?
4. Does occupational self-efficacy mediate the effects of a digital stress management intervention on perceived stress?
5. Do efforts and rewards mediate the effects of a digital stress management intervention on perceived stress?
6. Is a digital stress management intervention effective in reducing depressive symptom severity in employees with clinically relevant depression?
7. Does the efficacy of a digital stress management intervention in reducing depressive symptom severity differ between full guidance, adherence-focused guidance, and self-help?

### 1.5 Dissertation Structure

This dissertation is structured as follows:

In **Chapter 1**, the rationale for the three conducted studies examining the efficacy of the digital SMI GET.ON "Fit im Stress" is outlined, emphasising the importance of addressing stress in employees and identifying existing gaps in research that this dissertation aims to fill. Digital SMIs are introduced in this chapter, including their typical characteristics and guidance formats. Additionally, associations between stress (management) and depression are presented and a newly developed paradigm is introduced, proposing the indirect treatment of depression.

In **Chapter 2**, GET.ON "Fit im Stress" is described in detail, including the theoretical foundation and intervention modules. Following this, the three studies conducted in this dissertation are presented, each focusing on different aspects. Given the absence of trials comparing guidance formats on a head-to-head basis and the limited availability of research on mechanisms of prevention in SMIs, **Study 1** was conducted to address this gap. Previous studies have primarily focused on the individual level, while structural circumstances, such as working conditions, have been neglected. Therefore, **Study 2** was conducted to examine whether stress levels could be reduced through participation in the SMI despite adverse working conditions and aimed to identify relevant personal resources contributing to the efficacy. Additionally, following a newly developed paradigm proposing the indirect treatment of depression, **Study 3** was conducted as an individual participant data (IPD) meta-analysis to investigate the efficacy of the intervention on depression and the impact of guidance.

In **Chapter 3**, the results of the studies are summarised, and the main findings are discussed in relation to the existing body of research. Additionally, this chapter outlines objectives for future research that emerged from the studies included in this dissertation.

In **Chapter 4**, an overall conclusion is drawn from the three conducted studies.

# Chapter 2: Evaluations of a Digital Stress Management Intervention

## 2.1 Intervention GET.ON "Fit im Stress"

The digital SMI investigated in all three studies of this dissertation, called GET.ON "Fit im Stress" (Heber et al., 2013), was developed based on Lazarus' transactional model of stress (Lazarus & Folkman, 1984). Its primary focus is on problem-solving and emotion regulation, aiming to sustainably reduce stress in both work and life domains. The intervention consists of seven core modules, with an additional eighth module serving as a refresher session provided four weeks after completion. The modules incorporate various media types, including educational texts, videos, and audio-based exercises.

GET.ON "Fit im Stress" begins with Module 1, which introduces participants to the programme and provides psychoeducation on stress and its health implications. During this module, individual stress levels are assessed, and participants are encouraged to maintain a personal stress diary, ideally daily. Module 2 acquaints participants with problem-solving techniques and coping strategies, including various exercises to apply these skills. Central topics include daily habits and an additional stress assessment. Module 3 advances problem-solving techniques, motivating participants to engage with life challenges through various exercises. The primary focus of Module 4 is emotion regulation, encouraging participants to explore personal stressors and problems, and to learn muscle relaxation and breathing techniques, emphasising the importance of these exercises in managing emotions. Module 5 builds on these emotion regulation skills, focusing on the acceptance of emotions and understanding their valence, meaning, and potential benefits. It includes various exercises that foster engagement with emotion regulation strategies. In Module 6, the intervention further expands on emotion regulation skills, addressing the foundations of self-criticism, self-worth, self-care, and self-support through difficult times in life. Various exercises are incorporated to reinforce these concepts. Module 7 primarily focuses on future planning, helping participants to implement individual intentions, strengthen personal foundations, and recognise early physical warning signs of stress. Module 8 serves as an additional refresher session, reinforcing previous content and exercises, and directing participants to address personal challenges, realign goals, and apply the acquired stress management techniques.

Participants are advised to complete at least one module per week, with each session taking approximately 45 to 60 minutes. This results in a total participation period of approximately four to seven weeks, plus the optional refresher module. Each module is accessible via web

browser on a (tablet) computer or mobile phone. It is recommended to log in once or twice a week to make a brief entry in the provided personal daily stress diary. Throughout participation, the intervention's content is responsively tailored to individual needs, assessed through continuous feedback. Progress can be saved at any point, allowing flexible integration of the intervention into daily life. Additionally, participants may opt to receive automatic motivational messages and short exercises via mobile phone, designed to facilitate the transfer of learned skills into daily life. The frequency of these messages can be customised, ranging from a message every other day to multiple messages daily.

Before this dissertation, the efficacy of GET.ON "Fit im Stress" was demonstrated in several studies examining different formats, including a guided version (Heber et al., 2016), AFG (Ebert, Lehr, et al., 2016; Zarski et al., 2016), and SH (Ebert, Heber, et al., 2016). GET.ON "Fit im Stress" was furthermore shown to be effective as a universal prevention approach (Ebert et al., 2021) and was included in a meta-analysis (Heber et al., 2017). Additionally, studies highlighted its cost-effectiveness from both societal (Kählke et al., 2019) and occupational (Ebert, Kählke, et al., 2018) perspectives. A tailored version of the intervention, adapted to the target group of (distance-learning) university students, was found to sustainably reduce perceived stress (Harrer et al., 2018, 2021).

For this dissertation, GET.ON "Fit im Stress" was investigated using the guidance formats SH and AFG. Throughout participation, individuals in the SH condition did not receive support from an e-coach and could only contact an administration team in case of technical issues. In the AFG condition, guidance was operationalised as adherence monitoring and on-demand feedback from e-coaches, who were trained psychologists and assigned to participants on a one-to-one ratio, following a standardised manual. To monitor adherence, e-coaches frequently checked for module completion and sent reminders if at least one intervention module was not completed within seven days. To provide on-demand feedback, e-coaches responded to a request within 48 hours with personalised written feedback.

## 2.2 Introduction to Study 1

The efficacy for the intervention GET.ON „Fit im Stress" has been demonstrated with various types of guidance, including AFG and SH. However, there is a lack of data on the comparative efficacy of different guidance formats within a single, homogenous study. While previous studies have indicated that guided formats yield larger effects compared to unguided formats, providing GET.ON "Fit im Stress" solely as SH intervention could still be beneficial. Since there is no direct (head-to-head) evidence available for a comparison of different guidance formats for a digital SMI, the primary goal of the first research question is to address:

**Research Question 1: Does the efficacy of a digital stress management intervention in reducing stress differ between adherence-focused guidance and self-help, and how do adherence and acceptability compare?**

Previous studies have demonstrated that work-related stress could precede the onset of depressive symptoms, and that digital SMIs can have positive effects on these symptoms. While evidence on the efficacy of digital SMIs is accumulating, investigations into mechanisms of change are scarce. To address this gap, the second research question aims to uncover:

**Research Question 2: Do perceived stress and resilience mediate the effects of a digital stress management intervention on depression?**

## 2.3 Study 1: Comparative Efficacy of Guidance Formats in a Digital Stress Management Intervention and Health Mechanisms

Nixon, P., Boß, L., Heber, E., Ebert, D. D., & Lehr, D. (2021). A three-armed randomised controlled trial investigating the comparative impact of guidance on the efficacy of a web-based stress management intervention and health impairing and promoting mechanisms of prevention. *BMC Public Health,* 21(1), 1-18.

doi: 10.1186/s12889-021-11504-2.

Submitted: 14th July 2020

Accepted: 16th July 2021

Published: 5th August 2021

Nixon et al. BMC Public Health (2021) 21:1511
https://doi.org/10.1186/s12889-021-11504-2

BMC Public Health

RESEARCH ARTICLE Open Access

# A three-armed randomised controlled trial investigating the comparative impact of guidance on the efficacy of a web-based stress management intervention and health impairing and promoting mechanisms of prevention

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## Abstract

**Background:** Web-based stress management interventions (SMI) fit increasingly digital lifestyles, reduce barriers of uptake and are easily scalable. SMIs might lower levels of stress in employees and thereby contribute to the prevention of depressive symptomatology. Different guidance formats can impact the efficacy of SMIs, with higher intensity assumed to result in larger effects. However, head-to-head comparisons of guidance formats are rare. This is the first trial to examine the impact of adherence-focused guidance compared to self-help on the efficacy of an occupational SMI compared to a wait list control condition. Additionally, it will be investigated if the SMI enfolds its impact on preventing depressive symptomatology by different pathways through reducing health impairing and increasing promoting factors.

**Methods:** A three-armed randomised controlled trial (RCT) on an occupational SMI was conducted. 404 employees with elevated levels of perceived stress (PSS-10 ≥ 22) were randomly assigned to: adherence-focused guidance (AFG), self-help (SH) or a wait list control group (WLC). The primary outcome was perceived stress (PSS-10). Secondary outcomes included health- and work-related measures. A parallel mediation analysis with stress and resilience as mediators for the effect on depression (CES-D) was carried out. Data collection took place at baseline (T1), after 7 weeks (T2) and 6 months (T3).

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**Results:** The SMI was effective for all groups on the primary and secondary outcomes. For stress, analyses of covariance (ANCOVA) revealed significant group effects at T2 ($F_{2,400} = 36.08$, $P < .001$) and T3 ($F_{2,400} = 37.04$, $P < .001$) with large effect sizes for AFG (T2: d = 0.83; T3: d = 0.85) and SH (T2: d = 0.88; T3: d = 0.91) compared to WLC. No significant group differences were found for the efficacy between AFG and SH on the outcomes. Adherence in terms of completed modules was significantly higher for AFG compared to SH. The SMI's impact on depression was mediated by perceived stress: $a_1b_1 = -0.77$, 95% CI [− 1.26, − 0.34] and resilience: $a_2b_2 = -0.62$, 95% CI [− 1.05, − 0.26].

**Conclusions:** The SMI was effective for reducing stress and improving other health- and work-related outcomes, irrespective of the guidance format. Results did not demonstrate superiority of adherence-focused guidance for the efficacy but for adherence in terms of completed modules. Among other reasons, better communication strategies about offered guidance and awareness-raising measures are discussed. Results from mediation analysis suggest that preventive SMIs should be designed to reach two goals: reducing the risk factor of stress and simultaneously increasing health promoting factors such as resilience.

**Trial registration:** German Clinical Trial Registration (DRKS) DRKS00005687, 6/6/2014.

**Keywords:** Web-based, Occupational health, Stress management, Randomised controlled trial

## Background

Work-related stress is associated with increased risk for development and maintenance of adverse physical [1–3] and mental health consequences [4]. Experiencing stressors at work is associated with an elevated risk of sickness absence due to a diagnosed mental disorder [5] and can precede depressive symptoms over time, thereby increasing the risk for subsequent depression [6, 7]. As one of the three leading causes, unipolar depression largely contributes to the burden of disease and is predicted to be number one by 2030 [8]. The World Health Organization (WHO) therefore calls for prevention to effectively reduce this tremendous burden [9].

This in turn leads to substantial socio-economic harms. These can be divided into direct costs due to growing use of health care services and indirect costs resulting from productivity loss caused by work loss days, presenteeism, employee turnover and work impairment [10, 11]. Notably, indirect costs account for most of the total stress-related cost with 70–90% [10]. As a national example, work stress, depression and anxiety predominantly caused for 44% of ill health cases and 57% of lost working days in Great Britain in 2017/2018 [12].

Ongoing digitisation and rapidly developing technology altered the labour market profoundly with a transformation towards the Fourth Industrial Revolution. As a result, employees can experience severe stress due to unfavourable changes of workplace cultures, employee turnover or job insecurity [3, 13, 14]. The other side of the coin is the potential of using digital facilities to deliver web-based interventions which have been shown to be effective in reducing stress [15] and improving mental health in those affected by serious disorders such as depression [16, 17]. Not least, the COVID-19 pandemic has highlighted the need for the implementation of e-health interventions into routine health care and overcoming barriers to effectively do so [18].

From a public health point of view, Internet Interventions generally may offer many advantages compared to face-to-face approaches. They fit increasingly digital lifestyles, are easily scalable and reduce barriers of uptake [19]. Furthermore, health economic evaluations showed that a guided version of the utilised SMI from prior studies was cost-effective [20, 21].

Reaching a greater proportion of affected individuals that otherwise may remain untreated hence seems more feasible [22]. Substantial benefits of this delivery mode are the portability and time-spatial independent accessibility [23] allowing users to review contents at their own pace. The anonymity of the Internet might circumvent fears of possible stigmatisation or self-disclosure in traditional therapy settings that for such reasons may be rejected by many subjects in need [24, 25]. Supporting evidence stems from studies showing that the web-only delivery mode can be as effective as face-to-face settings [26–28].

Web-based occupational stress management interventions (SMI) seem to be a promising approach against this background. Studies have demonstrated treatment effects on various health outcomes within the occupational context [29] with maintaining reductions of stress for up to 6 months [15, 30]. Meta-analytic evidence showed that exposure to work-related stressors could precede the onset of depressive symptoms [31] and clinical depression [6]. There are three well investigated and prominent theories and models to explain these associations, namely the demand-control model, effort-reward imbalance model and organisational injustice framework [32]. There is evidence that each of these theoretical

approaches is valid and correctly predicts that stressors at work are linked to a moderately elevated risk of the onset of depression [32]. Against this background, effects of SMI on depression were also investigated and found to be positive at post-intervention and at 6-month follow-up, although larger for the former [15, 30, 33, 34]. Notably, these studies are characterised by moderate to high heterogeneity [15, 30].

A fundamental aspect varying along these studies that seems to be crucial in affecting the efficacy of SMI, is the impact of human guidance [35]. The intensity of guidance can differ regarding the format and scope of provided human support. On the one side, intensive guidance is expert driven, requiring a high invest of resources. It can for example be content-focused with personalised written feedback on completed exercises or modules [15]. On the other side and opposed to this format, a self-help format requires only few resources and provides no professional support [36]. This format can easily be scaled to maximum, is cost-effective and needed to sufficiently treat subjects who otherwise would not receive any professional service at all [20, 37]. Adherence-focused guidance is an attempt to find a good compromise between those two intensities in guidance. This guidance format was established in earlier studies and consists of adherence monitoring and feedback on demand [35, 38]. Therefore, adherence-focused guidance is client driven, requiring an active role and initiative of a participant when in need of support. Providing guidance by human support is expected to be conducive to the efficacy of Internet Interventions [15, 39, 40]. The support provided usually is of a technical or clinical kind or focusses on the correct usage of the intervention [41]. According to the Supportive Accountability Model [42], human support enhances adherence to e-health interventions. Social presence or performance monitoring by an e-coach that is perceived as benevolent and trustworthy are for example integral factors to foster accountability. Studies demonstrated declining clinical outcomes with decreasing coaching time spent on each participant, with an increasing likelihood of study dropout at the same time [38, 43, 44]. Further findings indicate that guidance also seems to impact user satisfaction and acceptance that both in turn affect adherence [45–47]. Previous trials suggested the use of adherence-focused guidance [48] and showed that it was effective for Internet Interventions targeting stress management [49] or subthreshold depression [50]. Investigating different guidance formats is particularly important since little or no adherence and low uptake rates are major issues of Internet Interventions [45, 51]. Until now, there is no evidence on the comparison of adherence-focused guidance to self-administered formats for SMI unguided interventions, although empirical validations of the effects of varying guidance formats are highly necessary for large-scale dissemination into routine health care. Against this background, this study aims at comparing the effectiveness for adherence-focused guidance which combines adherence-monitoring and human support, with a self-help mode.

While guidance is crucial for an evidence-based design of SMI, the underlying mechanisms of how such interventions come into effect have not been fully captured yet. Despite an increasing number of studies, the process by which SMI result in effects on depression is unclear. A theoretical framework that can be applied to address this gap is the job-demands-resources (JD-R) model that was developed to explain the genesis of job strain [52, 53]. According to this model, any occupational characteristics can be classified into one of the two underlying clusters: job demands or job resources. These two clusters initiate two diverging processes. Job demands that no longer can be met instigate a health impairment process, whereas the availability of sufficient job resources launches a motivational process. This model can be used for this study to examine the global issue of stress in a more detailed manner. In particular, to elucidate how the SMI can affect depressive symptoms. Based on the JD-R model and earlier research on the relationships between stress and health outcomes, the SMI may work through two different paths. One of these paths can be assumed to be health impairing with work stress often being precedent to depression. Hence, positive effects on depression might be preceded by an efficacious stress reduction. Opposed to this, available resources can promote resilience that can buffer such deleterious effects and prevent pathogenesis [54, 55]. Taken together, positive effects of SMI on depression might be the result of either one of these paths acting individually or a dual pathway working simultaneously.

This is the first investigation of the comparable efficacy of different guidance formats within a single, homogenous study on SMI yet. Therefore, this three-armed randomised controlled trial has three aims. First, to assess the comparative efficacy of adherence-focused guidance, self-help and a wait list control group, assuming each of the intervention groups will be superior to the waitlist control group and adherence-focused guidance will be superior to self-help. Second, to reveal further insights into utilisation rates and acceptability of the various guidance formats. And third, to investigate mediating paths of

how this SMI affects depression, considering perceived stress and resilience as potential mediators.

## Methods

### Study design and hypotheses

A three-armed randomised controlled trial (RCT) was conducted in compliance with the study protocol [35] and the Declaration of Helsinki and Good Clinical Practice (GCP). Subjects were randomised into three groups: (1) adherence-focused guidance (AFG), (2) self-help (SH) and (3) a wait list control condition (WLC). Accordingly, both AFG and SH received the same SMI, but guidance was different. Each group had full access to treatment as usual (TAU).

Based on data from an earlier pilot evaluation we expected a mean effect for the AFG condition compared to WLC of at least d = 0.70. Evidence available at the time of planning the study showed that meta-analytic data for cognitive-behavioural occupational SMI indicated an effect size of d = 0.68 [56] and that unguided Internet Interventions consistently seem to produce lower effect sizes compared to guided trainings [39]. Against this background, this study aimed to be able to detect a between group effect size of d = 0.30. To detect this effect with a power (1-ß) of 80% and α = .05 in multiple Bonferroni-adjusted tests (H1: AFG superior to WLC at post-intervention, H2: SH superior to WLC at post-intervention, H3: AFG superior to SH at post-intervention), a required sample size of 408 participants was calculated with PASS12 (NCSS).

After screening for eligibility (T0) and allocation, assessments were conducted at baseline (T1), 7 weeks post-intervention (T2) and at 6-month follow-up (T3) using a secured online-based self-report system (AES, 256-bit encrypted). Primary and secondary outcomes were used as dependent variables and treatment condition as the independent variable with respective baseline scores as covariates; for a description of the sample, baseline characteristics were assessed that are listed in the section Other measures. The University of Marburg ethics committee approved of this study (No. 2014-5 K). All participants gave informed consent. The trial was registered in the German Clinical Trials Register (DRKS00005687).

### Inclusion and exclusion criteria

Inclusion criteria required (1) participants being adults (aged ≥18), (2) current employment, (3) Internet access, (4) sufficient German reading and writing skills, (5) willingness to give informed consent and (6) scores ≥22 on the Perceived Stress Scale (PSS-10) [57]. The PSS-10 cut-off allows for the selection of subjects with elevated stress levels, as identified by one standard deviation (*SD* = 6.2) above the mean (*M* = 15.3) in a large sample of working people [58]. Exclusion criteria were previous or current diagnosis of psychosis or dissociative symptoms, or a notable suicidal ideation indicated by a score > 1 on the ninth item ("I feel I would be better off dead") of the Beck Depression Inventory (BDI) [59].

### Recruitment and randomisation

Between January and May 2014, nationwide recruitment took place trough newsletters, press releases and the support of a large German health insurance company that advertised the study in their member journal and regional offices (*n* = 918). Participation was not limited to the health company's insurants. Interested subjects signed up on the website (www.geton-training.de) by providing their e-mail address. After screening for eligibility, giving written informed consent and completing the baseline assessment, participants were randomly allocated to the three different intervention arms. A third independent party performed individual randomisation at a ratio of 1:1:1 and a block size of three using an automated computer-based random integer generator (DatInf® RandList). Thereafter, participants were not blinded to conditions and either received immediate access to the SMI or 6 months later if allocated to the WLC.

### Intervention

Based on Lazarus' transactional model of stress [60], the intervention was developed for employees and focusses on problem solving [61, 62] and emotion regulation skills [63, 64]. It comprises seven core modules for psychoeducation (module 1), problem solving (modules 2–3), emotion regulation (modules 4–6), planning future (module 7) and an optional booster session offered four weeks after training completion (module 8). Table 1 supplies a more detailed description of the contents. Within modules 2–6, participants could autonomously choose to adapt their intervention for additional modules covering time management, rumination and worrying, psychological detachment from work, sleep hygiene, rhythm and regularity of sleeping habits, nutrition and exercise, organising work breaks, and social support. In that way, the intervention was tailored to the subjects' individual needs depending on responses that they opted for. Subjects were advised to complete at least one and at maximum two modules per week. It took 45 to 60 min to complete a module, resulting in a total intervention period of approximately four to seven weeks. The interactive lessons incorporated units of various media formats, such as texts, audios and videos. Additionally, subjects could make use of an inbuilt read-out function. Further key elements

**Table 1** Contents of the GET.ON stress management intervention

| Module | Focus | Description |
|---|---|---|
| 1 | Psychoeducation | Introduction to the intervention and its flow, stress management basics (e.g. health impacts), individual stress analysis, stress diary, various exercises |
| 2 | Problem-solving I | Coping strategies, additional individual stress analysis, habits, problem-solving skills, various exercises |
| 3 | Problem-solving II | Advanced coping strategies and problem-solving skills, meeting challenges, various exercises |
| 4 | Emotion regulation I | Personal stressors and problems, muscle relaxation and breathing techniques, importance of regular exercising and positive health behaviours |
| 5 | Emotion regulation II | Acceptance, meaning and benefit of emotions, emotional valence, various exercises |
| 6 | Emotion regulation III | Foundations of self-criticism, self-worth, self-care, self-support in difficult times, various exercises |
| 7 | Plan for the future | Physical early warning systems, strengthening personal foundation in life, implementing intentions |
| 8 | Booster session | Reviews of previous content and exercises, realignment of goals, personal challenges, various exercises |

were exercises, the encouragement to keep a daily stress diary and homework assignments, as the intervention aimed to assist participants in fostering newly acquired stress management techniques in their everyday life. Furthermore, participants were able to decide if they wanted to receive automatic motivational text messages and short exercises (e.g., for relaxation) to their mobile phones and if their frequency should be rather low (one text message alternately) or intense (two to three text messages daily). The responsive web application could be accessed through mobile phones and (tablet) computers. A more comprehensive description of the intervention can be found in the study protocol [35].

#### *Adherence-focused guidance (AFG)*

Previous studies established AFG as guidance format which comprises (1) adherence monitoring and (2) feedback on demand by e-coaches [38]. Every subject was assigned to an e-coach in a one-to-one ratio throughout the intervention. The e-coaches were trained psychologists that followed guidelines for the feedback process based on the standardised manual for the intervention. Adherence was monitored by frequently checking for duly module completion and sending reminders if subjects did not finish at least one module within a week. In other studies, reminders (personal and automatic) ameliorated adherence to self-guided health promotion and health behaviour interventions [65–67]. Participants received personalised and written feedback on demand only upon request via the internal platform messaging system within 48 h. Contact to an e-coach could be established by clicking on the respective button. The provided feedback was expected to enhance adherence and therefore impact the comparative efficacy in favour of this study condition [42, 68]. Based on the Supportive Accountability Model [42], the provided human support by professional e-coaches was supposed to create perceived legitimacy and to be a requirement for positive effects of the monitoring part of AFG. Notably, it is assumed that the two elements of AFG (i.e., monitoring and feedback on demand) intertwine with each other in regard to their effects on adherence.

#### *Self-help (SH)*

Subjects in the SH-arm could contact the study administration and received support in case of technical issues.

#### *Wait list control group (WLC)*

The WLC-arm obtained access to the self-help intervention 6 months after randomisation. Priorly, they had full access to TAU through routine healthcare services.

### Measures

Data was collected online between March 2014 and July 2015 with German self-report measures at successive assessments in time: screening for eligibility (T0), at baseline (T1), 7 weeks after randomisation (T2) and at a 6-month follow-up (T3). Further questionnaires used [35] will be taken into account in future publications.

#### *Primary outcome measure*

Primary outcome was the subjective stress level measured by the German version of the 10-item Perceived Stress Scale (PSS-10) [57, 69]. Since the PSS-10 was developed based on Lazarus' transactional model of stress, it was assumed to be most suitable regarding the intervention's content. The self-report items of this well-established questionnaire assess to what extent participants experienced their lives as stressful, i.e. as overstraining, unmanageable and unforeseeable in the past month. To avoid confounding with the training period (from T1 to T2), subjects in this study were asked to answer the questions against the background of their past week [69]. Respondents evaluate the items on a five-point Likert scale from 0 (never) to 4 (very often), resulting in sum score ranges from 0 to 40. Accordingly, the higher the sum score values, the more elevated stress levels are perceived. Sample item: "How often have you felt that you were unable to control the important things

in your life?". The scale was psychometrically evaluated in a German community sample and shown to have good internal consistency and construct validity [70]. For different samples, internal reliabilities (Cronbach's α) were found to be .78 and .91 [71].

#### *Secondary outcome measures*

**Health impairing and promoting mediators** Secondary outcomes included the examination of depression severity with the short version of the Centre for Epidemiological Studies' Depression Scale (CES-D) [72, 73], with 15 items that are responded to on a four-point Likert scale from 0 to 3 (α = .95). Sample item: "I felt depressed". The Connor-Davidson Resilience Scale (CD-RISC) [74] was used to examine resilience, measured with ten items on a five-point Likert scale from 0 to 4 (α = .85). Sample item: "Deal with whatever comes my way". Emotional exhaustion was measured with the corresponding subscale of the Maslach Burnout Inventory (MBI-GS-D) [75, 76]. This scale is composed of five items that are rated from 1 to 6 (α = .85). Sample item: "I feel emotionally drained from my work".

**Work-related health** Work engagement was examined with the Utrecht Work Engagement Scale (UWES) [77, 78] that distinguishes between the three subcomponents dedication, vigour and absorption and consists of 9 items which are assessed on a 7-point Likert scale from 0 to 6 (α = .9). Sample item: "I am enthusiastic about my job".

**Work-related productivity** Presenteeism was assessed with the Work Limitations Questionnaire (WLQ) [79] and a single-item work ability question (WAI) [80]. Sample items: "Experience physical or mental problems speaking to others in person/on phone", and "How would you rate your current ability to work?" respectively. In addition, the Effort Reward Imbalance Questionnaire – Short Form (ERI-SF) [81] was used with 10 items with a Likert-scale from 1 to 4 that compose the three scales effort, reward and overcommitment (αs = .77, .82 and .83, respectively). Sample item: "I have many interruptions and disturbances while performing my job".

**Client satisfaction and intervention usage** The Client Satisfaction Questionnaire adapted to Internet-based interventions (CSQ-I) [82] was used to investigate the participants' satisfaction with the intervention. This comprises eight items with a range from 0 to 4. Reported values for the reliability indicated by McDonald omegas were .93–.95. Sample item: "I received the kind of training I wanted". For an in-depth analysis, participants were required to answer questions about the different guidance formats (e.g. "What kind of guidance would you prefer if you would participate in a training of this kind again?", "How often did you make use of the possibility to get in touch with an e-coach?"). In order to take these figures into account, the number of inquired feedbacks, as well as the amount of messages e-coaches sent to participants was checked for on the internal platform messaging system.

**Other measures** For a description of the sample, we assessed various demographic variables such as sex, age, marital status, ethnicity, educational level, employment, work sector of employment, income and the previous use of health services.

### Statistical analyses

The statistical analyses adhered to the pre-published study protocol [35]. They were carried out using IBM SPSS Statistics 25 [83] and according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [84, 85]. Consequently, analyses were conducted on the intention-to-treat (ITT) basis handling missing data with multiple imputations [86]. For this purpose, 10 estimates were calculated for each missing data point that were aggregated into a single overall value. To evaluate the efficacy of the intervention, analyses of covariance (ANCOVA) were conducted with respective outcome baseline values specified as covariates. Earlier simulation studies demonstrated the methodological robustness of ANCOVA for analysing experimental studies in terms of protecting against bias, higher precision and statistical power [87, 88]. For all analyses, a two-tailed significance level was set at $P < .05$. Deviating from the study protocol [35], Cohen's $d$ [89] was calculated by standardised deviations (SD) of the respective measurement points. Restricted variance in baseline scores would lead to smaller SD and the risk of an overestimation of effects. Therefore, effect sizes were calculated in a more conservative manner. Additionally, per protocol analyses (PPA) were performed for the primary outcome, including only satisfying protocol treatment and therefore solely subjects who completed at least six of the training modules.

#### *Response analyses*

To examine the clinical significance of a positive outcome, the reliable change index (RCI) defined by Jacobson and Truax was used [90]. In this manner, the SD of the norm population (6.2) and the reliability of the PSS-10 scale (α = .91) from samples in 2006 and 2009 were used in the respective formula [1.96*SD1*sqrt(2)*sqrt(1-rel)]. Eventually, an individual change over time was considered significantly reliable when the PSS-score differed more than ±5.16 points from T1 to T2 and T1 to T3. A cut-off value for symptom-free status was defined as more than 2 SDs below the mean (T1) value of the

primary outcome (PSS-10 < 17.33). The number needed to treat (NNT) was calculated which indicates the average number of participants that need to be treated to achieve an additional response compared to the control condition and therefore prevent a non-response.

#### *Mediation analysis*

To explore how an effective stress reduction could lead to a prevention of depression, a mediation analysis based on a framework considering multiple pathways was conducted. Since depression can be preceded by stress, this was considered as potentially health impairing process as opposed to a health promoting process with resilience as a protective factor against the development or maintenance of depressive symptoms. Within this framework, perceived stress measured with PSS-10 [57, 69] was considered as potential risk factor to depression, hence to instigate a health impairing process. Resilience assessed with CD-RISC [55] on the other hand was assumed to be protective against the development of depressive symptoms as a result of work stress. A dual pathway with both factors mediating the efficacy in concert was also examined. For this purpose, a parallel mediation analysis was carried out using the PROCESS macro (v3.3) for SPSS (model 4) [91]. Temporal precedence was established by using T2-measurements of the mediators and the outcome values assessed at T3. In this model, baseline score for the potential mediators and the outcome were included as covariates [92]. Bias-corrected bootstrap with 10,000 samples was applied for indirect effects that were considered significant if 95% confidence intervals (CI) did not cover zero [91].

## Results

### Participants

The sample consisted of 404 participants (77% female), aged 18–62 years (M = 41.93, SD = 9.14) that were randomly allocated to the three study conditions AFG ($n$ = 135), SH ($n$ = 134) or WLC ($n$ = 135). At enrolment, PSS-10 mean scores numbered in 26.44 for AFG (SD = 2.92), 26.82 for SH (SD = 3.44), and 26.36 for WLC (SD = 3.05). All assessed baseline characteristics are summarised in Table 2 and the study flow is depicted in Fig. 1. The study aimed to include 408 subjects at T1 for allocation but with four participants failing to fully meet employment requirement, they had to be excluded from the analysis at closer data inspection. At enrolment, 726 subjects were recruited of which 322 did not fulfil the inclusion criteria. Satisfying protocol treatment for PPA analysis (completion of at least six modules) was available for 101 subjects in AFG (75%) and 80 in SH (60%). Study dropout rates for the assessments were as follows: at T2, AFG $n$ = 12 (9%), SH $n$ = 7 (5%), WLC $n$ = 3 (2%) and at T3, AFG $n$ = 29 (21%), SH $n$ = 22 (16%), WLC $n$ = 15 (11%). For the primary outcome, data were missing for 5% at T2 and 16% at T3. To examine if data was missing completely at random (MCAR) Little's test was applied. The null hypothesis for Little's test is that data are MCAR, thus patterns of missing scores are not associated with observed and unobserved factors among the subjects' values. Little's test of randomness failed statistical significance ($P$ = 0.16), indicating the hypothesis of data MCAR did not need to be rejected. Therefore, multiple imputations were conducted [86].

### Primary outcome analysis

All three study groups showed an improvement in perceived stress levels from T1 to T2 and T3 (Fig. 2). At T2, analysis of covariance according to the study protocol [35] revealed a significant group effect ($F_{2,400}$ = 36.08, $P$ < .001) with large between group effect sizes for both AFG (d = 0.83; 95% CI 0.58–1.08) and SH (d = 0.88; 95% CI 0.63–1.13) in comparison to the control group (Table 3). A significant between group effect was also found for T3 ($F_{2,400}$ = 37.04, $P$ < .001) with large effect sizes for AFG (d = 0.85; 95% CI 0.60–1.10) and SH (d = 0.91; 95% CI 0.66–1.16) compared to WLC. No significant group differences were found between AFG and SH for the primary outcome. See Table 4 for means and standard deviations for all study groups on primary and secondary outcomes.

#### *Reliable change, symptom-free status, NNT*

At T2, the majority of subjects in the intervention groups showed a reliable improvement on perceived stress assessed with PSS-10 (AFG: 84/123, 68%; SH: 80/127, 63%) compared to participants in WLC (39/131, 30%). Fewer symptom deterioration was found in the intervention groups (AFG: 3/123, 2%; SH: 3/127, 2%) than for WLC (7/131, 5%). These differences were statistically significant [$\chi^2$ = 4, ($N$ = 381) = 45.11, $P$ < .001].

At T3, a reliable improvement was present for both AFG (77/106, 73%) and SH (72/112, 64%) whereas this number was lower for WLC (26/119, 22%). Reliable deterioration again turned out lower for AFG (3/106, 3%) and SH (2/112, 2%) in comparison to WLC (7/119, 6%). Again, these differences were statistically significant [$\chi^2$ = 4, ($N$ = 337) = 68.66, $P$ < .001]. The NNT to achieve reliable improvement between T1 and T3 is 6, 95% CI [3.1, 26.7]. Furthermore, a significantly larger number of participants in the intervention groups could be considered as symptom-free (SH: 57, 43%; AFG: 69, 51%) compared to WLC (24, 18%) at T3 [$\chi^2$ = 2, ($N$ = 404) = 34.64, $P$ < .001].

**Table 2** Baseline characteristics

| Characteristics | AFG (*n* = 135) | SH (*n* = 134) | WLC (*n* = 135) |
|---|---|---|---|
| Socio-demographic | | | |
| Age, mean (SD) | 42.68 (9.09) | 41.88 (9.01) | 41.47 (9.22) |
| Women, n (%) | 109 (80.70) | 103 (76.90) | 100 (74.10) |
| Marital status, n (%) | | | |
| Single | 44 (32.60) | 39 (29.10) | 43 (31.90) |
| Married | 65 (48.10) | 65 (48.50) | 63 (46.70) |
| Cohabited | 14 (10.40) | 14 (10.40) | 15 (11.10) |
| Divorced | 10 (7.40) | 12 (9.00) | 13 (9.60) |
| Widowed | 2 (1.50) | 4 (3.00) | 1 (0.70) |
| Ethnicity, n (%) | | | |
| Caucasian/white | 102 (75.60) | 110 (82.10) | 116 (85.90) |
| Asian | / | 1 (0.70) | / |
| Hispanic | 2 (1.50) | 1 (0.70) | / |
| Prefer not to say | 31 (23.00) | 22 (16.40) | 19 (14.10) |
| Educational level, n (%) | | | |
| Low | 5 (3.70) | 3 (2.20) | 4 (3.00) |
| Middle | 43 (31.90) | 38 (28.40) | 25 (18.50) |
| High | 87 (64.40) | 93 (69.40) | 106 (78.50) |
| Employment | | | |
| Full-time, n (%) | 107 (79.30) | 93 (69.40) | 106 (78.50) |
| Part-time, n (%) | 26 (19.20) | 39 (29.10) | 26 (19.30) |
| Sick leave, n (%) | 2 (1.50) | 2 (1.50) | 3 (2.20) |
| Managerial position, n (%) | 53 (39.30) | 48 (35.80) | 56 (41.50) |
| Work experience in years, mean (SD) | 17.87 (9.79) | 17.29 (10.42) | 17.76 (10.57) |
| Work sectors, n (%) | | | |
| Service | 28 (20.70) | 27 (20.10) | 29 (21.50) |
| Economy | 24 (17.80) | 24 (17.90) | 27 (20.00) |
| Health | 13 (9.60) | 21 (15.70) | 18 (13.30) |
| Social | 22 (16.30) | 26 (19.40) | 26 (19.30) |
| Information technologies | 19 (14.10) | 14 (10.50) | 13 (9.60) |
| Other | 29 (21.50) | 22 (16.40) | 22 (16.20) |
| Income, n (%) | | | |
| Low | 45 (33.30) | 37 (27.60) | 43 (31.90) |
| Middle | 27 (20.00) | 35 (26.10) | 19 (14.10) |
| High | 51 (37.80) | 52 (38.80) | 60 (44.40) |
| Use of health services | | | |
| Previous or current psychotherapy, n (%) | 62 (45.90) | 71 (53.00) | 72 (53.30) |
| Previous health training, n (%) | 18 (13.30) | 9 (6.70) | 20 (14.80) |

### *Sensitivity analyses*

In accordance with the study protocol [35], PPA including only subjects' satisfying protocol treatment were conducted to test for the robustness of the main analyses (ITT) and revealed similar results. Significant between group effects were observed at T2 ($F_{2,217} = 19.75$, $P < .001$) with large effect sizes for AFG (d = 1.00, 95% CI 0.61–1.38) and SH (d = 1.11, 95% CI 0.71–1.52) compared to WLC. At T3, a significant group effect was found ($F_{2,217} = 23.88$, $P < .001$), again with large effect

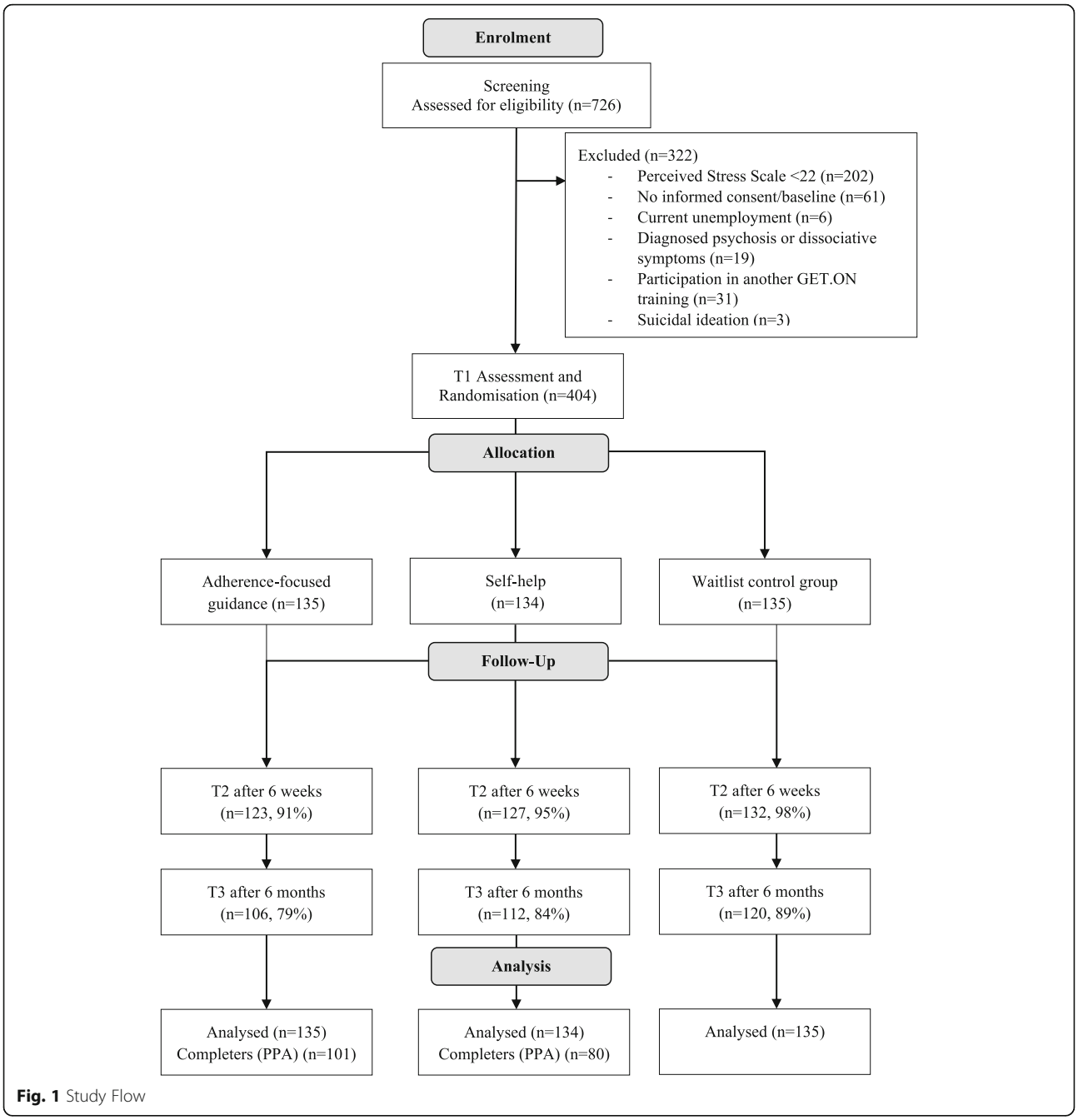


**Fig. 1** Study Flow

sizes for AFG (d = 1.22; 95% CI 0.83–1.62) and SH (d = 1.10; 95% CI 0.70–1.50). Again, the guided (AFG) and unguided (SH) conditions did not differ significantly from each other.

In addition, sensitivity analyses were performed to prevent bias due to the choice of the statistical approach. Therefore, all hypotheses were also tested applying repeated measures analysis of variance (ANOVA). All results could be replicated as indicated by the respective time x group effect.

### Secondary outcome analyses

Results of the ITT-analyses for the secondary outcomes are shown in Table 3. For both T2 and T3, ANCOVAs resulted in highly significant between-group effects with significance levels of $P < .001$ for most of the outcomes. The only non-significant result was the between-group effect assessed for ERI-effort at T2 ($P = 0.67$). At T2, effect sizes ranged from small (e.g., ERI-reward with d = 0.21 for AFG and d = 0.19 for SH) to moderate (e.g., WAI with d = 0.40 for AFG

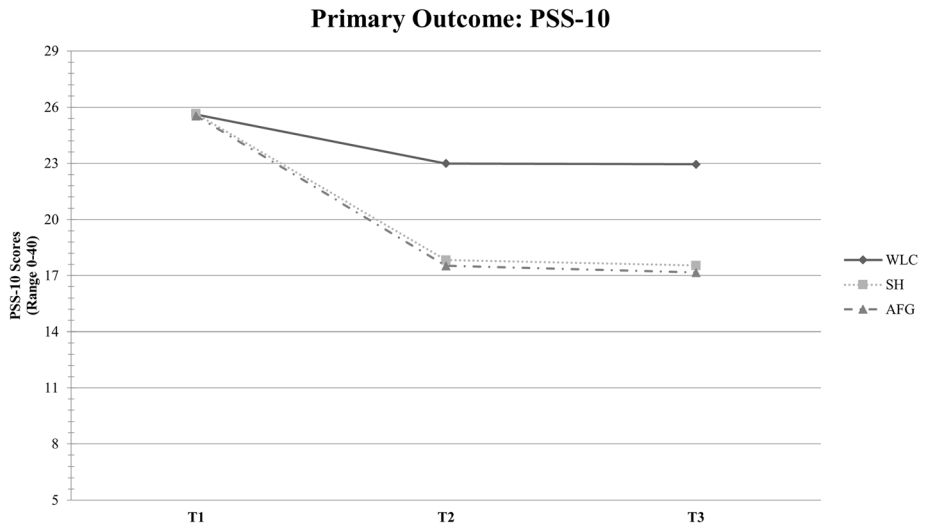


**Fig. 2** Comparison of adherence-focused guidance (AFG), self-help (SH) and waitlist control condition (WLC) on development of perceived stress measured with PSS-10 at T1 (baseline), T2 (after 7 weeks) and T3 (6-month follow-up)

and d = 0.43 for SH) to large (e.g., MBI-GS-D with d = 0.80 for AFG and d = 0.83 for SH). For T3, detected changes in the effect sizes were mixed with partly decreases of already low effect sizes (e.g., ERI-reward with d = 0.13 for AFG and d = 0.25 for SH) and partly enhancements of large effect sizes (e.g., MBI-GS-D with d = 0.84 for AFG and d = 0.91 for SH).

### Training satisfaction and intervention usage

Client satisfaction assessed with CSQ-I did not significantly differ for the study arms, neither at T2

**Table 3** Results of the ANCOVAs and Cohen's d based on respective imputed means and standard deviations for all study groups on the primary and secondary outcomes

| Outcome | T2[a] between-groups effect | | | T3[a] between-groups effect | | |
|---|---|---|---|---|---|---|
| | d (95% CI) | | ANCOVA | d (95% CI) | | ANCOVA |
| | AFG vs. WLC | SH vs. WLC | $F_{(400,2)}$ | AFG vs. WLC | SH vs. WLC | $F_{(400,2)}$ |
| **Primary Outcome** | | | | | | |
| PSS-10 | 0.83 (0.58–1.08) | 0.88 (0.63–1.13) | 36.08*** | 0.85 (0.60–1.10) | 0.91 (0.66–1.16) | 37.04*** |
| PSS-10 (PPA)[b] | 1.00 (0.61–1.38) | 1.11 (0.71–1.52) | 19.75*** | 1.22 (0.83–1.62) | 1.10 (0.70–1.50) | 23.88*** |
| **Secondary Outcomes** | | | | | | |
| CES-D | 0.74 (0.50–0.99) | 0.62 (0.37–0.86) | 28.64*** | 0.61 (0.37–0.85) | 0.68 (0.43–0.92) | 23.6*** |
| CD-RISC | 0.69 (0.44–0.94) | 0.54 (0.29–0.78) | 27.82*** | 0.54 (0.30–0.78) | 0.60 (0.35–0.84) | 19.71*** |
| ERI (effort) | 0.21 (0.03–0.45) | 0.19 (0.05–0.43) | 2.72 | 0.29 (0.05–0.53) | 0.40 (0.16–0.64) | 5.87** |
| ERI (reward) | 0.23 (0.01–0.70) | 0.19 (0.05–0.43) | 6.93** | 0.13 (0.11–0.37) | 0.25 (0.01–0.49) | 4.23* |
| MBI-GS-D | 0.80 (0.55–1.05) | 0.83 (0.58–1.08) | 31.83*** | 0.84 (0.59–1.09) | 0.91 (0.66–1.17) | 34.73*** |
| UWES (vigor) | 0.36 (0.12–0.60) | 0.31 (0.07–0.55) | 9.52*** | 0.33 (0.09–0.57) | 0.42 (0.18–0.66) | 12.66*** |
| UWES (dedication) | 0.30 (0.06–0.54) | 0.14 (0.10–0.38) | 7.62** | 0.16 (0.07–0.40) | 0.20 (0.04–0.44) | 4.69** |
| UWES (absorption) | 0.26 (0.02–0.50) | 0.18 (0.06–0.42) | 4.61* | 0.31 (0.07–0.55) | 0.28 (0.04–0.52) | 6.12** |
| WLQ (presenteeism) | 0.27 (0.04–0.51) | 0.46 (0.22–0.70) | 5.45** | 0.71 (0.46–0.95) | 0.69 (0.44–0.93) | 20.47*** |
| WAI | 0.40 (0.16–0.64) | 0.43 (0.19–0.67) | 7.51** | 0.42 (0.17–0.66) | 0.57 (0.33–0.82) | 11.61*** |

*Abbreviations*: *PSS-10* Perceived Stress Scale, *PPA* Per protocol analysis, *CES-D* Centre for Epidemiological Studies' Depression Scale, *CD-RISC* Connor-Davidson-Resilience scale, *ERI* Effort-reward imbalance, *MBI-GS-D* Maslach Burnout Inventory, *UWES* Utrecht Work Engagement Scale, *WLQ* Work limitations questionnaire, *WAI* Work ability index

Bonferroni-adjusted significance levels used *$p < 0.017$; **$p < 0.003$; ***$p < 0.0003$

[a]Missing data handled by multiple imputation

[b]$F_{(217,2)}$

**Table 4** Means and standard deviations for all study groups on primary and secondary outcomes

| | T1 (baseline) | | | | | | T2 (7 weeks post-baseline)[a] | | | | | | T3 (6 months post-baseline)a | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | AFG | | SH | | SH | | AFG | | SH | | WDC | | AFG | | SH | | WLC | |
| | M | SD | M | SD | M | SD | M | SD | M | SD | M | SD | M | SD | M | SD | M | SD |
| **Primary Outcome** | | | | | | | | | | | | | | | | | | |
| PSS-10 | 25.54 | 4.39 | 25.65 | 4.05 | 25.60 | 3.97 | 17.52 | 5.91 | 17.83 | 5.90 | 22.98 | 6.48 | 17.17 | 6.18 | 17.54 | 6.31 | 22.95 | 6.43 |
| PSS-10 (PPA) | 25.88 | 4.36 | 25.73 | 4.03 | 25.63 | 3.58 | 17.04 | 6.00 | 16.48 | 5.76 | 23.20 | 6.50 | 16.69 | 6.18 | 16.73 | 7.13 | 24.35 | 6.34 |
| **Secondary Outcomes** | | | | | | | | | | | | | | | | | | |
| CES-D | 19.28 | 7.21 | 18.44 | 6.63 | 18.59 | 6.63 | 11.90 | 6.92 | 12.65 | 7.60 | 17.58 | 8.27 | 12.61 | 7.39 | 12.08 | 7.41 | 17.38 | 8.20 |
| CD-RISC | 20.01 | 6.13 | 19.94 | 5.92 | 19.49 | 6.40 | 24.00 | 6.20 | 22.96 | 6.04 | 19.49 | 6.82 | 23.54 | 6.63 | 23.89 | 6.54 | 19.99 | 6.49 |
| ERI (effort) | 10.80 | 1.45 | 10.49 | 1.60 | 10.76 | 1.37 | 9.64 | 1.73 | 9.67 | 1.84 | 10.02 | 1.88 | 9.60 | 1.89 | 9.33 | 2.15 | 10.16 | 2.00 |
| ERI (reward) | 16.39 | 4.13 | 16.72 | 3.76 | 16.82 | 3.65 | 17.42 | 3.90 | 17.23 | 3.70 | 16.53 | 3.79 | 17.42 | 3.71 | 17.90 | 3.87 | 16.93 | 3.83 |
| MBI-GS-D | 4.73 | 0.82 | 4.70 | 0.76 | 4.84 | 0.67 | 3.95 | 0.92 | 3.92 | 0.92 | 4.67 | 0.89 | 3.81 | 0.99 | 3.73 | 0.99 | 4.60 | 0.89 |
| UWES (vigor) | 2.83 | 1.26 | 2.83 | 1.25 | 2.84 | 1.28 | 3.13 | 1.24 | 3.08 | 1.24 | 2.67 | 1.33 | 3.03 | 1.25 | 3.14 | 1.23 | 2.60 | 1.32 |
| UWES (dedication) | 3.24 | 1.46 | 3.16 | 1.48 | 3.28 | 1.45 | 3.59 | 1.34 | 3.37 | 1.41 | 3.17 | 1.50 | 3.26 | 1.37 | 3.32 | 1.41 | 3.03 | 1.42 |
| UWES (absorption) | 3.09 | 1.49 | 3.04 | 1.50 | 3.06 | 1.55 | 3.31 | 1.36 | 3.21 | 1.48 | 2.94 | 1.50 | 3.17 | 1.35 | 3.13 | 1.41 | 2.74 | 1.42 |
| WLQ (presenteeism) | 5.12 | 2.61 | 4.97 | 2.56 | 5.55 | 2.51 | 4.17 | 2.42 | 3.71 | 2.48 | 4.85 | 2.46 | 3.26 | 2.33 | 3.24 | 2.51 | 4.93 | 2.40 |
| WAI | 5.86 | 1.99 | 5.78 | 1.83 | 5.57 | 2.04 | 6.68 | 1.98 | 6.72 | 1.86 | 5.88 | 2.05 | 7.01 | 2.00 | 7.31 | 1.93 | 6.19 | 1.94 |

Abbreviations: *PSS-10* Perceived Stress Scale; *PPA* Per protocol analysis; *CES-D* Centre for Epidemiological Studies' Depression Scale; *CD-RISC* Connor-Davidson-Resilience scale; *ERI* Effort-reward imbalance; *MBI-GS-D* Maslach Burnout Inventory; *UWES* Utrecht Work Engagement Scale; *WLQ* Work limitations questionnaire; *WAI* Work ability index
a = Missing data handled by multiple imputation

($F_{267,1} = 0.61$, $P = .437$), nor at T3 ($F_{267,1} = 0.47$, $P = .494$). Frequencies for module completion differed significantly from each other ($F_{267,1} = 35.31$, $P = .008$). On average, subjects in the AFG group completed 5.9 modules ($SD = 2.01$) compared to 5.17 in the SH condition ($SD = 2.38$). As shown in Fig. 3, the majority in AFG completed the seven core modules (97/135, 72%) compared to SH (71/135, 53%).

### Frequencies of given feedback and reminders

Table 5 shows the frequency distribution of responses to the questionnaire used to gather feedback on the provided guidance format. In the AFG condition, 17 subjects stated they have made use of feedback on demand. However, the manual check for these numbers on the messaging platform showed that 37 participants attempted to establish contact to an e-coach. 60 feedbacks were inquired in total across all participants (per subject: $M = 0.44$, $SD = 0.94$,

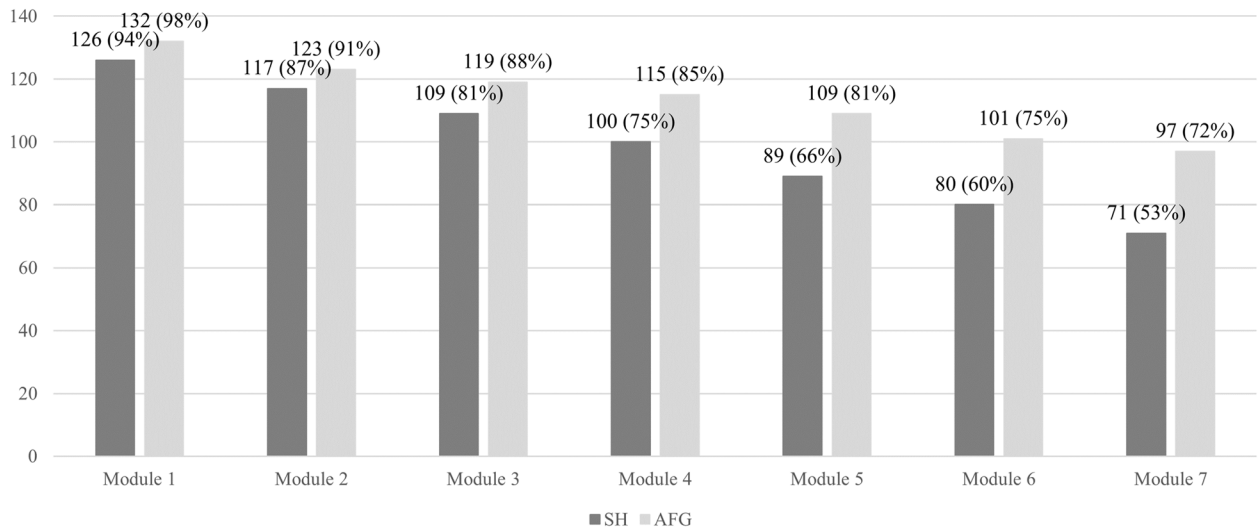


**Fig. 3** Number (percentages) of participants who completed the module (based on log-data)

**Table 5** Frequencies of answers to the guidance format questionnaire

| | AFG ($n = 134$)[a] | SH ($n = 135$)[a] |
|---|---|---|
| **1 Which study group were you assigned to?** | | |
| AFG | 51 (38%) | 6 (4%) |
| SH | 71 (53%) | 119 (88%) |
| **2 Did you make use of feedback on demand?** | | |
| Yes | 17 (13%) | n/a |
| No | 39 (29%) | 7 (5%) |
| **3 Would you have preferred regular feedback by an e-coach on your assignments?** | | |
| Yes | 58 (43%) | 58 (43%) |
| No | 39 (29%) | 31 (23%) |
| No preference | 25 (19%) | 36 (27%) |
| **4 Which guidance format would you prefer if you would participate in a similar training again?** | | |
| Regular feedback by an e-coach | 64 (48%) | 56 (41%) |
| Feedback-on-demand | 47 (35%) | 48 (36%) |
| Self-help (no feedback) and only technical support | 11 (8%) | 21 (16%) |

[a]Percentages in relation to total samples

range 0–5). Additionally, 453 reminders were sent (per subject: $M = 3.36$, $SD = 1.88$, range 0–9). Hence, e-coaches spent most of the time rather on adherence monitoring than giving feedback.

### Mediation analysis

As depicted in Fig. 4, perceived stress assessed with PSS-10 at T2 significantly mediated the intervention effect on depression (CES-D) at T3: $a_1b_1 = -0.77$, 95% CI [– 1.26, – 0.34]. Resilience measured with CD-RISC at T2 also significantly mediated the intervention effect on depression (CES-D) at T3: $a_2b_2 = -0.62$, 95% CI [– 1.05, – 0.26]. After these mediators were incorporated into the model, the direct effect of the intervention on depression remained significant: c' = – 1.08 [– 1.95, – 0.21].

## Discussion

This study aimed to investigate the comparative efficacy of different guidance formats on perceived stress within a web-based occupational SMI. Three arms were included in this trial to compare adherence-focused guidance, self-help and a wait list control group. With work stress being a major risk factor for the pathogenesis of depression which again is a leading cause for the contribution to the burden of disease [8], another objective was to reveal important insights into mechanisms of

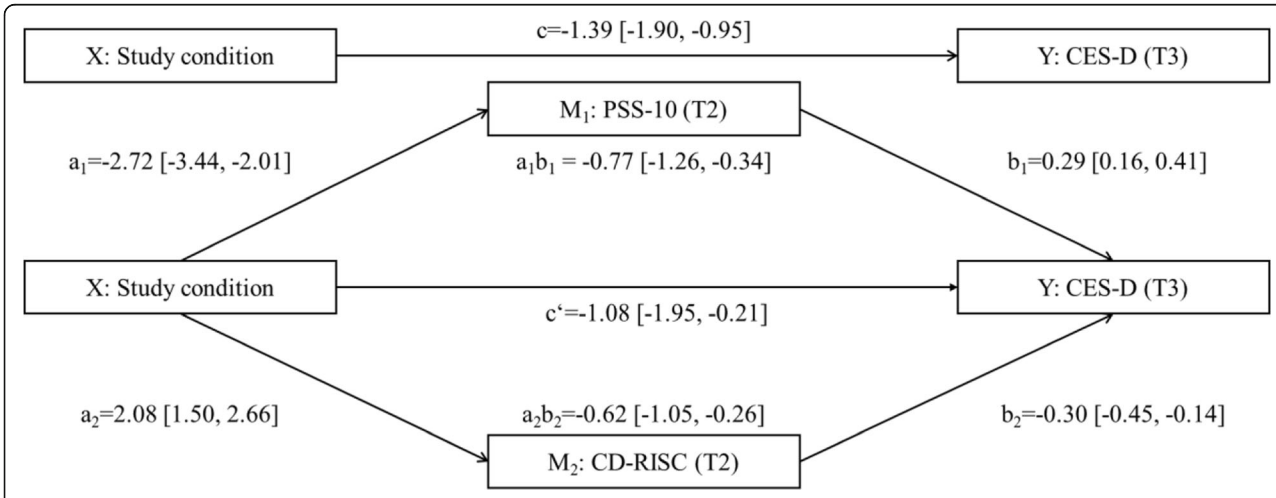


**Fig. 4** Parallel multiple mediation analysis with study condition as independent variable (coded 0 = waitlist control group, 1 = self-help, 2 = adherence-focused guidance), perceived stress (PSS-10) and resilience (CD-RISC) scores at post-intervention (T2) as mediators, 6-month follow-up depression values (T3) as outcome variable, and baseline values of mediators and outcome as covariates. Unstandardised beta coefficients are shown with 95% (bootstrapped biased corrected) CIs in parentheses

change to explore by which processes the SMI could have an impact on depressive symptoms. Understanding these mechanisms of change is of great interest and importance for health promotion, as offering SMI is a regarded strategy to prevent depression. To investigate potential mediators of the SMI's efficacy on a reduction of depressive symptomatology, perceived stress was regarded as potentially health impairing mediator while resilience opposingly was considered a protective factor.

The results suggest that the intervention could effectively reduce perceived stress in employees, irrespective of the guidance format. Thus, the expected difference in efficacy between the two delivery modes AFG or SH was not found. For both intervention groups, the effect could be maintained at T3. Sensitivity analyses corroborated results of the ITT analyses and revealed even larger effect sizes.

The present study demonstrated higher effect sizes than a recent meta-analysis across 26 studies on web-based SMI with various guidance formats compared to different kinds of control groups (wait list control, attention control, alternative or no treatment) with an overall effect size of d = 0.43 for stress as primary outcome [15]. The yielded lower overall effect size compared to the higher effect sizes found in this study could be due to several reasons. It is important to note that heterogenous, not-specifically occupational interventions were included in this meta-analysis. Thus, study conditions, guidance formats, delivery mode or the length of these interventions could be various. This also accounts for the applied recruitment strategy which can vary between the studies and was shown to enhance treatment effects when open recruitment was used like in this trial [29]. The high levels of perceived stress subjects reported in this study at enrolment might indicate a high intrinsic motivation for the participation in this SMI and could have led to a greater benefit compared to subjects with lower baseline scores. Furthermore, higher levels of perceived stress at baseline might lead to a greater effect size due to the potential of improvement compared to lower scores at study enrolment.

Another potential explanation for the higher effect sizes found in this study might be found in the fact that the training comprises just two main components, namely emotion regulation and problem solving that are theoretically grounded in Lazarus' transactional model of stress [60], comprising the two core components emotion regulation and problem solving. Research on traditional stress management programs suggests focussing on fewer components could be more effective than adding numerous modules [93]. This could possibly facilitate positive exercise effects and foster learning experiences due to the repeated revision of training contents. To the best of our knowledge, this is the first study on a web-based SMI investigating the comparative efficacy of different guidance formats within one trial, thus evidence for differential effects is limited and the present results can only be compared to heterogenous studies that each individually examined mostly only one type of guidance. Results of two individual trials investigating the same web-based SMI with each AFG [49] and SH [36] both also demonstrated comparably high effect sizes. In brief summary, this study is in line with previous research and adds to the hitherto missing evidence of the comparative efficacy of different guidance formats within one trial.

Concerning the non-significant differences between AFG and SH with regard to effects on the primary outcome, it should be noted that the intensity of guidance for AFG was per se low, and most resources were spent on adherence monitoring instead of providing feedback on demand. Albeit non-significant differences for the primary outcome, adherence in terms of completed modules was significantly higher for AFG than SH in this study. Another study investigated the comparative efficacy of AFG and SH under similar conditions within an Internet Intervention for problematic drinking in employees and also showed that despite missing between group differences, adherence was better for AFG [94]. Equally in the present trial, participants in the AFG condition completed significantly more modules (5.90) compared to SH (5.17). Additional to the monitoring, participants in the AFG condition could receive feedback on demand. 28% of the subjects in this group (37/134) made use of the latter and received 60 feedbacks in total, next to 453 reminders that were sent in sum. Similarly small numbers of participants demanding feedback were found before in trials on the same SMI, with e-coaches also spending more time on adherence monitoring [50]. In these trials, the amount of subjects making use of feedback on demand numbered 6% (8/132) [49] and 11% (15/102) [50]. In the aforementioned RCT on a web-based intervention for problematic drinking in employees, 10% (15/144) made use of feedback on demand [94].

At first glance, this could lead to the conclusion that guidance might not be conducive to the efficacy of web-based SMI. However, this needs to be considered cautiously. First, this would be a false conclusion since the utilisation rate of AFG was low, not only in the present trial but also previous ones [50, 94]. Second, reasons for this can be manifold. For example, results of the questionnaire on utilisation of and satisfaction with AFG indicated that the majority of this group was not even aware of their assigned condition. Instead, more than half of the AFG-subjects (53%) assumed receiving a pure SH-intervention. Moreover, 43% of the AFG-subjects

(SH: 43%) stated they would have preferred regular feedback by an e-coach on their assignments which would furthermore be preferred by 48% (SH: 41%) if they would participate in a similar training again. In conclusion, it seems that the low utilisation rate of feedback on demand as part of AFG could possibly be due to a lack of awareness of what was offered. It can be speculated that information on the availability of personal feedback from the e-coach should have been presented more prominently and that such awareness-raising measures could have been helpful. In this way, e-coaches could for example contact participants more actively by encouraging them to make us of the AFG and offering their feedback. Another possibility to promote acceptance could be the use of educational videos to explain the delivery mode in more detail. To conclude, it seems that the monitoring component of AFG might promote adherence but might not be sufficient to enhance efficacy with such low utilisation rates of the offered feedback on demand. The superiority of AFG for adherence was not mirrored for the outcomes since results demonstrated high effect sizes for SH and adherence defined as the average amount of completed modules was satisfying for this group. On the one hand, this leads to the question if the usage of AFG is justifiable against the background of required resources. On the other hand, the level of guidance was per se low for AFG, thus differences compared to SH might be challenging to detect because they could be small by default.

Analyses of secondary measures demonstrated that the present web-based SMI came into effect on the majority of the outcomes such as depression, resilience, emotional exhaustion, work engagement, presenteeism and work ability. In more detail, effect sizes for the reduction of depressive symptoms were found to be high for each intervention group compared to WLC (at post-intervention, $d = 0.62$ for SH and $d = 0.74$ for AFG). These effect sizes are higher than those observed in a meta-analysis on the efficacy of SMI on depression ($d = 0.34$) [15]. Notably, earlier studies reported consistently higher effect sizes for guided Internet Interventions than unguided interventions [15, 39]. It seems interesting to note that all variables directly related to the subjects changed over time and that no significant effect was found for ERI-effort at T2 ($P = .67$) which from a conceptual point of view is a measure of the workplace situation. Comparable to the primary outcome, no significant differences were found between AFG and SH, although this should again be interpreted cautiously for already stated reasons.

Another important objective of this study was to examine mediating interventional effects on depressive symptoms. This is of great interest for practical and theoretical reasons and there is a growing need for such research [95, 96]. To date, research is limited to observational studies that identified stress as risk factor for the development of depression [6]. The use of SMI to prevent depression therefore seems reasonable, though interventional studies and more in-depth analyses of this relationship are missing yet. Beyond the reduction of perceived stress, the present SMI became efficacious on a pathological dimension by also reducing depressive symptoms. This result highlights the potential of the SMI in regard to the prevention of mental health disorders.

Results of the mediation analysis demonstrated the applicability of the proposed framework and showed that both considered paths mediated the intervention's effect on depressive symptoms. On the one side, the intervention could positively affect perceived stress which again had a positive preventive effect on depressive symptoms. On the other side, the intervention also positively affected resilience which seemed conducive to a health promoting process and depressive symptoms eventually. These results reveal interesting insights into the question of how depressive symptoms could be reduced and prevented. Depressive symptomatology was less pronounced when participants on the one side perceived less stress and on the other side were more resilient. A similar pattern with interventional effects based on reducing negative factors on the one hand and building up positive ones on the other hand was also found in an earlier study on a web-based gratitude training which examined mediation analyses based on the same approach of a dual pathway [97].

Despite years of research on the effects of stress and resilience in an occupational context, mechanisms of change of SMI have not received attention yet. However, research not limited to interventional studies showed that resilience as a core protective factor can be developed at work and comes into effect especially in employees at a greater risk of experiencing high strain [98]. Taken together with the present results, important implications for practitioners and health intervention developers can be drawn. The present interventional study is in line with results of earlier observational studies and adds further evidence. Taken together, the findings suggest a contentual integration of both, the health impairing and health promoting processes. Participants should be supported in reducing risk factors such as stress and building up protective factors such as resilience.

Previous research has shown that Internet Interventions could be as effective as face-to-face settings [26–28]. However, evidence is only available on indirect comparisons; well designed and adequately powered head-to-head comparisons are yet missing [99]. Traditional face-to-face settings are characterised by certain features such as a group setting, a fixed venue or a pace

depending on the training schedule which obviously are different to the typical characteristics of Internet Interventions (see [99] for a full comparison of both). The differences in the typical characteristics of both delivery modes can be an advantage for one participant (e.g. experiencing a motivating group atmosphere) and an obstacle for the other (e.g. high threshold to participate in group setting with social anxiety). Unfortunately, evidence for selective indication is missing. Interestingly, several studies on web-based SMI reported that the vast majority of participants have no experiences with previous face-to-face trainings [36, 49, 61], indicating that both delivery modes (traditional vs. online) reach their audience and thereby increase the overall reach and uptake of SMI.

This study had several limitations. First, the utilised SMI was for the indicated prevention of work stress related adverse health outcomes. This required an elevated stress level for participants to be included in the study. Therefore, resulting conclusions from this study cannot be generalised to populations showing lower stress levels or to a setting in universal prevention. However, from a methodological perspective, this allows for comparisons to studies with similar inclusion criteria. Second, limited generalisability of the results due to the recruitment strategy in this trial must be considered. This trial directly addressed subjects and therefore provides no insights with regard to an implementation into Corporate Health Management. In future research, it should therefore be considered offering SMI for employees in actual occupational setting, e.g. company health management programs. Third, only few participants in the AFG condition made use of the personalised feedback and many of them were not aware that their guidance comprised this opportunity. The low utilisation rate of the guidance suggests it would have been advisable to conduct a pretest. This could ensure that participants who do not engage with the offered components of guidance (i.e. feedback on demand) deliberately decide against this but are aware of their options.

Finally, further research is needed to fully capture the comparative efficacy of different guidance formats. Participants should receive guidance facilitating and awareness-raising measures to know that and how they can make use of the accompanying guidance. Ideally, they could make an informed decision about the extent to which they would like to inquire feedbacks and determine the dose-response relationship. Other reasons for the low utilisation rate for AFG could also be considered and influencing factors examined, for example if and to what extent personal presence of e-coaches is necessary. Due to the low intensity of guidance for AFG, existing differences for the comparative efficacy could be difficult to detect compared to SH. Therefore, more heterogeneous trials on the impact of guidance are still necessary and could for example compare adherence-focused to content-focused guidance [38]. For future studies, it could also be an interesting approach to explore and disentangle the effects of the two single components of AFG, namely monitoring and giving feedback on demand.

## Conclusions

The present study contributes to the scarce evidence on the comparative impact of guidance to the efficacy of SMI, next to mechanisms of change of depressive symptoms. To the best of our knowledge, no previous study has compared different guidance formats within a single trial on SMI. The results showed that the SMI was effective in reducing perceived stress as primary outcome, next to various other work- and mental health-related outcomes such as depression or burnout. However, no between group differences were found for the effect sizes when comparing AFG to SH. This supports a growing body of research showing that SMI with a limited amount of resources can be effective. Despite missing significant between group differences for the outcomes, it should be noted that adherence in terms of module completion was significantly better for AFG than SH. Due to the low utilisation rate of AFG, the results should furthermore be interpreted cautiously regarding the question of how much guidance is necessary for an efficacious and well-accepted SMI. Future studies should therefore focus on further capturing differences between different guidance formats and explore how the better adherence for AFG could also lead to better outcomes compared to SH. Guidance formats could for example be more distinguishable than AFG compared to SH to examine the incremental value of more intensive guidance. Another important conclusion for future studies is to attempt higher utilisation rates when guidance is offered, irrespective of its kind. Furthermore, the results showed that stress and resilience mediated the effects on depressive symptomatology. This interventional study therefore adds evidence to earlier observational studies on the relationships between stress and depression and resilience and depression. Important implications for practitioners and research can be derived to consider both pathways of a health impairing and health promoting process in designing such interventions.

### Abbreviations

AFG: Adherence-focused guidance; ANCOVA: Analysis of covariance; ANOVA: Analysis of variance; BDI: Beck depression inventory; CD-RISC: Connor-Davidson resilience scale; CES-D: Centre for epidemiological studies' depression scale; CI: Confidence interval; CONSORT: Consolidated standards of reporting trials; CSQ-I: Client satisfaction questionnaire adapted to Internet-based interventions; ERI-SF: Effort reward imbalance questionnaire – short form; GCP: Good clinical practice; ITT: Intention-to-treat; JD-R: Job-demands-resources model; MBI-GS-D: Maslach burnout inventory;

MCAR: Missing completely at random; NNT: Number needed to treat; PPA: Per protocol analysis; PSS-10: Perceived stress scale; RCI: Reliable change index; RCT: Randomised controlled trial; SD: Standard deviation; SH: Self-help; SMI: Stress management intervention; TAU: Treatment as usual; UWES: Utrecht work engagement scale; WAI: Work ability index; WHO: World health organization; WLC: Wait list control group; WLQ: Work limitations questionnaire

### Acknowledgements
The authors thank Angelina Scheel and Torsten Tarnowski for contributing to the study administration.

### Authors' contributions
DE and DL obtained funding for this study. EH, DE and DL contributed to the development of the GET.ON Stress training. DE was responsible for the initial study-design draft, EH, DL and LB contributed to the final study design. EH, DE, DL and LB oversaw the conduct of the study and data collection. PN conducted data analyses. DL, LB oversaw data analyses, DL contributed to interpretation of data and supervised the writing process. PN drafted the manuscript that was revised by EH, DE, DL and LB. All authors read and approved the final manuscript.

### Funding
This study is funded by the European Union (EFRE: ZW6–80119999, CCI 2007DE161PR001) and the BARMER GEK. Open Access funding enabled and organized by Projekt DEAL.

### Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate
The University of Marburg ethics committee approved of this study (No. 2014-5 K). All participants gave informed written consent. The trial was registered in the German Clinical Trials Register on 06/06/2014 (DRKS00005687).

### Consent for publication
Not applicable.

### Competing interests
DE, DL and EH are stakeholders in the Institute for Online Health Training which aims to transfer scientific knowledge related to the present research into routine health care. LB and PN do not have any conflicts of interest.

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Received: 14 July 2020 Accepted: 16 July 2021
Published online: 05 August 2021

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## Publisher's Note

## 2.4 Introduction to Study 2

Meta-analytic evidence has demonstrated the efficacy of digital SMIs in sustainably reducing perceived stress. However, environmental factors in the workplace have been neglected, and there is a lack of data on the efficacy of digital SMIs among employees facing adverse working conditions. For this reason, the third research question of this dissertation aims to reveal:

**Research Question 3: Is a digital stress management intervention effective in reducing stress in employees facing adverse working conditions?**

Occupational self-efficacy has been identified as a relevant personal factor influencing employee health, as it reflects an individual's belief in their capability to effectively meet job demands. However, the role of occupational self-efficacy as a mediator in the relationship between a digital SMI and perceived stress remains unexplored. To address this gap, the fourth research question aims to uncover:

**Research Question 4: Does occupational self-efficacy mediate the effects of a digital stress management intervention on perceived stress?**

The impacts of an effort-reward imbalance, defined as the perceived disproportion between the efforts employees invest in their workplace and the rewards they receive in return, have been extensively researched in the past, with meta-analytic evidence demonstrating substantial effects on employee health. Despite the recognised impact of this external factor, the intricate associations between a digital SMI and work environment conditions have not yet been examined. Therefore, the fifth research question seeks to examine:

**Research Question 5: Do efforts and rewards mediate the effects of a digital stress management intervention on perceived stress?**

## 2.5 Study 2: Digital Stress Management for Employees in Adverse Working Conditions: Efficacy and Mediators

Nixon, P., Ebert, D. D., Boß, L., Angerer, P., Dragano, N., & Lehr, D. (2022). The Efficacy of a Web-Based Stress Management Intervention for Employees Experiencing Adverse Working Conditions and Occupational Self-efficacy as a Mediator: Randomized Controlled Trial. *Journal of Medical Internet Research*, 24(10):e40488.

doi: 10.2196/40488.

Submitted: 23rd June 2022

Accepted: 24th August 2022

Published: 20th October 2022

Original Paper

# The Efficacy of a Web-Based Stress Management Intervention for Employees Experiencing Adverse Working Conditions and Occupational Self-efficacy as a Mediator: Randomized Controlled Trial

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## Abstract

**Background:** Work stress is highly prevalent and puts employees at risk for adverse health consequences. Web-based stress management interventions (SMIs) promoting occupational self-efficacy might be a feasible approach to aid employees to alleviate this burden and to enable them to improve an unbalanced situation between efforts and rewards at work.

**Objective:** The first aim of this randomized controlled trial was to investigate the efficacy of a web-based SMI for employees perceiving elevated stress levels and an effort-reward imbalance in comparison to a waitlist control (WLC) group. Second, we investigated whether the efficacy of an SMI could be explained by an increase in occupational self-efficacy and whether this personal resource enables employees to change adverse working conditions.

**Methods:** A total of 262 employees reporting effort-reward imbalance scores over 0.715 and elevated stress levels (10-item Perceived Stress Scale [PSS-10] score ≥22) were randomly assigned to either the intervention group (IG; SMI) or the WLC group. The primary outcome was perceived stress measured using the PSS-10. The secondary outcomes included mental and work-related health measures. Four different mediation analyses were conducted with occupational self-efficacy, efforts, and rewards as mediators. After eligibility screening, data were collected web based at baseline (T1), 7 weeks (T2) and 6 months (T3).

**Results:** Study participation was completed by 80% (105/130, 80.8%) in the IG and 90% (119/132, 90.2%) in the WLC group. Analyses of covariance revealed that stress reduction was significantly higher for the SMI group compared with the WLC group at T2 (d=0.87, 95% CI 0.61-1.12, P<.001) and T3 (*d*=0.65, 95% CI 0.41-0.90, P<.001). Mediation analyses indicated that occupational self-efficacy mediated the beneficial effect of the SMI on stress directly. Furthermore, the analyses revealed a significant indirect effect of occupational self-efficacy via rewards (*b*=0.18, $t_{259}$=4.52, P<.001), but not via efforts (b=0.01, $t_{259}$=0.27, P>.05) while efforts still had a negative impact on stress (*b*=0.46, $t_{257}$=2.32, P<.05).

**Conclusions:** The SMI was effective in reducing stress and improving occupational self-efficacy in employees despite them experiencing an effort-reward imbalance at work. Results from mediation analyses suggest that fostering personal resources such as occupational self-efficacy contributes to the efficacy of the SMI and enables employees to achieve positive changes regarding the rewarding aspects of the workplace. However, the SMI seemed to neither directly nor indirectly impact efforts, suggesting

that person-focused interventions might not be sufficient and need to be complemented by organizational-focused interventions to comprehensively improve mental health in employees facing adverse working conditions.

**Trial Registration:** German Clinical Trials Register DRKS00005990; https://tinyurl.com/23fmzfu3

***(J Med Internet Res 2022;24(10):e40488)*** doi: 10.2196/40488

**KEYWORDS**

occupational eMental health; stress; occupational self-efficacy; effort-reward imbalance; randomized controlled trial

## Introduction

More than a decade ago, the World Health Organization identified stress as major risk factor for adverse consequences on physical and mental health for the 21st century [1]. In particular, the workplace can be a source of stress that can be associated with an increased risk of depression and cardiovascular diseases [2-4]. Next to such harmful effects on employees' personal lives and health, experiencing high strain at work can entail substantial societal costs [5].

One of the most prominent theoretical frameworks to investigate workplace stressors is the effort-reward imbalance model [6]. In short, this model is based on the premise of an imbalance between efforts invested and low rewards received in return. Both efforts and rewards therefore reflect subjectively perceived working conditions employees are exposed to. Rewards can be distinguished between financial payments, job security, or career prospects, and intangible compensation such as esteem or praise. During the past few decades, the model was well researched. It was shown that employees experiencing an effort-reward imbalance have an increased risk of depression [7], lower immunity [8], or coronary heart disease [9]. Multiple systematic reviews demonstrated robust evidence for the links between an effort-reward imbalance and health, and suggested that it can instigate psychological, physical, and behavioral health–impairing pathways [10-12].

Psychosocial hazards were identified as one of the key emerging health risks [13] and there were significant developments to address psychosocial risk factors at work. For example, the National Standard of Canada for Psychological Health and Safety in the Workplaces provides a comprehensive framework for an approach to ensure a psychologically healthy workplace [14]. Notably, changing adverse working conditions requires a timely and complex transformational process that can be a considerable source of work stress itself and is associated with different risks such as an increase of stress-related medication intake [15].

Workers already affected by high levels of stress are in an acute need of relief, and so waiting for the successful implementation of organizational changes can be challenging. In this situation, a stress management intervention (SMI) might be a first step to support those in need of help sooner [16]. There is evidence for the beneficial effects of SMIs in traditional face-to-face settings [17], which was complemented by a more recent and growing body of research for the web-based delivery [16,18,19]. Web-based interventions allow the workforce to benefit from low-threshold access and highly flexible participation in terms of time and location, and employers to profit from easy scalability and low required resources [20]. Furthermore, they might have the potential to alleviate the burden of workplace stressors by promoting self-efficacy and improving various health outcomes such as insomnia or depression [21-24] in both short and long term [25,26]. However, until today, evidence is missing on whether a web-based SMI could also effectively reduce perceived stress in employees who are exposed to adverse working conditions in terms of an imbalance between efforts and rewards. Moreover, no trial has yet examined mechanisms of change within this high-risk population and whether an increase in personal resources could enable employees to improve the unbalanced situation between efforts and rewards at work.

An effective implementation of a web-based SMI for employees who are exposed to adverse working conditions could be a person-centered intervention helping workers to initiate changes, a strategy known as problem-focused coping following the transactional model by Lazarus and Folkman [27]. A necessary personal resource for self-initiated changes employees make to redesign working conditions is self-efficacy, which is believed to trigger proactive behaviors undertaken at work [28]. Initially, Bandura [29] defined self-efficacy as confidence to meet difficult challenges or prospective problems by oneself. Individuals with high self-efficacy experience lower levels of work strain and engage more in problem-focused coping [30]. Another study confirmed that a problem-solving training for teachers could strengthen the ability to cope with problems and stressful situations as well as increase self-efficacy [31]. Within this organizational context, occupational self-efficacy can be described as personal belief in work-related abilities [32]. Studies on occupational self-efficacy have demonstrated positive associations with job performance, employee satisfaction, employability, and work commitment, and negative relationships with job insecurity [32,33]. A study on the same SMI that was examined in this randomized controlled trial (RCT) provided first evidence for effects on occupational self-efficacy [34], while the previously stated need for research on self-efficacy as a mechanism of change in an occupational SMI has not been addressed yet [35]. Moreover, there is no evidence on the effects of occupational self-efficacy on the perception of adverse working conditions yet despite the assumption that self-efficacy as a function of self-regulation conducive to health relies on successful exchange of efforts and rewards [36].

To the best of our knowledge, this is the first RCT to investigate the efficacy of a web-based occupational SMI in employees perceiving high stress levels and an effort-reward imbalance and to explore mediating effects of occupational self-efficacy, efforts, and rewards on stress reduction. This trial will examine the hypothesis that the SMI will effectively reduce perceived

stress in the intervention group (IG) compared with a waitlist control (WLC) group. The second study aim is to investigate mediating effects of the personal resource of occupational self-efficacy and environmental factors, specifically efforts, and rewards at the workplace in the association between the intervention and perceived stress.

# Methods

## Study Design and Conditions

A primary RCT including 264 participants experiencing an effort-reward imbalance was conducted in compliance with the Declaration of Helsinki and Good Clinical Practice and following the CONSORT (Consolidated Standards of Reporting Trials) guidelines [37,38] (Multimedia Appendix 1). Based on meta-analytic evidence for web-based SMI revealing moderate effects (Hedges $g$=0.54) [19] and considering the impact of adverse working conditions, this study aimed to detect differences between groups with an effect size of Cohen $d$=0.35 based on a power (1–β) of 0.80 in a 2-tailed test with α=.05. Participants were randomly assigned to the IG or the WLC group at a ratio of 1:1 using an automated computer-based random integer generator (DatInf RandList; Datinf GmbH). Participants were allocated to the study groups by an independent researcher not otherwise involved in the study. Self-reported outcomes were assessed between May 2014 and May 2015 with a secured online-based self-report system (AES; 256-bit encrypted) at screening for eligibility (T0), baseline (T1), and 7 weeks (T2), and 6 months (T3) after randomization. After allocation, participants in the IG received immediate access to the intervention, whereas those in the WLC group obtained access after 6 months. Treatment as usual was not restricted and monitored. None of the obtained data presented here were published before.

## Participants and Recruitment

Participants were recruited from the general working population via the research project website and mass media (eg, articles in health insurance magazines). Inclusion criteria were the willingness to give informed consent; legal age (18 years); employment; 10-item Perceived Stress Scale (PSS-10) [39,40] score ≥22; effort-reward imbalance [41] score >0.715, which was found to indicate a highly hazardous imbalance between effort and rewards at the workplace [42]; no notable suicidal risk, as indicated by a score of >1 on item 9 (I feel I would be better off dead) of the Beck Depression Inventory [43]; and no previous or current diagnosis of dissociative symptoms or psychosis. Interested participants signed up on the open access website with their email address to receive a link to the eligibility screening questionnaire. Eligible applicants were required to provide informed consent and baseline data (T1).

## Intervention

Psychologists developed the intervention for employees based on Lazarus' transactional model of stress focusing on problem solving and emotion regulation skills [27]. The intervention encouraged participants to reflect on meaningful issues that were not restricted to either work or personal life. The efficacy was demonstrated before in an indicated prevention sample and with different guidance formats, namely, adherence-focused guidance and self-help [22,44,45]. The SMI consisted of 7 core modules and an optional booster session 4 weeks after termination. Module completion required 45-60 minutes and participants were advised to complete at least one per week, adding up to an intervention period of 4-7 weeks. Participants could choose whether and how often they preferred to receive short automatic motivational SMS text messages to their mobile device (infrequent or intensive, ie, 1-3 SMS text messages daily). In addition, participants could inquire feedback-on-demand, which was provided by an e-coach within 48 hours only upon request on the internal messaging platform. E-coaches were skilled psychologists following feedback guidelines from the standardized manual for the intervention. Participants were assigned to an e-coach in a 1-to-1 ratio.

## Primary Outcome Measure

The primary outcome was perceived stress appraised with the German version of PSS-10 [39,40], which was also developed based on Lazarus' transactional model of stress. The items assess to what extent participants experienced their lives as stressful within the past week on a 5-point Likert scale from 0 (never) to 4 (very often), resulting in sums from 0 to 40, with higher scores reflecting higher levels of stress. In this study, values for the internal reliability (Cronbach α) were .81 at T1, .89 at T2, and .92 at T3.

## Secondary Outcome Measures

Included measures for the secondary outcomes are listed in the following sections, with number of items, item range, and reliabilities assessed at T2.

### *Mediators*

Among the secondary outcomes, 2 measures were assessed for the inclusion as mediators. First, the Effort Reward Imbalance Questionnaire Short Form [41] with the subscales *efforts* (3 items; α=.78) and *rewards* (7 items; α=.79; score range 1-4). And second, the short form of the Occupational Self-Efficacy Scale (OSS-SF [32]; 6 items; α=.89; score range 1-6).

### *Work-Related Health*

The subscale *emotional exhaustion* of the Maslach Burnout Inventory (MBI-GS-D; 5 items; α=.87; score range 1-6) was used to evaluate work-related health [46]. The Utrecht Working Scale (UWES) [47] was used to examine work engagement (9 items; α=.93; score range 0-6). A single-item question was used to assess work ability (Work Ability Index) [48] and the Work Limitations Questionnaire [49] was administered to examine presenteeism.

### *Mental Health*

The short version of the Centre for Epidemiological Studies' Depression scale (CES-D) [50,51] was used to assess depression (15 items; α=.84; score range 0-3). The Connor-Davidson Resilience Scale [52] was used to examine resilience (10 items; α=.88; score range 0-4). The Assessment of Quality of Life (AQoL)-8D Multi-Attribute Utility Instrument [53] was used to examine health-related quality of life (35 items, different ranges from 1 to 5 and 1 to 6; α=.96) at T3.

### *Other Measures*

To assess the level of satisfaction with the intervention, the Client Satisfaction Questionnaire adapted to web-based interventions was used (CSQ-I; 8 items; α=.92; score range 1-4) [54]. In addition, self-developed measures were used to assess demographics, current occupation, work sector, income, educational level, and previous use of health services.

### Statistical Analyses

Statistical analyses were performed according to the recommendations of the CONSORT statement [37]. Data were analyzed with SPSS Statistics version 25 (IBM Corp.) [55] based on the intention-to-treat principle. An additional per-protocol analysis was conducted for the primary outcome, including only participants who completed at least six modules. Analyses of covariance (ANCOVA) were calculated with outcome baseline scores as covariates and a 2-tailed significance level at P<.05 to detect between-group differences for the IG and the WLC group at T2 and T3. Simulation studies have already demonstrated the methodological robustness of ANCOVA against bias, higher precision, and statistical power for experimental studies [56,57]. To handle missing data, multiple imputations were conducted for the intention-to-treat and per-protocol analyses with 10 estimates for each value that were aggregated into an overall value [58].

### Response Analyses

The Reliable Change Index of Jacobson and Truax [59] was used to investigate improvements of the primary outcome on an individual level. The SD of 6.2 and the reliability of PSS-10 of the norm population [60] were used in the formula [1.96 × SD1 × sqrt(2) × sqrt(1–rel)] to calculate that a reduction in perceived stress could be defined as *reliably improved* if changes of more than ±5.16 points were detected from T1 to T2. Symptom-free status was achieved according to Jacobson and Truax [59] when participants scored more than 2 SDs below the baseline mean (T1) of the primary outcome in the IG (mean 23.76, SD 5.11). The number needed to treat and 95% CI were calculated to indicate the average number of participants who need to be treated to achieve an additional response compared with the control group [61].

### Mediation Analyses

Four mediation analyses were conducted using the PROCESS macro (version 4.0) for SPSS [62]. The models build up on each other to explore their individual and shared contribution in stress reduction. In all models, the independent variable (X) was the study condition, and the dependent variable (Y) was perceived stress (PSS-10 at T3). The proposed mediators were occupational self-efficacy at T2 (PROCESS model 4); occupational self-efficacy at T2 and efforts at T3 (PROCESS model 6); occupational self-efficacy at T2 and rewards at T3 (PROCESS model 6); and occupational self-efficacy, efforts, and rewards at T3 (PROCESS model 81). Baseline scores of the outcome and mediator were considered covariates. For indirect effects that were considered significant if P<.05 and 95% CIs did not cover 0, 10,000 bias-corrected bootstrap samples were applied [62]. An additional sensitivity analysis including only study completers was performed.

### Ethics Approval

The Ethical Committee of the Leuphana University of Lueneburg approved the study (reference Ebert201408_Stresstraining). The trial was registered in the German Clinical Trials Register (DRKS00005990).

## Results

### Participants and Baseline Characteristics

The sample initially consisted of 264 participants of which 2 requested the deletion of assessed data after trial conduction. Consequently, the final sample included 262 participants (182/262, 69.4% female) aged 20-65 years (mean 42.2 years, SD 9.76 years), allocated to either the IG (n=130) or the WLC (n=132) group. Figure 1 depicts the study flow and Table 1 summarizes detailed baseline characteristics. A multivariate ANOVA indicated there was no meaningful difference in baseline outcomes between groups ($F_{19,232}$=1.08, P=.37). Primary outcome data were missing for 9.9% (n=26) at T2 and 15.3% (n=40) at T3. The Little missing completely at random test failed significance, indicating that the null hypothesis proposing patterns of missing values being not dependent on observed and unobserved factors among the participants' values need not be rejected.

**Figure 1.** Participant flow.

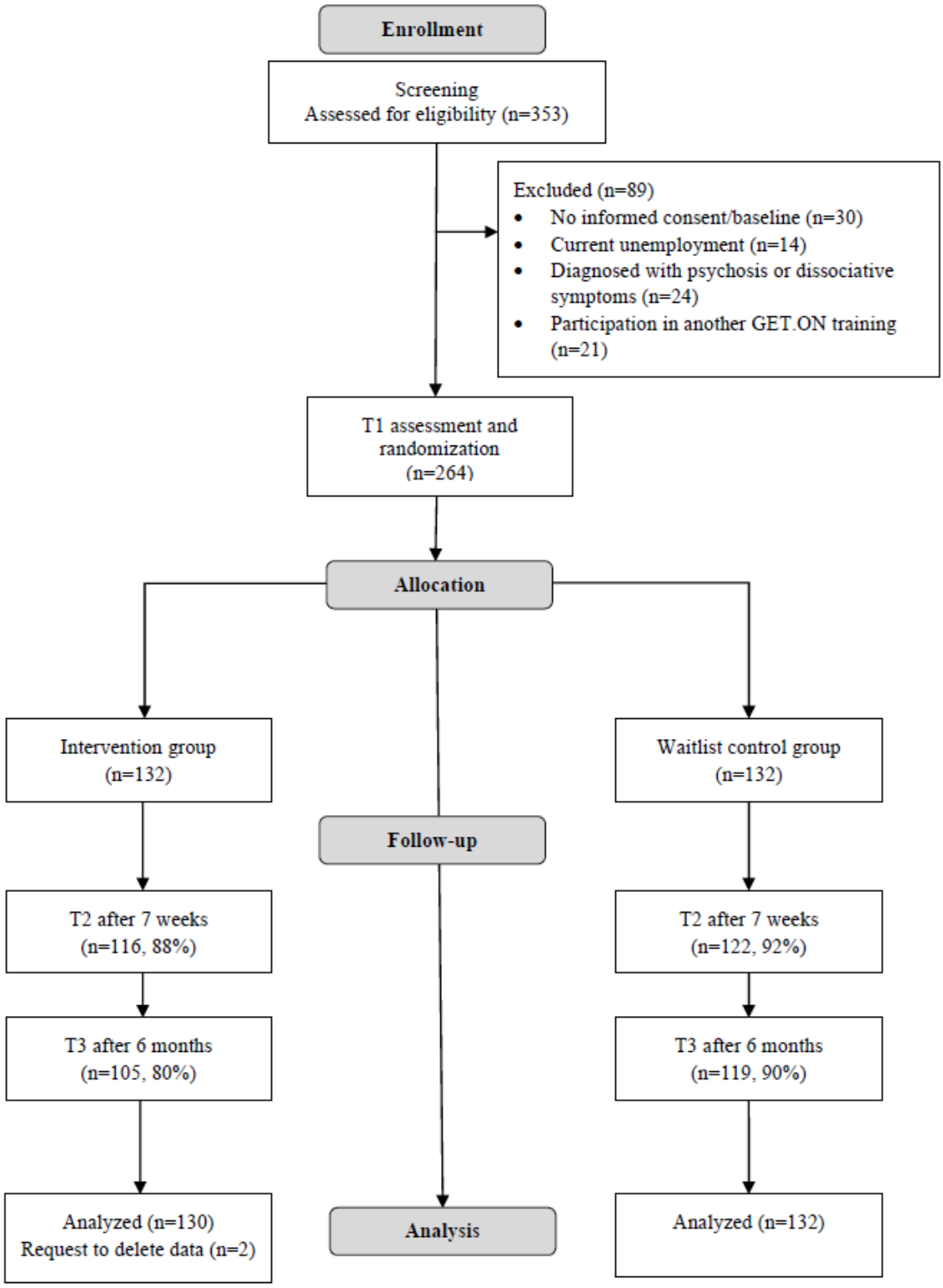


**Table 1.** Baseline characteristics[a].

| Characteristics | All participants (N=262) | IG[b] (n=130) | WLC[c] group (n=132) |
|---|---|---|---|
| **Sociodemographic** | | | |
| Age, mean (SD) | 42.20 (9.76) | 42.87 (9.54) | 43.42 (10.02) |
| Men, n (%) | 80 (30.5) | 45 (34.60) | 35 (26.5) |
| Women, n (%) | 182 (69.5) | 85 (65.40) | 97 (73.5) |
| Diverse, n (%) | N/A[d] | N/A | N/A |
| **Marital status, n (%)** | | | |
| Single | 78 (29.8) | 41 (31.5) | 37 (28.0) |
| Married | 123 (46.9) | 59 (45.4) | 64 (48.5) |
| Cohabited | 29 (11.1) | 16 (12.3) | 13 (9.8) |
| Divorced | 31 (11.8) | 14 (10.8) | 17 (12.9) |
| Widowed | 1 (0.4) | N/A | 1 (0.8) |
| **Educational level, n (%)** | | | |
| Low | 6 (2.3) | 2 (1.5) | 4 (3.0) |
| Middle | 54 (20.6) | 22 (16.9) | 32 (24.2) |
| High | 202 (77.1) | 106 (81.5) | 96 (72.7) |
| **Employment** | | | |
| Full-time, n (%) | 205 (78.2) | 105 (80.8) | 100 (75.8) |
| Part-time, n (%) | 53 (20.2) | 23 (17.7) | 30 (22.7) |
| Sick leave, n (%) | 4 (1.5) | 2 (1.5) | 2 (1.5) |
| Managerial position, n (%) | 100 (38.2) | 50 (38.5) | 50 (37.9) |
| Work experience in years, mean (SD) | 18.40 (10.83) | 17.79 (10.86) | 19.01 (10.81) |
| **Work sectors, n (%)** | | | |
| Service | 62 (23.7) | 26 (20) | 36 (27.3) |
| Economy | 56 (21.4) | 22 (16.9) | 34 (25.8) |
| Health | 33 (12.6) | 22 (16.9) | 11 (8.3) |
| Social | 44 (16.8) | 19 (14.6) | 25 (18.9) |
| Information technologies | 24 (9.2) | 15 (11.5) | 9 (6.8) |
| Other | 36 (13.7) | 19 (14.6) | 17 (12.9) |
| **Income, n (%)** | | | |
| Low | 73 (27.9) | 29 (22.3) | 44 (33.3) |
| Middle | 45 (17.2) | 26 (20) | 19 (14.4) |
| High | 123 (46.9) | 64 (49.2) | 59 (44.7) |
| **Use of health services, n (%)** | | | |
| Previous or current psychotherapy | 119 (45.4) | 55 (42.3) | 64 (48.5) |
| Experience in health trainings | 38 (14.5) | 15 (11.5) | 23 (17.4) |

[a]Values presented only for participants who provided the respective data.

[b]IG: intervention group.

[c]WLC: waitlist control.

[d]N/A: not applicable.

### Primary Outcome Measure

ANCOVAs to detect differences between the IG and the WLC group at T2 and T3 revealed significantly lower stress levels assessed with the PSS-10 for the IG at T2 ($F_{259,1}$=46.14, P<.001, $d$=0.87, 95% CI 0.61-1.12, Δ5.00) and T3 ($F_{259,1}$=24.82, P<.001, $d$=0.65, 95% CI 0.41-0.90, Δ4.19). The per-protocol analysis corroborated those results with significant between-group differences at T2 ($F_{173,2}$=34.86, P<.001, $d$=1.04, 95% CI 0.69-1.40, Δ5.79) and T3 ($F_{173,2}$=20.15, P<.001, $d$=0.56, 95% CI 0.22-0.90, Δ3.68). For all outcome measures at T2 and T3, Table 2 displays the means and SDs and Table 3 shows ANCOVA results.

**Table 2.** Means and SDs of outcome variables at baseline (T1), 7 weeks (T2), and 6 months (T3) after the intervention.

| Outcome | T1 | | T2[a] | | T3[a] | |
|---|---|---|---|---|---|---|
| | IG[b] | WLC[c] | IG | WLC | IG | WLC |
| **Primary outcome measure** | | | | | | |
| Perceived stress | 23.76 (5.11) | 24.81 (5.03) | 18.33 (6.18) | 23.33 (5.32) | 17.53 (6.42) | 21.72 (6.39) |
| Perceived stress (per-protocol analysis) | 23.89 (5.63) | 24.79 (5.04) | 17.5 (6.14) | 23.29 (5.32) | 18 (6.97) | 21.68 (6.39) |
| **Secondary outcome measures** | | | | | | |
| Mental health and work related | | | | | | |
| Quality of life | 0.58 (0.15) | 0.55 (0.13) | N/A[d] | N/A | 0.68 (0.17) | 0.57 (0.17) |
| Depression | 17.05 (6.09) | 18.05 (6.43) | 13.68 (7.41) | 15.76 (7.43) | 11.56 (6.74) | 14.8 (8.46) |
| Resilience | 20.12 (6.67) | 20.29 (6.37) | 22.5 (6.08) | 19.38 (6.12) | N/A | N/A |
| Emotional exhaustion | 4.57 (0.78) | 4.62 (0.73) | 4.05 (0.89) | 4.52 (0.81) | 3.87 (0.94) | 4.42 (0.95) |
| Occupational self-efficacy | 22.06 (6.14) | 21.58 (6.24) | 24.38 (5.41) | 22.2 (6.08) | N/A | N/A |
| Work engagement (vigor) | 2.95 (1.21) | 2.99 (1.18) | 3.06 (1.17) | 2.72 (1.15) | 3.1 (1.18) | 2.75 (1.21) |
| Work engagement (dedication) | 3.31 (1.3) | 3.28 (1.37) | 3.36 (1.17) | 2.98 (1.36) | 3.37 (1.27) | 3.02 (1.3) |
| Work engagement (absorption) | 3.01 (1.39) | 3.01 (1.51) | 3.14 (1.28) | 2.84 (1.38) | 3.14 (1.27) | 2.85 (1.38) |
| Work ability index | 5.92 (1.96) | 5.86 (1.96) | 6.55 (1.88) | 5.83 (2.08) | N/A | N/A |
| Presenteeism | 5.01 (2.25) | 5.27 (2.58) | 4.5 (2.37) | 4.94 (2.39) | N/A | N/A |
| Effort-reward imbalance | | | | | | |
| Efforts | 10.67 (1.42) | 10.5 (1.52) | 10.01 (1.76) | 10.11 (1.76) | 9.72 (1.76) | 9.89 (1.83) |
| Rewards | 16.29 (3.74) | 15.77 (3.86) | 16.69 (3.8) | 15.61 (3.96) | 17.06 (3.62) | 16.03 (3.9) |
| Ratio | 1.62 (0.49) | 1.64 (0.49) | 1.5 (0.55) | 1.62 (0.56) | 1.43 (0.47) | 1.55 (0.54) |

[a]Missing data handled by multiple imputation.

[b]IG: intervention group.

[c]WLC: waitlist control.

[d]N/A: not applicable.

**Table 3.** Between-group differences at 7 weeks (T2) and 6 months (T3) after the intervention.

| Outcomes | T2[a] | | T3[a] | |
|---|---|---|---|---|
| | *d* (95% CI) | ANCOVA[b] ($F_{259,1}$) | *d* (95% CI) | ANCOVA ($F_{259,1}$) |
| **Primary outcome measure** | | | | |
| Perceived stress | 0.87 (0.61 to 1.12) | 46.14[c] | 0.65 (0.41 to 0.90) | 24.82[c] |
| Perceived stress (per-protocol analysis)[d] | 1.04 (0.69 to 1.40) | 34.86[c] | 0.56 (0.22 to 0.90) | 20.15[c] |
| **Secondary outcome measures** | | | | |
| Mental health and work related | | | | |
| Quality of life[e] | N/A[f] | N/A | 0.65 (0.37 to 0.93) | 14.44[c] |
| Depression | 0.28 (–0.04 to 0.52) | 3.55 | 0.42 (0.18 to 0.67) | 9.99[g] |
| Resilience | N/A | N/A | 0.51 (0.26 to 0.76) | 31.72[c] |
| Emotional exhaustion | 0.56 (0.31 to 0.80) | 25.36[c] | 0.59 (0.34 to 0.83) | 25.79[c] |
| Occupational self-efficacy | 0.38 (0.13 to 0.62) | 10.65[g] | N/A | N/A |
| Work engagement (vigor) | 0.29 (0.05 to 0.53) | 9.30[g] | 0.29 (0.05 to 0.53) | 7.61[g] |
| Work engagement (dedication) | 0.30 (0.06 to 0.54) | 8.71[g] | 0.27 (0.03 to 0.52) | 6.22[h] |
| Work engagement (absorption) | 0.41 (0.66 to 0.17) | 5.80[h] | 0.22 (0.03 to 0.46) | 3.97[h] |
| Presenteeism | 0.18 (–0.06 to 0.43) | 1.61 | N/A | N/A |
| Work ability index | 0.36 (0.12 to 0.60) | 9.19[g] | N/A | N/A |
| Effort-reward imbalance | | | | |
| Efforts | 0.05 (–0.19 to 0.30) | 1.72 | 0.09 (–0.15 to 0.34) | 1.87 |
| Rewards | 0.28 (0.04 to 0.52) | 4.42[h] | 0.27 (–0.03 to 0.52) | 3.72 |
| Ratio | 0.22 (0.03 to 0.50) | 4.21[h] | 0.24 (0.01 to 0.48) | 4.07[h] |

[a]Missing data handled by multiple imputation.

[b]ANCOVA: analysis of covariance

[c]Significance level used: P<.001.

[d]$F_{173,2}$.

[e]$F_{200,1}$.

[f]N/A: not applicable.

[g]Significance level used: P<.01.

[h]Significance level used: P<.05.

## Response Analyses

At T2, significantly more participants in the IG (65/130, 50%) showed a reliable improvement in perceived stress measured with the PSS-10 compared with the WLC group (33/132, 25%) and significantly fewer participants in the IG (4/130, 3.1%) experienced symptom deterioration compared with the WLC group (14/132, 10.6%; $\chi^2_2$=19.94, P<.001). The number needed to treat to achieve reliable improvement was 4 (95% CI 2.8-7.3). The number of symptom-free participants at T2 was significantly higher in the IG (39/130, 30%) compared with the WLC group (7/132, 5.3%; $\chi^2_1$=23.52, P<.001).

## Secondary Outcome Measures

The ANCOVAs showed significant between-group differences for most secondary outcome measures (Table 3). Positive impacts for participants in the IG compared with the WLC group were found at T2 and T3 for occupational self-efficacy (measured with the OSS-SF), burnout (assessed with the MBI-GS-D), work engagement (assessed with the UWES), and work ability (Work Ability Index). Effect sizes (*d*) ranged from 0.29 (95% CI 0.05-0.53; UWES scale vigor) to 0.56 (95% CI 0.31-0.80; MBI-GS-D) at T2 and from 0.22 (95% CI 0.03-0.46; UWES scale absorption) to 0.65 (95% CI 0.37-0.93; AQoL) at T3. Scores between groups did not significantly differ for depression (CES-D; *d*=0.28, 95% CI –0.04 to 0.52, P=.06) and work limitations (Work Limitations Questionnaire; *d*=0.18, 95% CI –0.06 to 0.43, P=.21) at T2. Regarding the effort-reward imbalance, participants in the IG showed significantly higher values for rewards at T2 (*d*=0.28, 95% CI 0.04-0.52, P=.04), whereas between-group scores did not significantly differ for efforts at T2 (*d*=0.05, 95% CI –0.19 to 0.30, P=.19) and T3

($d$=0.09, 95% CI –0.15 to 0.34, P=.17), and for rewards at T3 ($d$=0.27, 95% CI –0.03 to 0.52, P=.06).

### Mediation Analyses

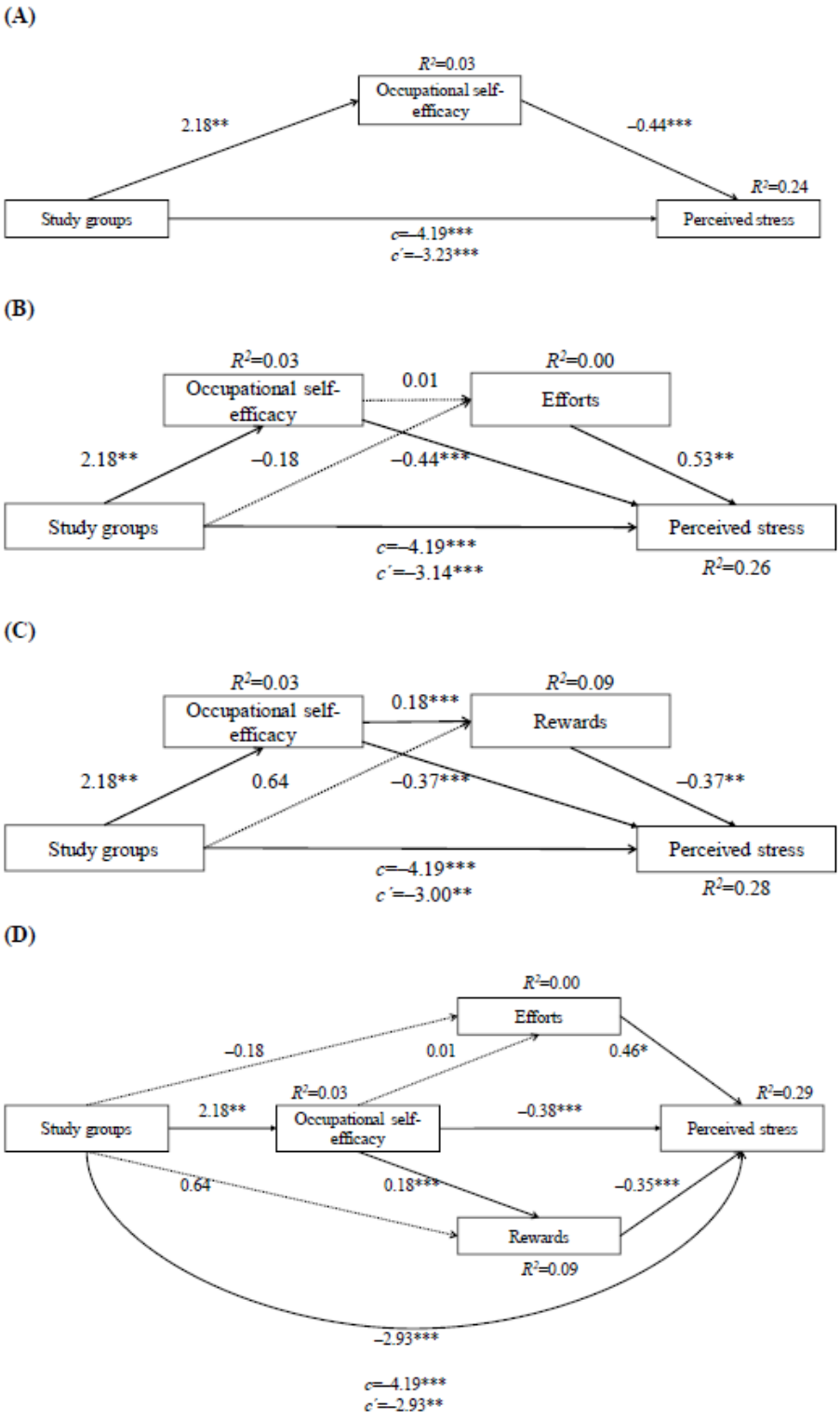
Figure 2 depicts the 4 mediation analyses performed. Results of the first model (Figure 2A) showed that the unstandardized regression coefficient for the study groups (X) predicting stress (Y) was significant ($c$=–4.19, $t_{260}$=–5.29, P<.001). Occupational self-efficacy (M) was found to be a significant mediator for this effect ($b$=–0.44, $t_{258}$=–6.87, P<.001). Furthermore, the study group had a significant effect on occupational self-efficacy ($b$=2.18, $t_{260}$=3.06, P<.002). The direct effect remained significant after incorporating the mediating variable into the model ($c'$=–3.23, $t_{260}$=–4.36, P<.001). The indirect effect was significant ($b$=0.95, 95% CI –1.73 to –0.32, P<.001). This model accounted for 24% of the variance ($R^2$) in stress reduction.

The second mediation model (Figure 2B) with occupational self-efficacy as $M_1$ and efforts as $M_2$ revealed significant total ($c$=–4.19, $t_{260}$=–5.29, P<.001) and direct ($c'$=–3.14, $t_{260}$=–4.36, P<.001) effects. Occupational self-efficacy ($M_1$) significantly mediated the effect on stress ($b$=–0.44, $t_{258}$=–6.59, P<.001), whereas it had no significant effect on efforts ($M_2$; $b$=0.01, $t_{259}$=0.27, P=.79). However, efforts ($M_2$) were significantly associated with stress ($b$=0.53, $t_{258}$=2.64, P=.008). The study group had no significant effect on efforts ($M_2$; $b$=–0.18, $t_{258}$=–0.79, P=.43). Therefore, a significant indirect mediating effect was only found for the association of occupational self-efficacy with the study group ($b$=–0.14, 95% CI –0.25 to –0.05, P<.001). Together, 26% of the variance ($R^2$) in perceived stress was explained.

After incorporating occupational self-efficacy as $M_1$ and rewards as $M_2$, the mediation model (Figure 2C) resulted in significant total ($c$=–4.19, $t_{260}$=–5.29, P<.001) and direct ($c'$=–3.00, $t_{260}$=–4.12, P<.001) effects. Occupational self-efficacy ($M_1$) significantly mediated the effect on stress ($b$=–0.37, $t_{258}$=–5.76, P<.001) and rewards ($M_2$; $b$=0.18, $t_{259}$=4.52, P<.001). Rewards ($M_2$) could significantly predict stress ($b$=–0.37, $t_{258}$=–3.79, P<.001). Comparable to the preceding mediation model, a significant indirect mediation effect for the association between the intervention and stress as an outcome could be found for occupational self-efficacy ($b$=–0.12, 95% CI –0.22 to –0.04, P<.001). Furthermore, the indirect path taking occupational self-efficacy ($M_1$) and rewards ($M_2$) between the study group and perceived stress into account was significant ($b$=–0.02, 95% CI –0.05 to –0.01, P<.001). Participation in the intervention did not significantly predict rewards ($M_2$; P=.16). In total, all variables accounted for $R^2$=0.28.

The fourth mediation model (Figure 2D) that incorporated all mediators ($M_1$: occupational self-efficacy, $M_2$: efforts, and $M_3$: rewards) again resulted in significant total ($c$=–4.19, $t_{260}$=–5.29, P<.001) and direct ($c'$=–2.93, $t_{260}$=–4.06, P<.001) effects. Occupational self-efficacy ($M_1$) significantly predicted perceived stress ($b$=–0.38, $t_{257}$=–5.91, P<.001) and rewards ($M_3$) ($b$=0.18, $t_{259}$=4.52, P<.001), yet not efforts ($M_2$; $b$=0.01, $t_{259}$=0.27, P=.79). The effect on stress was also significantly predicted by both efforts ($M_2$; $b$=0.46, $t_{257}$=2.32, P=.02) and rewards ($M_3$; $b$=–0.35, $t_{257}$=–3.56, P<.001). The study group did not significantly predict neither efforts ($M_2$) nor rewards ($M_3$) directly. Altogether, significant indirect paths between the study group and perceived stress were found for occupational self-efficacy ($M_1$; $b$=–0.12, 95% CI –0.22 to –0.04, P<.001) as well as for occupational self-efficacy ($M_1$) and rewards ($M_3$; $b$=–0.02, 95% CI –0.05 to –0.01, P<.001). This final model including all proposed mediators together explained 29% of the variance ($R^2$) in stress reduction. For all models, sensitivity analyses performed including only study completers corroborated the results.

**Figure 2.** Mediation analyses with study condition as independent variable (X) and perceived stress (PSS-10) at T3 as dependent variable (Y) for all models. Proposed mediators: (A) Occupational self-efficacy at T2; (B) Occupational self-efficacy at T2 and efforts at T3; (C) Occupational self-efficacy at T2 and rewards at T3; and (D) Occupational self-efficacy at T2, and efforts and rewards at T3. Study conditions are coded 0=wait list control group, 1=intervention group. The figure includes unstandardized β coefficients and illustrates significant (solid line) and non-significant (dotted line) effects between variables, total (c) and direct (c′) effects. Significance levels used: ***$P$<.001, **$P$<.01, *$P$<.05.




## Discussion

### Principal Findings

Results of this study confirm that the SMI could effectively reduce stress in employees perceiving elevated stress levels and even when they were exposed to a high load of efforts that is not adequately balanced by rewards. Secondary analyses demonstrated the beneficial effects for mental health and work-related outcomes as well as for rewards. Step-by-step mediation analyses revealed that the participation in the intervention significantly predicted occupational self-efficacy,

which describes the confidence of an individual to handle any challenges at work and which was a mediator in the effect on stress and rewards that again predicted stress. All 3 investigated mediators (ie, occupational self-efficacy, efforts, and rewards) were significantly associated with perceived stress. However, neither participation in the SMI nor the increase in occupational self-efficacy enabled employees to achieve favorable effects on the level of efforts, while efforts still enfolded an adverse effect on perceived stress.

The results revealed practically meaningful effect sizes for stress reduction. A similar effect was found in another trial on the same SMI with adherence-focused guidance [45] and our study extend those results by the inclusion of a high-risk population that experiences adverse working conditions. Compared with a study on the same SMI with more intensive guidance [22], the effect sizes were not as large at follow-up. This raises the question as to whether more personal support from a mental health expert, which is expected to be conducive to the efficacy of an SMI [19,22], might aid participants that experience greater difficulties in their stress management due to adverse working conditions. Considering the efficacy of occupational web-based interventions in general, results from this study are in line with demonstrated average effect sizes in a recent meta-analysis [19] and revealed significant improvements in a variety of outcomes on mental health and work-related levels. For example, participants in the IG showed lower levels of emotional exhaustion, more resilience, and higher work engagement, as well as vigor, dedication, and absorption at work. No significant between-group effects were found for presenteeism, while mixed results were obtained for depression. The detected effect sizes for engagement and presenteeism compare with a recent meta-analysis for occupational web-based interventions [63]. Moreover, the participation significantly increased occupational self-efficacy that was shown to be a relevant mediator in the efficacy of the SMI on stress reduction. These results support findings of another RCT on the same SMI showing significant effects on occupational self-efficacy [34] and positive associations between stress levels and self-efficacy [30]. The obtained results for the effort-reward imbalance tie well with mixed effects found in studies on the same SMI for the effort-reward imbalance ratio [34] and for efforts and rewards evaluated as separate outcomes [45], demonstrating that web-based SMIs enfold substantially larger effects on individuals' health compared with perceived working conditions and organizational characteristics [17].

To examine whether and how an increase in personal resources could support participants in achieving successful stress reduction despite facing adverse working conditions, mediating effects were investigated not only for occupational self-efficacy, but also for efforts and rewards of the workplace. The 4 mediation analyses conducted progressively accounted for the variance in perceived stress. The first model (Figure 2A) confirmed that the participation in the intervention successfully increased occupational self-efficacy, which in turn had a significant effect on stress reduction. This is in line with evidence showing that higher levels of self-efficacy are associated with lower levels of work stress and the assumption that problem-solving skills increase the confidence of an individual to be able to proactively reduce stressors and increase rewarding situations [30]. The second mediation model (Figure 2B) showed that the intervention's positive effect on occupational self-efficacy did not affect efforts that were negatively associated with stress. This is in line with another SMI study on teachers which showed that participants could influence rewards, yet not efforts [64]. One potential reason for the lack of association could be the design of the intervention that did not predefine the topics participants should reflect on in the problem-solving exercises and if the focus was on job-related or personal stressors. Furthermore, this portrays one of the core premises of the effort-reward imbalance model [6], that is, an increased degree of efforts necessary to spend at work is associated with high strain. The third mediation analysis (Figure 2C) revealed a significant relationship between participation in the SMI, occupational self-efficacy, and rewards. This is in line with evidence showing that occupational self-efficacy is substantially associated with affective commitment that might motivate employees to increase their job resources within their company [65]. Comparable to the precedent mediation model, rewards were significantly associated with stress, which is in line with the effort-reward imbalance model [6]. The final mediation analysis (Figure 2D) incorporated the 3 models. Occupational self-efficacy was significantly increased and a mediator in the relationship between the study group and outcome. Although both efforts and rewards predicted levels of stress, the intervention only had an impact on rewards, but not on efforts, with occupational self-efficacy seemingly playing a mediating role in this association. However, both efforts and rewards had significant effects on stress.

## Limitations

Several limitations should be considered. Despite the positive effects of the individual-focused intervention on employees' mental health, the persisting adverse effects of efforts indicate that this approach might be incomplete. Therefore, it should be investigated whether a combination of individual- and organizational-focused digital interventions will contribute to more comprehensive effects on employees' mental health [66]. Positive effects of occupational self-efficacy in individual-focused interventions might help employees to engage more confidently in organizational-focused interventions. Furthermore, the generalizability of the results might be limited. In contrast to recruitment on a company level, the applied open recruitment strategy addressed participants directly, which was shown to be associated with effects on personal health outcomes for occupational SMIs [19]. In this study, participants in the IG received adherence-focused guidance that was established and shown to be effective in previous studies [45,67]. Given the notion that guidance is supposed to be conducive to the efficacy of SMIs [19,68] and its low intensity in the adherence-focused format, further research could investigate whether a higher intensity in guidance might facilitate the efficacy of the SMI for participants that experience greater difficulties for successful changes due to adverse workplace conditions. Concerning the mediators, a methodological limitation might be the selection of measures in this study because participants might have been encouraged to make changes to aspects of their work that were

not captured in this trial (eg, conflict between work and private life) [69]. Despite this, this trial provides valuable first insights into if and how a web-based SMI can be effective within a high-risk population despite their exposure to adverse working conditions.

### Conclusion and Practical Implications

To conclude, this trial aimed to expand research on the efficacy of web-based SMIs and to add valuable insights into the scarce evidence for high-risk populations. To the best of our knowledge, this is the first trial demonstrating positive effects of a web-based SMI on stress reduction in employees despite their adverse working conditions. In-depth analyses examining mechanisms of change suggest that the SMI increased occupational self-efficacy that mediated the intervention's effect on stress. Furthermore, both efforts and rewards predicted levels of stress, yet the intervention only had an impact on rewards, with occupational self-efficacy seemingly playing a mediating role in this association. It seems vital to note that this web-based intervention could improve health at work within a short period and without any direct changes to working conditions. Further medium- and long-term improvements would be possible if complex organizational interventions were introduced to reduce stressors in the workplace. For practice, these results have several implications. First, the implementation of the web-based SMI can be recommended due to its beneficial health effects even if employees experience adverse working conditions. Second, occupational self-efficacy should be considered as an important concept in the design of an SMI. Third, the limited effects of the SMI on the perception of working conditions underline that organizational top-down changes are still indispensable. Future studies could further investigate which factors contribute to the efficacy of a person-centered intervention on working conditions and examine, for example, the role of guidance.

## Acknowledgments

The German health care insurance company BARMER and the European Commission funded this study (EFRE: ZW6-80119999, CCI 2007DE161PR001).

## Conflicts of Interest

DDE is a stakeholder in the Institute for Online Health Training that aims to transfer scientific knowledge related to this research into routine health care.

## Multimedia Appendix 1

CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1220 KB-Multimedia Appendix 1]

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## Abbreviations

**ANCOVA:** analysis of covariance
**AQoL:** Assessment of Quality of Life 8D Multi-Attribute Utility Instrument
**CES-D:** Centre for Epidemiological Studies' Depression Scale
**CONSORT:** Consolidated Standards of Reporting Trials
**IG:** intervention group
**MBI-GS-D:** Maslach Burnout Inventory
**N/A:** not applicable
**OSS-SF:** short form of the Occupational Self-Efficacy Scale
**PSS-10:** 10-item Perceived Stress Scale
**RCT:** randomized controlled trial
**SMI:** stress management intervention
**UWES:** Utrecht Work Engagement Scale
**WLC:** waitlist control

**WLQ:** Work Limitations Questionnaire

*Edited by T Leung; submitted 23.06.22; peer-reviewed by E Stratton; comments to author 21.07.22; revised version received 11.08.22; accepted 24.08.22; published 20.10.22*

*Please cite as:*
*Nixon P, Ebert DD, Boß L, Angerer P, Dragano N, Lehr D*
*The Efficacy of a Web-Based Stress Management Intervention for Employees Experiencing Adverse Working Conditions and Occupational Self-efficacy as a Mediator: Randomized Controlled Trial*
*J Med Internet Res 2022;24(10):e40488*
*URL: https://www.jmir.org/2022/10/e40488*
*doi: 10.2196/40488*
*PMID:*

### 2.6 Introduction to Study 3

Compelling evidence suggests that a digital SMI can serve as an indirect intervention to sustainably reduce depression. However, a systematic evaluation of such potential effects has not yet been conducted. For this reason, the sixth research question of this dissertation aims to answer:

**Research Question 6: Is a digital stress management intervention effective in reducing depressive symptom severity in employees with clinically relevant depression?**

Existing evidence indicates that guided digital interventions may be superior to self-help formats in terms of efficacy and participant satisfaction. While initial studies have shown positive effects of digital SMIs on depression, potential differences in the efficacy of various guidance formats have not been fully explored. Consequently, the seventh research question of this dissertation addresses:

**Research Question 7: Does the efficacy of a digital stress management intervention in reducing depressive symptom severity differ between full guidance, adherence-focused guidance, and self-help?**

## 2.7 Study 3: Indirect Treatment: Efficacy of a Digital Stress Management Intervention for Depression

Harrer, M., Nixon, P., Sprenger, A. A., Heber, E., Boß, L., Heckendorf, H., Buntrock, C., Ebert, D. D., Lehr, D. (2024). Are web-based stress management interventions effective as an indirect treatment for depression? An individual participant data meta-analysis of six randomised trials. *BMJ Mental Health*, 27: 1-8.

doi: 10.1136/bmjment-2023-300846.

Submitted: 29th July 2023

Accepted: 15th November 2023

Published: 13th February 2024

BMJ Mental Health

# Are web-based stress management interventions effective as an indirect treatment for depression? An individual participant data meta-analysis of six randomised trials

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► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bmjment-2023-300846).

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Received 29 July 2023
Accepted 15 November 2023



**To cite:** Harrer M, Nixon P, Sprenger AA, *et al*. *BMJ Ment Health* 2024;**27**:1–8.

## ABSTRACT

**Question** Depression is highly prevalent and associated with numerous adverse consequences for both individuals and society. Due to low uptake of direct treatment, interventions that target related, but less stigmatising problems, such as perceived stress, have emerged as a new research paradigm. This individual participant data (IPD) meta-analysis examines if a web-based stress management intervention can be used as an 'indirect' treatment of depression.

**Study selection and analysis** Bayesian one-stage models were used to estimate pooled effects on depressive symptom severity, minimally important improvement and reliable deterioration. The dose–response relationship was examined using multilevel additive models, and IPD network meta-analysis was employed to estimate the effect of guidance.

**Findings** In total, N=1235 patients suffering from clinical-level depression from K=6 randomised trials were included. Moderate-to-large effects were found on depressive symptom severity at 7 weeks post-intervention (d=−0.65; 95% credibility interval (CrI): −0.84 to −0.48) as measured with the Center for Epidemiological Studies' Depression Scale. Effects were sustained at 3-month follow-up (d=−0.74; 95% CrI: −1.01 to −0.48). Post-intervention symptom severity was linearly related to the number of completed sessions. The incremental impact of guidance was estimated at d=−0.25 (95% CrI: −1.30 to 0.82), with a 35% posterior probability that guided and unguided formats produce equivalent effects.

**Conclusions** Our results indicate that web-based stress management can serve as an indirect treatment, yielding effects comparable with direct interventions for depression. Further research is needed to determine if such formats can indeed increase the utilisation of evidence-based treatment, and to corroborate the favourable effects for human guidance.

**Study registration** Open material repository: osf.io/dbjc8, osf.io/3qtbe.

**Trial registration number** German Clinical Trial Registration (DRKS): DRKS00004749, DRKS00005112, DRKS00005384, DRKS00005687, DRKS00005699, DRKS00005990.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Web-based interventions have been shown to be effective in treating depression, but uptake rates remain low. This individual participant data meta-analysis explores the potential of a novel paradigm, in which web-based stress management is used as a low-threshold, 'indirect' treatment for depression.

### WHAT THIS STUDY ADDS

⇒ In this first systematic examination of web-based stress management as an indirect intervention for depression, we collected data from K=6 randomised trials with N=1235 patients suffering from clinically relevant symptoms of depression (Center for Epidemiological Studies' Depression Scale ≥20; M=28.57). We found clinically relevant and sustained reductions in depressive symptom severity. Completing more sessions and providing guidance enhanced the anti-depressive effect.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Large-scale provision of web-based stress management interventions might be an innovative, low-threshold approach to reduce the burden of depression in the general population.

## BACKGROUND

Depression is highly prevalent, a leading cause of years lived with disability and poses a challenge for healthcare services worldwide.[1] Only a fraction of affected individuals receive any help at all, and mostly not even minimally adequate treatment.[2] Besides structural barriers, attitudinal factors play a major role in explaining this treatment gap for depression.[3] Fear of stigmatisation has repeatedly been suggested as a major barrier to help-seeking,[4] and suffering from depression appears to further increase the magnitude of this barrier.[5]

Delivering mental health interventions over the internet has been argued to have numerous advantages.[6] Web-based interventions allow for an easy

and low-threshold dissemination of evidence-based interventions on a large scale and at low costs. They can be used regardless of time and location[6] and may overcome barriers associated with fear of stigmatisation due to the perceived anonymity of the internet.[7] Further research has been called for to examine the effectiveness of such interventions aimed at the physical and mental health of patients with mental illness, and to promote their real-world implementation.[8 9]

Meta-analyses demonstrate the efficacy of web-based interventions targeting depression,[10] but the uptake of such interventions is often low.[11 12] Preliminary evidence suggests that fear of stigmatisation might also be a major barrier to depression treatment for web-based formats.[13]

A novel paradigm was introduced by Cuijpers to address this problem, proposing an 'indirect' prevention and treatment of depression.[14] Indirect interventions do not focus on depression itself, but on related risk or aggravating factors that might be better aligned with patients' perceived needs or preferences.

Stress management was suggested as a promising method for the indirect treatment of depression.[14] Compared with direct or transdiagnostic treatments, stress management interventions (SMIs) do not specifically focus on characteristic symptoms of clinical diagnoses. Instead, they target perceived stressors that a person feels exposed to, with the goal to minimise them or their negative emotional impact.[15] Although the exact implementation differs, many web-based SMIs implement problem-solving, as well as reappraisal and relaxation techniques for stressors that cannot be directly removed.[16] Stress and depression are closely interlinked,[17] and engaging in web-based stress management might be easier for some patients with depression, avoiding potential stigma associated with the label 'depression'. Previous studies suggest that the 'framing' of therapeutic contents is a crucial and under-rated factor in the dissemination of digital interventions.[18 19]

There is evidence that web-based SMIs may also alleviate depressive symptoms when evaluated as a secondary outcome. First, several meta-analyses demonstrated the efficacy of web-based SMIs on depressive symptoms in general[20] and working[21] populations. Second, stress reduction was identified as a mechanism of change in the prevention of depressive symptoms using web-based SMIs.[22] Third, a moderator study of a web-based SMI found that participants with high stress and depression at baseline showed greater reductions in depressive symptoms over time than those with lower symptoms.[23] Lastly, since the majority of participants were first-time help seekers, this suggests SMIs might be appealing to those who otherwise might not seek help.[24]

## OBJECTIVE

While positive evidence is accumulating, no meta-analysis has yet systematically examined the potential of web-based SMIs as an indirect treatment for depression. This individual participant data (IPD) meta-analysis allows for more sophisticated types of analyses, based on randomised controlled trials (RCTs) evaluating the web-based SMI 'GET.ON Fit im Stress'.[25] We test if (1) participants with clinically relevant depressive symptoms show lower levels of depressive symptom severity at post-intervention and 6-month follow-up, compared with control; (2) if rates of patients with minimal clinically important improvement of depressive symptoms are higher, and rates of reliable symptom deterioration are lower; and (3) if a dose–response relationship can be found between the completed SMI modules and effects on depressive symptoms. IPD network meta-analysis is used to explore the effect of human guidance. Additionally, we examine the overall satisfaction with the intervention.

## METHODS

The present study has been preregistered (osf.io/wa4h5). The code used for the analyses is openly available (osf.io/p3q6t). All analyses were implemented using R V.4.2.0. Where applicable, we resort to elements of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-IPD statement.[26]

### Eligibility criteria

We included (1) RCTs in which (2) the effect of the web-based SMI 'GET.ON Fit im Stress'[25] was compared with (3) an inactive control group (waitlist, care as usual or combinations thereof) at (4) post-test (7 weeks) and 6-month follow-up. A detailed description of the eligible programme is provided in the online supplemental file 2. Since we aimed to analyse effects of the web-based SMI as an indirect treatment for depression, (5) analyses were restricted to patients with a Center for Epidemiological Studies' Depression Scale (CES-D) score ≥20 at baseline, indicating clinically relevant symptoms of depression.[27] We focused on one specific programme because contents of web-based SMIs vary between interventions.[16] Standardised treatments across all trials were assumed to enhance the internal validity of our analyses, especially those concerning the dose–response relationship and effect of guidance.

### Identification and selection of studies

Three authors (DL, EH, DDE) contributed to the development of the web-based SMI examined in this IPD meta-analysis. The intervention is not openly accessible, and it cannot be employed for research or commercial purposes without explicit permission by the copyright holder Leuphana University (represented by DL). Instead of a systematic search, the number of trials was therefore assumed to be known, and the involved researchers were consulted to identify eligible studies. Once permission was granted to create an adapted intervention for college students ('StudiCare Stress'), whereby substantial changes were made to the contents and presentation (see online supplemental file 2). Evaluations of this new intervention were therefore not considered. Principal investigators of eligible trials were then contacted to obtain the IPD.

### Data harmonisation and variable selection

Data of the included studies were harmonised to allow for joint analyses. Depressive symptom severity measures were extracted at baseline (T1), 7 weeks post-test (T2) and 3-month follow-up (T3) from each study, as well as sociodemographic information and putative prognostic variables. In all trials, the CES-D was used to measure depressive symptom severity. Following our protocol, for all assessment points, these scores were transformed into a common metric using the generalised partial credit model by Wahl *et al*.[28] This common metric is standardised to have a population mean of $\theta=50$, as well as a population SD of $\sigma=10$. All studies employed the same intervention, but with various degrees of human guidance. We coded a study's guidance concept as 'full guidance' if human assistance was provided after each module, as 'adherence-focused guidance'[21] if human feedback was available on demand and as 'unguided' otherwise.

### Risk of bias assessment

Risk of bias assessment was conducted using the revised Cochrane Risk of Bias tool.[29] To minimise allegiance biases, the assessment

was conducted by trained personnel not otherwise involved in this study or any of the included trials (see the Acknowledgements section). Disagreements were resolved through discussion.

### Missing data handling

All analyses were conducted according to the intention-to-treat principle. Two missing data handling approaches were used. For the main one-stage IPD meta-analysis, we used a Bayesian model-based imputation approach. This method jointly imputes missing values and estimates model parameters, thus ensuring compatibility with the substantive analysis model.[30] Potentially prognostic baseline variables were added as covariates, as well as an interaction between initial depressive symptom severity and treatment effects.

For the two-stage, dose–response relationship and network IPD model, missing values were imputed using the multivariate imputation by chained equations algorithm (m=100 sets; groupwise multilevel imputation model with individual and cluster-level effects). Due to the relatively small number of trials, a maximum penalised likelihood-based approach was used to estimate the heterogeneity variances $\tau^2$.[31] Parameters were pooled by combining the posterior draws of all models fitted in the multiply imputed data. The imputation matrix and trace line plots are depicted in the online supplemental files 3 and 4.

### Outcome measures

The primary outcome was depressive symptom severity at 7 weeks post-test (T2), based on the common metric scores derived from the CES-D values in each trial. Additionally, we examined meta-analytical effects on (1) depressive symptom severity at 3-month follow-up (T3; common metric), (2) minimally important improvement of depressive symptoms (post-test and follow-up) and (3) reliable deterioration of depressive symptoms (post-test and follow-up). Minimally important improvement was defined as a decrease of ≥10.1 points on the CES-D, compared with baseline. This threshold was derived from the cut-off value established in Ohno *et al*,[32] who used an anchor-based approach based on the Patient Global Impression of Change. Reliable deterioration was determined using the reliable change index,[33] corresponding with an increase of >8.99 points on the CES-D.

### Statistical analyses

*Average treatment effect (IPD meta-analysis)*. The pooled effect of the intervention was calculated using one-stage IPD meta-analysis. Meta-analytical models were implemented in a Bayesian framework using Gibbs sampling (JAGS V.4.3.0). The model included putative prognostic factors of post-test depression as predictors (baseline depressive symptom severity, perceived stress, age and sex) and terms to capture varying treatment effects conditional on the depressive symptom severity at baseline. The treatment effect size (ie, Cohen's d) was calculated by dividing the estimated between-group mean difference at the analysed endpoint by the pooled SD of the outcome. Dichotomous outcomes (minimally important improvement, reliable deterioration) were modelled using a binomial logit-link. Priors for model parameters had been determined beforehand (see 'statistical models' in the preregistration); a weakly informative Half-Cauchy $HC\left(0,5\right)$ prior was selected to estimate the heterogeneity variance $\tau^2$. A more detailed model specification is provided in online supplemental file 5 (equations 1 and 2). As a sensitivity analysis, we (1) also estimated effects using Bayesian two-stage models, (2) reran all analyses using a less heavy-tailed $HC\left(0,3\right)$ prior and (3) estimated effects on minimally important change when defined as a one-third reduction in CES-D scores. The one-third reduction criterion was used as approximation of a 9-point decrease on the 15-item CES-D, a reference value recently put forward by German national guidelines to define minimal clinically important differences.[34]

*Dose–response relationship*. To explore the (potentially non-linear) relationship between post-test depression and the number of completed sessions, Bayesian generalised additive mixed models (GAMMs) were employed in the intervention groups. First, we fitted one overall GAMM using all participants, followed by a separate model for respondents (ie, patients showing minimally important improvement at post-test) and non-respondents. Online supplemental file 5 presents a detailed model specification (equation 3).

*Effect of guidance (IPD network meta-analysis)*. To estimate differences in effects between the three guidance formats, an IPD network meta-analysis was conducted. In this model, the guided, adherence-focused and unguided intervention formats were treated as distinct treatments. We also estimated the posterior probability $P\left(\left|\delta_{ung,gui}\right| < MID \mid X\right)$ that the effect of (full) guidance does not exceed a minimally important difference (MID) of d=0.24 (ie, the probability that effects of both formats are practically equivalent from a patient perspective[35]). The same posterior probability $P\left(\left|\delta_{ung,afg}\right| < MID \mid X\right)$ was also calculated for adherence-focused guidance. The model specification is described in online supplemental file 5 (equations 4 and 5).

*User satisfaction*. A pooled analysis of intervention group participants' satisfaction with the intervention was conducted. We analysed individuals' agreement with items of the Client Satisfaction Questionnaire-8, which was administered in all trials at post-test. Descriptive statistics were calculated separately for the unguided versus guided intervention format and for both formats combined.

## Findings

The harmonised dataset contained records of N=1852 individuals, 617 (33.3%) of which reported CES-D scores <20. After excluding these individuals, data of N=1235 patients (intervention: n=661; control: n=574) examined in K=6 trials remained for further analyses. In all trials, the same version of the intervention was used, and control conditions were all waitlists with full access to treatment as usual. Table 1 presents descriptive information about each included trial. The risk of bias ratings for each study can be found in online supplemental file 6. Baseline sample characteristics across all trials are displayed in table 2. Means and SDs of the primary outcome at all assessment points, expressed as the common metric and CES-D scores, are provided in online supplemental file 8.

### Treatment effect

Table 3 shows results of the one-stage IPD meta-analysis. The pooled effect on depressive symptom severity at post-test was d=−0.65 (95% credibility interval (CrI): −0.84 to −0.48; number needed to treat (NNT)=7.19). The between-study heterogeneity was moderate ($\tau$=0.11; 95% CrI: 0 to 0.33). The 95% prediction interval (PI) did not include zero (95% PI: −1.06 to −0.30), pointing to the robustness of the effect in future studies. A forest plot of the analysis is depicted in figure 1. Similar findings emerged in sensitivity analyses using a two-stage pooling model (see online supplemental file 9), and when using

**Table 1** Descriptive summary of the included primary studies

| Study | Inclusion (cut-off) | Conditions | $n_{condition}$ | Primary outcome measure | Guidance | Intervention adherence* | Study dropout | | Assessments (weeks) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Post-test | FU | |
| Ebert, 2016a | PSS-10 ≥22 | GET.ON Fit im Stress | 132 | Perceived stress, 7 weeks (PSS-10) | Guided (AFG) | 79.2% | 15.2% | 26.5% | 7, 24 |
| | | Waitlist+TAU | 131 | | – | – | 3.0% | 7.6% | |
| Ebert, 2016b | PSS-10 ≥22 | GET.ON Fit im Stress | 131 | Perceived stress, 7 weeks (PSS-10) | Unguided | 63.4% | 9.8% | 1.52% | 7, 24 |
| | | Waitlist+TAU | 132 | | – | – | 17.4% | 2.27% | |
| Ebert, 2021 | None | GET.ON Fit im Stress | 198 | Perceived stress, 7 weeks (PSS-10) | Unguided | 70.3% | 11.1% | 5.6% | 7, 24 |
| | | Waitlist+TAU | 198 | | – | – | 32.3% | 9.6% | |
| Heber, 2016 | PSS-10 ≥22 | GET.ON Fit im Stress | 132 | Perceived stress, 7 weeks (PSS-10) | Guided (FG) | 81.6% | 12.1% | 3.8% | 7, 24, 52 (intervention only) |
| | | Waitlist+TAU | 132 | | – | – | 12.9% | 8.3% | |
| Nixon, 2021 | PSS-10 ≥22 | GET.ON Fit im Stress | 135 | Perceived stress, 7 weeks (PSS-10) | Guided (AFG) | 80.6% | 8.9% | 21.5% | 7, 24 |
| | | GET.ON Fit im Stress | 134 | | Unguided | 77.3% | 5.2% | 16.4% | |
| | | Waitlist+TAU | 135 | | – | – | 2.2% | 11.1% | |
| Nixon, 2022 | ERI >0.715, PSS-10 ≥22 | GET.ON Fit im Stress | 130 | Perceived stress, 7 weeks (PSS-10) | Guided (AFG) | 74.4% | 9.0% | 22.0% | 7, 24 |
| | | Waitlist+TAU | 132 | | – | – | 2.3% | 12.6% | |

References of the included studies are provided in online supplemental file 7.
*Defined as number of completed sessions/total number of sessions.
AFG, adherence-focused guidance; ERI, Effort-Reward Imbalance Questionnaire; FG, full guidance; FU, follow-up; PSS-10, Perceived Stress Scale; TAU, treatment as usual.

a less heavy-tailed $HC(0, 3)$ prior for $\tau$ (see online supplemental tables 10 and 11).

We also detected a pooled effect on minimally important improvement in depressive symptom severity, with an OR of 4.85 (95% CrI: 2.89 to 7.45). This equals an NNT of 2.82 and means that approximately 3 patients need to receive the intervention to achieve an additional case of minimally important improvement. Similar results were obtained when minimally important change was defined as a one-third symptom reduction on the CES-D (see online supplemental 12). In the one-stage model, the intervention was also found to reduce the number of participants experiencing reliable symptom deterioration (OR=0.19; 95% CrI: 0 to 0.75), with an NNT of 18.07. However, no effect on reliable deterioration was found using the two-stage approach (OR=0.43; 95% CrI: 0 to 1.52). Raw count data and non-adjusted (marginal) ORs are presented in online supplemental tables 13 and 14. Overall, n=19 (2.87%) participants in the intervention group experienced reliable symptom deterioration (follow-up: n=14; 2.12%), compared with n=38 (6.62%) in the control group (follow-up: n=48; 8.36%).

**Table 2** Participant characteristics at baseline

| Characteristic | Overall (N=1235) | Control (N=574) | Intervention (N=661) |
|---|---|---|---|
| Sociodemographics | | | |
| Age, M (SD) | 42.46 (9.82) | 42.43 (10.04) | 42.49 (9.63) |
| Gender, female, n (%) | 936 (75.79) | 431 (73.34) | 505 (76.40) |
| Gender, other, n (%) | 3 (0.24) | 2 (0.35) | 1 (0.15) |
| Income, low, n (%) | 705 (57.09) | 333 (58.01) | 372 (56.28) |
| Ethnicity, non-white, n (%) | 216 (17.49) | 94 (16.38) | 122 (18.46) |
| Children, yes, n (%) | 636 (51.50) | 301 (52.44) | 335 (50.68) |
| Working years, M (SD) | 17.95 (10.57) | 18.15 (10.89) | 17.78 (10.29) |
| Training experience, yes, n (%) | 171 (13.85) | 89 (15.51) | 82 (12.41) |
| Psychotherapy experience, yes, n (%) | 568 (45.99) | 269 (46.86) | 299 (45.23) |
| Marital status | | | |
| Single, n (%) | 376 (30.45) | 179 (31.18) | 196 (29.65) |
| Relationship/married, n (%) | 702 (56.84) | 311 (54.18) | 391 (59.15) |
| Divorced/separated/widowed, n (%) | 157 (12.71) | 84 (14.63) | 73 (11.04) |
| Educational level | | | |
| Up to high school (7–9 years), n (%) | 166 (13.44) | 87 (15.16) | 79 (11.95) |
| High school education (12–13 years), n (%) | 360 (29.15) | 163 (28.57) | 197 (29.80) |
| After high school, n (%) | 708 (57.33) | 323 (56.27) | 385 (58.25) |

**Table 3** Pooled intervention effects on depressive symptom severity, minimally important improvement and reliable deterioration

| | Effect size (95% CrI) | NNT (95% CrI) | τ (95% CrI) |
|---|---|---|---|
| Depressive symptom severity | | | |
| Post-test (d) | −0.65 (−0.84; −0.48) | 7.19 (6.18; 8.93) | 0.11 (0.00; 0.33) |
| Follow-up (d) | −0.74 (−1.01; −0.48) | 5.61 (4.71; 7.67) | 0.21 (0.00; 0.52) |
| Minimally important improvement | | | |
| Post-test (OR) | 4.85 (2.89; 7.45) | 2.82 (2.20; 4.43) | 0.21 (0.00; 0.82) |
| Follow-up (OR) | 4.94 (2.23; 8.50) | 2.67 (2.04; 5.55) | 0.42 (0.00; 1.28) |
| Reliable deterioration | | | |
| Post-test (OR) | 0.19 (0.00; 0.75) | 18.07 (14.52; 62.39) | 1.67 (0.00; 4.64) |
| Follow-up (OR) | 0.09 (0.00; 0.33) | 13.14 (11.91; 18.19) | 1.28 (0.00; 5.39) |

CrI, credibility interval; NNT, number needed to treat.

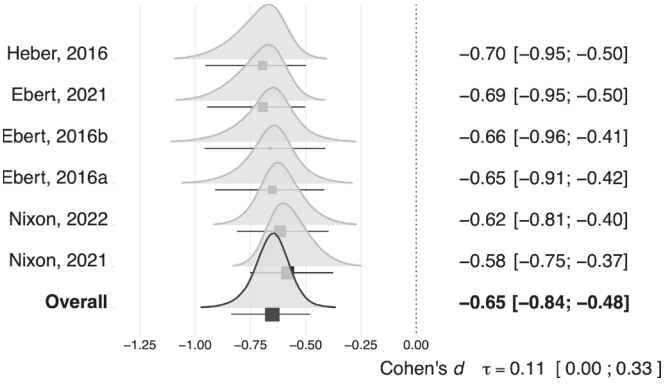


**Figure 1** Forest plot (effects on depressive symptom severity at post-test). Study densities represent the estimated model-based effect, not empirical values of d found in the original studies.

For all analysed outcomes, similar findings emerged at 3-month follow-up. However, effects on depressive symptom severity were slightly higher (d=−0.74; 95% CrI: −1.01 to −0.48; NNT=5.61).

## DOSE–RESPONSE RELATIONSHIP

Estimated smoothing parameters $\lambda$ of the fitted GAMMs can be found in online supplemental file 15. Inspection of the dose–response relationship revealed a roughly linear association between the number of completed sessions and post-test depression scores (see figure 2). A non-linear trend was found in the subset of intervention non-respondents, where no additional benefits were visible after session 4. For the overall model, we compared the fit of our regression spline with a simpler model assuming a linear dose–response relationship. This model proved to be more parsimonious (Deviance Information Criterion=4679 vs 4731). Based on the linear model, each additional completed session was associated with a 0.63-point decrease on the 20-item CES-D at post-test (β=−0.631; 95% CrI: −0.93 to −0.329; $\tau_0$=0.29).

### Effect of guidance

A network graph of the included treatment comparisons is provided in figure 3. Using network IPD meta-analysis, the effect $\delta_{ung,gui}$ between the fully guided and unguided intervention format was estimated at d=−0.25, with a wide 95% CrI that included 0

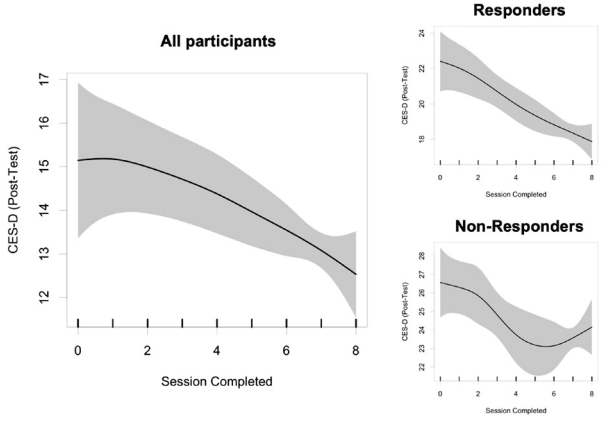


**Figure 2** Dose–response relationship estimated by additive mixed models. CES-D, Center for Epidemiological Studies' Depression Scale.

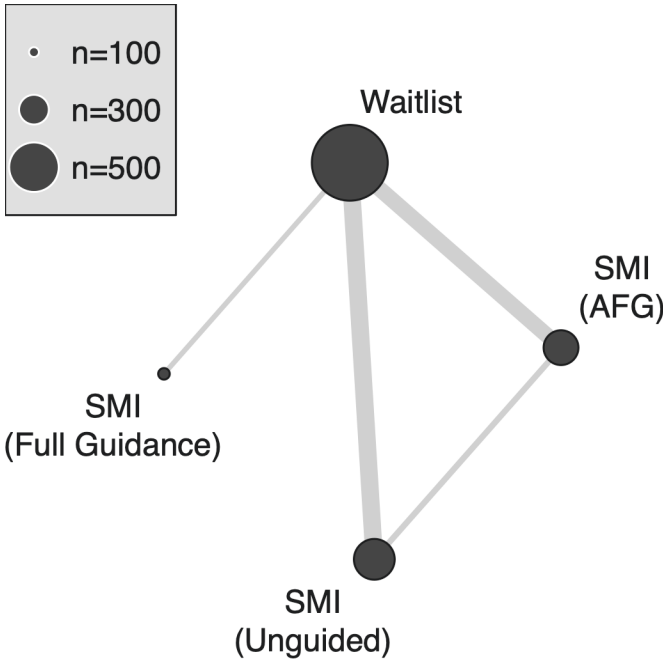


**Figure 3** Network graph. Edge sizes represent the number of available data for the specific comparison. AFG, adherence-focused guidance; SMI, stress management intervention.

(−1.30 to 0.82). The impact of adherence-focused guidance was estimated at d=0.09 (95% CrI: −0.57 to 0.73). Online supplemental table 16 provides effect estimates for all comparisons implicated by the treatment network. The model's estimate of $P\left(\left|\delta_{ung,gui}\right| < MID \mid X\right)$ and $P\left(\left|\delta_{ung,afg}\right| < MID \mid X\right)$ was 0.35 and 0.60, respectively. This represents a 60% posterior probability that adherence-focused guidance provides no clinically relevant added benefits, while, for full guidance, this probability is considerably lower (only 35%).

### User satisfaction

Complete results of the user satisfaction analysis are presented in online supplemental file 17. Overall user satisfaction was high (91.5% 'very' or 'mostly' satisfied; n=529), with 94.6% (n=547) rating the intervention quality as 'excellent' or 'good', and 89.5% (n=517) indicating that they would recommend the intervention to a friend. There were minor differences between guidance formats, with guided intervention participants reporting slightly higher satisfaction.

## DISCUSSION

This IPD meta-analysis examined the effects of a web-based SMI as indirect treatment for depression, including 1235 patients with clinically relevant depressive symptoms. Results revealed moderate-to-large effects at 7 weeks post-test (d=−0.65) and 3-month follow-up (d=−0.74) which were corroborated with sensitivity analyses.

To the best of our knowledge, this is the first meta-analysis demonstrating that a specific web-based SMI can reduce depressive symptoms in clinical samples, with stronger effects compared to an earlier meta-analysis examining a variety of web-based SMIs (d=−0.34[20]). One explanation for these favourable effects might be that the present intervention employed problem-solving and behavioural activation techniques, methods that are also found in direct treatments for depression. Furthermore,

prior studies included participants with lower levels of distress,[20] while the current study focuses on participants with clinical levels of depression.

IPD meta-analyses with comparable inclusion criteria found that the effect of direct web-based interventions for depression, compared with waitlists, was d=−0.33 to −0.60 for self-guided and d=−0.80 for guided interventions.[10 36] The effect of psychotherapy for depression compared with waitlists, regardless of the delivery mode, is d=−0.62 to −0.92.[37] Thus, our effects compare with those of direct treatments. Use of co-interventions during the study period was low (8.3%) and equally distributed between groups, suggesting that the web-based SMI primarily accounted for the observed benefits. An anchor-based approach was employed to calculate response rates, following recent recommendations.[38 39] The effect on minimally important improvement was OR=4.85, NNT=2.82. Prior meta-analyses, using non-anchor-based methods, found similar effects for direct web-based depression interventions (OR=3.49[40] compared with inactive control), and for depression psychotherapy in general (NNT=3.9[41] vs waitlists). These results further corroborate that benefits of the intervention are comparable with a direct depression treatment.

User safety is important when web-based SMIs are used 'off-label' in the treatment of depression. Notably, the deterioration rate was low (2.87%) and comparable with direct web-based interventions for depression (3.57%).[42] Overall, there were no indications that the indirect treatment approach might be more harmful than direct treatment.

User satisfaction was slightly higher when personal support was available, and identical or higher than direct web-based interventions targeting depression prevention,[43] diabetes[44] and formally diagnosed depression.[45]

IPD network meta-analysis estimated benefits of the 'fully' guided intervention at d=−0.82, with lower effects for adherence-focused guidance (d=−0.48) and for unguided treatment (d=−0.57). However, CrIs of estimates were wide and included zero. Nevertheless, our findings imply a low (35%) posterior probability that the fully guided and unguided formats produce equivalent effects, and the majority preferred the guided format.[22] In contrast, adherence-focused guidance might not provide relevant benefits, and very few patients in this condition made use of this opportunity.[22 46 47]

The dose–response relationship indicated that post-treatment depression scores were linearly associated with the number of completed sessions, emphasising the importance of adherence. Importantly, while plausible, this analysis alone cannot show if some intervention components have 'specific' effects on depression. It is also possible that the intervention primarily reduces perceived stress, which ameliorates depressive symptoms; or that even more complex working factors are at play. Component network meta-analyses or fractional factorial designs could allow to illuminate this in the future.

Several limitations should be considered. First, the specific SMI we examined in this study might not be representative of other SMIs that include different techniques. Second, included patients were not diagnosed using a diagnostic interview. Third, adverse events other than reliable symptom deterioration were not considered. Fourth, while we found effect sizes comparable with direct interventions for depression, clinical trials with head-to-head comparisons are needed to confirm the non-inferiority of indirect treatment. This is important because all included trials used waitlist comparators, which could have inflated effect estimates.[24] It could also allow to examine between-group effects for patients with similar adherence levels, which was not possible in the current dose–response analysis. Lastly, the user satisfaction found in this study does not imply a generally higher intention to engage in indirect interventions compared with those explicitly targeting depression.

The goal of the indirect treatment paradigm is to increase the uptake of anti-depressive interventions in the population, and the present study suggests web-based SMIs should be considered in this novel strategy. The next step is to generate empirical evidence if offering web-based SMIs will lead to a higher uptake of evidence-based depression treatment, as indicated by the high rate of first-time help-seekers in the present sample (54%).

Indirect treatment is based on the conjecture that factors such as stress, insomnia, perfectionism or low self-esteem are related to depression. In contrast to the clinical label 'depression', these factors are assumed to better reflect some individuals' concept of their own mental health, thus increasing the willingness to engage in targeted psychological interventions. Indirect interventions probably share many 'specific' working factors with conventional depression treatments, but they are distinct in their therapeutic rationale, and in how they approach patients' perceived needs. More research is needed to test this paradigm, particularly how patients with depression cognitively represent their own symptomatology, and how this relates to (differential) help-seeking attitudes. It is possible that some patients will not even be willing to partake in an intervention that aligns better with their perceived mental health problem. Research on indirect interventions could allow to elucidate the scale of this problem.

We conclude that the web-based SMI evaluated in this meta-analysis can be an effective indirect treatment of depression. User satisfaction with the intervention was high. No increased harmful effects were found. Preliminary evidence suggests that professional guidance leads to better effects.

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**Acknowledgements** The authors would like to thank Sarah Koop and Lea Schuurmans for conducting an independent RoB rating of studies included in this analysis.

**Contributors** MH and AAS conducted the statistical analyses for this study. MH and PN wrote the first draft of the manuscript under the supervision of DL. LB, HH, EH, CB, DDE and DL contributed to the further development of the manuscript. MH, PN and DL are responsible as guarantors for the overall contents of this study. All authors read and approved the final manuscript.

**Funding** The European Union (EFRE) funded the six RCTs included as part of the Innovation Incubator at Leuphana University (EFRE: ZW6-80119999, CCI 2007DE161PR001). MH is supported by a fellowship of the Bavarian Research Institute for Digital Transformation (BIDT), an institute of the Bavarian Academy of Sciences and Humanities. We acknowledge support by the German Research Foundation (DFG).

**Disclaimer** The funding sources played no role in the study design, collection, analysis, and interpretation of data, or in the writing or submission process.

**Competing interests** DDE reports to have received consultancy fees or served in the scientific advisory board from several companies such as Novartis, Sanofi, Lantern, Schön Kliniken, Minddistrict and German health insurance companies (BARMER, Techniker Krankenkasse). DDE and EH are stakeholders and MH is a part-time employee of the Institute for Health Trainings Online (GET.ON), which aims to implement scientific findings related to digital health interventions into routine care.

**Patient consent for publication** Not required.

**Ethics approval** This study involves human participants. This is an individual participant data meta-analysis of multiple independently conducted studies, which themselves have been approved by the respective Ethics Committees. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request. The code used for the analyses is openly available in an online repository (osf.io/p3q6t). The original data used to perform the analyses are available upon reasonable request.

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# Are Web-based Stress Management Interventions Effective as an Indirect Treatment for Depression? An Individual Participant Data Meta-Analysis of Six Randomized Trials

Supplement



Harrer M, *et al. BMJ Ment Health* 2024; 27:e300846. doi: 10.1136/bmjment-2023-300846

**S1.** PRISMA-IPD Checklist.

| PRISMA-IPD Section/topic | Item No | Checklist item | Reported on page |
|---|---|---|---|
| **Title** | | | |
| Title | 1 | Identify the report as a systematic review and meta-analysis of individual participant data. | 1 |
| **Abstract** | | | |
| Structured summary | 2 | Provide a structured summary including as applicable: | 2-3, 15 (Funding) |
| | | **Background**: state research question and main objectives, with information on participants, interventions, comparators and outcomes. | |
| | | **Methods**: report eligibility criteria; data sources including dates of last bibliographic search or elicitation, noting that IPD were sought; methods of assessing risk of bias. | |
| | | **Results**: provide number and type of studies and participants identified and number (%) obtained; summary effect estimates for main outcomes (benefits and harms) with confidence intervals and measures of statistical heterogeneity. Describe the direction and size of summary effects in terms meaningful to those who would put findings into practice. | |
| | | **Discussion:** state main strengths and limitations of the evidence, general interpretation of the results and any important implications. | |
| | | **Other:** report primary funding source, registration number and registry name for the systematic review and IPD meta-analysis. | |
| **Introduction** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 4-5 |
| Objectives | 4 | Provide an explicit statement of the questions being addressed with reference, as applicable, to participants, interventions, comparisons, outcomes and study design (PICOS). Include any hypotheses that relate to particular types of participant-level subgroups. | 5 |
| **Methods** | | | |
| Protocol and registration | 5 | Indicate if a protocol exists and where it can be accessed. If available, provide registration information including registration number and registry name. Provide publication details, if applicable. | 5 |

| | | | |
|---|---|---|---|
| Eligibility criteria | 6 | Specify inclusion and exclusion criteria including those relating to participants, interventions, comparisons, outcomes, study design and characteristics (e.g. years when conducted, required minimum follow-up). Note whether these were applied at the study or individual level i.e. whether eligible participants were included (and ineligible participants excluded) from a study that included a wider population than specified by the review inclusion criteria. The rationale for criteria should be stated. | 6 |
| Identifying studies - information sources | 7 | Describe all methods of identifying published and unpublished studies including, as applicable: which bibliographic databases were searched with dates of coverage; details of any hand searching including of conference proceedings; use of study registers and agency or company databases; contact with the original research team and experts in the field; open adverts and surveys. Give the date of last search or elicitation. | 6 |
| Identifying studies - search | 8 | Present the full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | - |
| Study selection processes | 9 | State the process for determining which studies were eligible for inclusion. | 6 |
| Data collection processes | 10 | Describe how IPD were requested, collected and managed, including any processes for querying and confirming data with investigators. If IPD were not sought from any eligible study, the reason for this should be stated (for each such study). | 6-7 |
| | | If applicable, describe how any studies for which IPD were not available were dealt with. This should include whether, how and what aggregate data were sought or extracted from study reports and publications (such as extracting data independently in duplicate) and any processes for obtaining and confirming these data with investigators. | |
| Data items | 11 | Describe how the information and variables to be collected were chosen. List and define all study level and participant level data that were sought, including baseline and follow-up information. If applicable, describe methods of standardising or translating variables within the IPD datasets to ensure common scales or measurements across studies. | 6-7 |
| IPD integrity | A1 | Describe what aspects of IPD were subject to data checking (such as sequence generation, data consistency and completeness, baseline imbalance) and how this was done. | 6-7 |
| Risk of bias assessment in individual studies. | 12 | Describe methods used to assess risk of bias in the individual studies and whether this was applied separately for each outcome. If applicable, describe how findings of IPD checking were used to inform the assessment. Report if and how risk of bias assessment was used in any data synthesis. | 7 |
| Specification of outcomes and effect measures | 13 | State all treatment comparisons of interests. State all outcomes addressed and define them in detail. State whether they were pre-specified for the review and, if applicable, whether they were primary/main or secondary/additional outcomes. Give the principal measures of effect (such as risk ratio, hazard ratio, difference in means) used for each outcome. | 8 |

| | | | |
|---|---|---|---|
| Synthesis methods | 14 | Describe the meta-analysis methods used to synthesise IPD. Specify any statistical methods and models used. Issues should include (but are not restricted to):<br>• Use of a one-stage or two-stage approach.<br>• How effect estimates were generated separately within each study and combined across studies (where applicable).<br>• Specification of one-stage models (where applicable) including how clustering of patients within studies was accounted for.<br>• Use of fixed or random effects models and any other model assumptions, such as proportional hazards.<br>• How (summary) survival curves were generated (where applicable).<br>• Methods for quantifying statistical heterogeneity (such as $I^2$ and $\tau^2$).<br>• How studies providing IPD and not providing IPD were analysed together (where applicable).<br>• How missing data within the IPD were dealt with (where applicable). | 8-9 |
| Exploration of variation in effects | A2 | If applicable, describe any methods used to explore variation in effects by study or participant level characteristics (such as estimation of interactions between effect and covariates). State all participant-level characteristics that were analysed as potential effect modifiers, and whether these were pre-specified. | - |
| Risk of bias across studies | 15 | Specify any assessment of risk of bias relating to the accumulated body of evidence, including any pertaining to not obtaining IPD for particular studies, outcomes or other variables. | - |
| Additional analyses | 16 | Describe methods of any additional analyses, including sensitivity analyses. State which of these were pre-specified. | 8-9 |
| **Results** | | | |
| Study selection and IPD obtained | 17 | Give numbers of studies screened, assessed for eligibility, and included in the systematic review with reasons for exclusions at each stage. Indicate the number of studies and participants for which IPD were sought and for which IPD were obtained. For those studies where IPD were not available, give the numbers of studies and participants for which aggregate data were available. Report reasons for non-availability of IPD. Include a flow diagram. | 9-10 |
| Study characteristics | 18 | For each study, present information on key study and participant characteristics (such as description of interventions, numbers of participants, demographic data, unavailability of outcomes, funding source, and if applicable duration of follow-up). Provide (main) citations for each study. Where applicable, also report similar study characteristics for any studies not providing IPD. | 10 |
| IPD integrity | A3 | Report any important issues identified in checking IPD or state that there were none. | - |

| | | | |
|---|---|---|---|
| Risk of bias within studies | 19 | Present data on risk of bias assessments. If applicable, describe whether data checking led to the up-weighting or down-weighting of these assessments. Consider how any potential bias impacts on the robustness of meta-analysis conclusions. | 9-10 |
| Results of individual studies | 20 | For each comparison and for each main outcome (benefit or harm), for each individual study report the number of eligible participants for which data were obtained and show simple summary data for each intervention group (including, where applicable, the number of events), effect estimates and confidence intervals. These may be tabulated or included on a forest plot. | 9 |
| Results of syntheses | 21 | Present summary effects for each meta-analysis undertaken, including confidence intervals and measures of statistical heterogeneity. State whether the analysis was pre-specified, and report the numbers of studies and participants and, where applicable, the number of events on which it is based. | 10-11 |
| | | When exploring variation in effects due to patient or study characteristics, present summary interaction estimates for each characteristic examined, including confidence intervals and measures of statistical heterogeneity. State whether the analysis was pre-specified. State whether any interaction is consistent across trials. | |
| | | Provide a description of the direction and size of effect in terms meaningful to those who would put findings into practice. | |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias relating to the accumulated body of evidence, including any pertaining to the availability and representativeness of available studies, outcomes or other variables. | Suppl. (S5) |
| Additional analyses | 23 | Give results of any additional analyses (e.g. sensitivity analyses). If applicable, this should also include any analyses that incorporate aggregate data for studies that do not have IPD. If applicable, summarise the main meta-analysis results following the inclusion or exclusion of studies for which IPD were not available. | 11-12 |
| **Discussion** | | | |
| Summary of evidence | 24 | Summarise the main findings, including the strength of evidence for each main outcome. | 12 |
| Strengths and limitations | 25 | Discuss any important strengths and limitations of the evidence including the benefits of access to IPD and any limitations arising from IPD that were not available. | 13-14 |
| Conclusions | 26 | Provide a general interpretation of the findings in the context of other evidence. | 13-14 |
| Implications | A4 | Consider relevance to key groups (such as policy makers, service providers and service users). Consider implications for future research. | 13-14 |

| **Funding** | | | |
|---|---|---|---|
| Funding | 27 | Describe sources of funding and other support (such as supply of IPD), and the role in the systematic review of those providing such support. | 15 |

*Note*. Page numbers refer to the authors' version of the manuscript. This version can be made available upon request.

**S2.** Contents of the „GET.ON Fit im Stress" web-based stress intervention.

The web-based stress management intervention **"GET.ON Fit im Stress"** is grounded in Lazarus' transactional model of stress (Lazarus & Folkman, 1984), with a primary focus on emotion regulations skills and problem-solving. The overarching aim is to facilitate a sustainable reduction in stress levels for participants, in both life and work domains.

The intervention comprises seven weekly core modules, each to be completed within 45-60 minutes. Additionally, a refresher module (a so-called booster session) is provided after participants completed the intervention. The modules offer textual contents, videos, and audio materials. The following table provides a more detailed description of the contents.

In its original version, the SMI was examined in a total of six trials (Ebert, 2016a; Ebert, 2016b; Ebert, 2021; Heber, 2016; Nixon, 2021; Nixon, 2022; references presented in S7).

| Module | Contents |
|---|---|
| *Psychoeducation* | Introduction to intervention and psychoeducation: Overview of the program and its structure, fundamental aspects of stress management such as its health implications. This module includes an individualized stress assessment, a stress diary, and a variety of practical exercises. |
| *Problem-Solving I* | Introduction to problem-solving: Introduction to coping techniques, various exercises to apply acquired problem solving skills, further individualized stress assessment and habits in life. |
| *Problem-Solving II* | Advanced problem-solving: Advanced problem-solving skills and coping strategies, challenges in life and various exercises to engage with. |
| *Emotion Regulation I* | Introduction to emotion regulation: Introduction to personal stressors and problems, muscle relaxation and breathing techniques, importance of exercises. |
| *Emotion Regulation II* | Advanced emotion regulation: Advanced emotion regulation skills focusing on the acceptance of emotions, their valence, meaning and benefit and various exercises to engage with. |
| *Emotion Regulation III* | Advanced emotion regulation: Advanced emotion regulations skills to understand the foundations of self-criticism, self-worth, self-care and self-support through difficult times in life and various exercises to engage with. |

| Module | Contents |
|---|---|
| *Plan for the future* | Future planning: Learning how to implement intentions, strengthen personal foundations and listen to physical early warning systems. |
| *Booster session* | Refresher: Booster session to reinforce previous contents and exercises, realign goals, engage in various practical exercises and address personal challenges. |

**"StudiCare Stress"** is a web-based program for college students that has been derived from "GET.ON Fit im Stress". As part of this process, third-wave CBT components were added to the intervention (including metacognitive strategies for self-criticism and "detached mindfulness" techniques), as well as cognitive restructuring for perfectionism and "mini-modules" for, e.g., time management, procrastination, test anxiety, or dealing with writer's block. Texts, videos and "patient testimonials" were replaced to better suit the target group, and the intervention was enhanced with a mobile diary app.

"StudiCare Stress" was evaluated in two independent trials (Harrer et al., 2018, 2021). These were not considered in this meta-analysis because this adapted intervention deviates substantially in form and content from "GET.ON Fit im Stress".

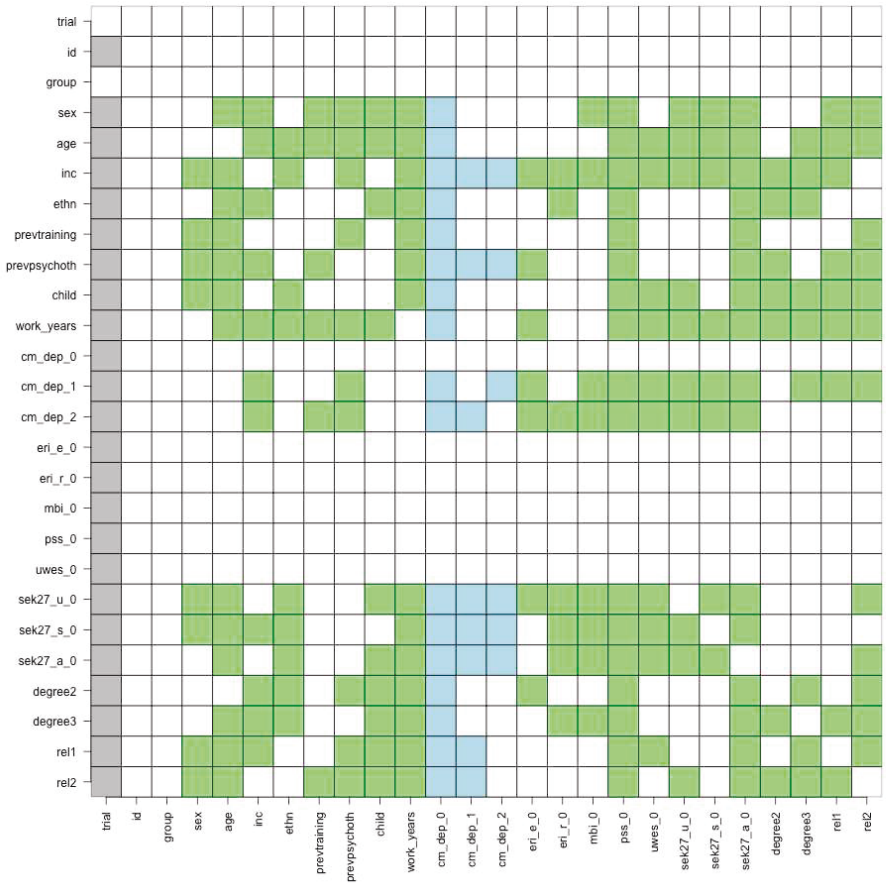
## References

Harrer, M., Adam, S. H., Fleischmann, R. J., Baumeister, H., Auerbach, R., Bruffaerts, R., ... & Ebert, D. D. (2018). Effectiveness of an internet-and app-based intervention for college students with elevated stress: randomized controlled trial. *Journal of medical Internet research*, *20*(4), e136.

Harrer, M., Apolinário-Hagen, J., Fritsche, L., Salewski, C., Zarski, A. C., Lehr, D., ... & Ebert, D. D. (2021). Effect of an internet-and app-based stress intervention compared to online psychoeducation in university students with depressive symptoms: Results of a randomized controlled trial. *Internet interventions*, *24*, 100374.

Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York: Springer

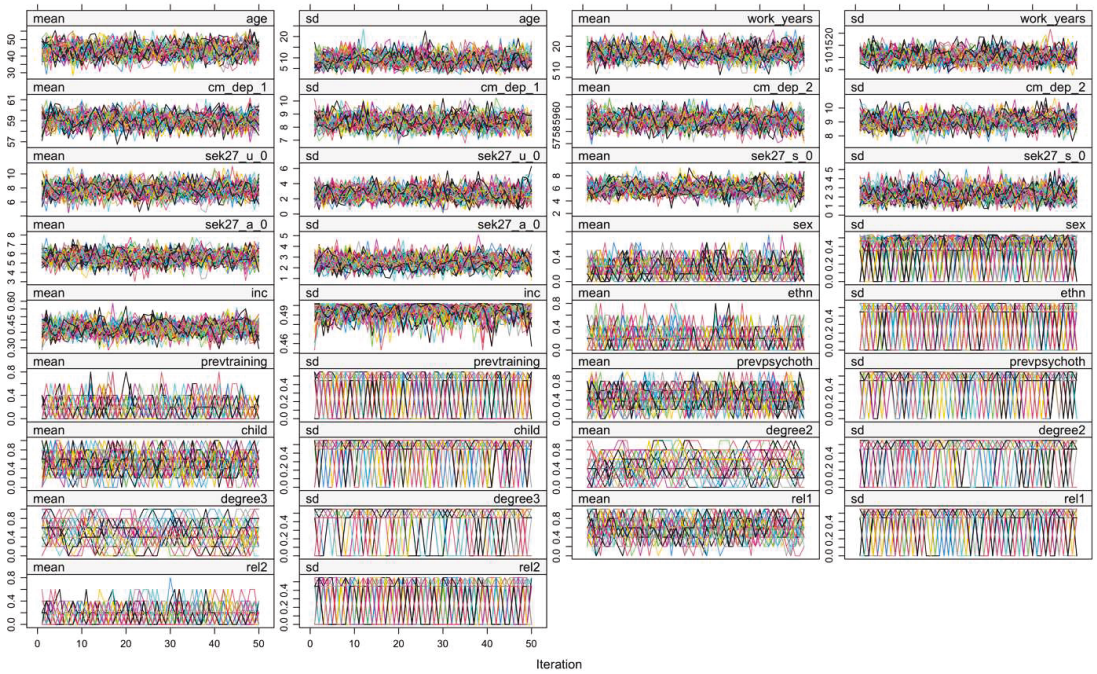
**S3.** Imputation matrix.




*Note*: The non-white column variable cells are used to model the MAR assumption when imputing the row variables. Grey cells represent the (random intercept) clustering variable in the multilevel imputation model; green cells represent that the variable was modeled as an overall effect; blue cells represent that the variable was modeled both as an individual and trial-level effect. To avoid computational issues, we only modeled the depressive symptom severity measurements as individual and trial-effect variables and reduced the complexity of the FCS model specification by requiring a minimal correlation of $r$=0.05 for a predictor to be used for imputation.

*Abbreviations*: "age" = Age, "cm_dep_0" = Depressive Symptom Severity (T0), "cm_dep_1" = Depressive Symptom Severity (T1), "cm_dep_2" = Depressive Symptom Severity (T2), "degree2" = Education, 12-13 years, "degree3" = Education, >13 years, "eri_e_0" = Effort (ERI), "eri_r_0" = Reward (ERI), "ethn" = Ethnicity, "group" = Treatment, "id" = Patient ID, "inc" = Income, "mbi_0" = Emotional Exhaustion, "prevpsychoth" = Previous Psychotherapy, "prevtraining" = Previous Psychological Training, "pss_0" = Perceived Stress (PSS-10), "rel1" = Married/In A Relationship, "rel2" = Widowed/Separated, "sek27_a_0" = Acceptance (ERSQ-27), "sek27_s_0" = Self-Support (ERSQ-27), "sek27_u_0" = Understanding (ERSQ-27), "sex" = Sex, "trial" = Trial Indicator, "uwes_0" = Work Engagement (UWES), "work_years" = Work Years.

**S4.** Trace line plot the MICE algorithm for all incomplete variables (mean and standard deviation of the imputed values).




**S5.** Model specification.

*One-Stage Bayesian Model*

Let $y_{ik}$ be the (post-test or follow-up) depression score of some participant $i$ included in study $k$ (with $k$=1, ..., $K$ studies included the meta-analysis). The one-stage meta-analysis model is defined as:

$$\mu_{ik} = \alpha_k + \delta_T T_{ik} + \sum_{j=1}^{J}\sum_{k=1}^{K} \gamma_{j,k}\left(X_{j,ik} - \bar{X}_{\bullet j,k}\right) + \sum_{j=1}^{J} \gamma_{\bullet,j}\bar{X}_{\bullet j,k} + u_{T,k}T_{ik} \quad (1)$$

$$y_{ik} \sim \mathcal{N}(\mu_{ik}, \sigma_k^2) \qquad u_{T,k} \sim \mathcal{N}(0, \tau^2)$$

$$\tau \sim \mathcal{HC}(0{,}5)$$
$$\sigma_k \sim \mathcal{U}(0{,}100)$$
$$\alpha_k, \delta_T, \gamma_{kj}, \gamma_{\bullet,j} \sim \mathcal{N}(0{,}1 \times 10^4)$$

Where $T_{ik}$ is the treatment indicator, $X_{j,ik}$ is the value of $i$ on some covariate $j$, $\bar{X}_{\bullet j,k}$ is the mean of $j$ in trial $k$, and $u_{T,k}$ is the trial-specific random slope of the average treatment effect $\delta_T$.

*One-Stage Bayesian Model (Logistic Model)*

To model binary outcome data (response, reliable deterioration), the same one-stage model is used with a logit-link:

$$log_e\left(\frac{\pi_{ik}}{1-\pi_{ik}}\right) = \alpha_k + \delta_T T_{ik} + \sum_{j=1}^{J}\sum_{k=1}^{K}\gamma_{kj}\left(X_{j,ik} - \bar{X}_{\bullet j,k}\right) + \sum_{j=1}^{J}\gamma_{\bullet,j}\bar{X}_{\bullet j,k} + u_{T,k}T_{ik} \quad (2)$$

$$y_{ik} \sim Bern(\pi_{ik}) \qquad u_{T,k} \sim \mathcal{N}(0,\tau^2)$$

$$\tau \sim \mathcal{HC}(0,5)$$
$$\alpha_k, \delta_T, \gamma_{kj}, \gamma_{\bullet,j} \sim \mathcal{N}(0,1\times 10^4)$$

*Generalized Additive Mixed Model (GAMM)*

A GAMM is used to model the "dose-response relationship" between post-test depression scores and the number of completed intervention modules. Only data of intervention group participants can be considered for this model. The effect of the completed modules variable is modeled using a rank 8 thin plate regression spline.

Let **S** denote a matrix of known coefficients for the completed modules variable *x* and $\lambda$ the smoothing parameter to be estimated from the data. The additive mixed model can is defined like this:

$$\mu_{ik} = \alpha + \boldsymbol{X\beta} + u_k \quad (3)$$

$$y_{ik} \sim \mathcal{N}(\mu_{ik}, \sigma_k^2) \qquad u_k \sim \mathcal{N}(0,\tau^2)$$

$$\alpha \sim \mathcal{N}(0,1\times 10^4)$$
$$\boldsymbol{\beta} \sim \boldsymbol{\mathcal{N}}(\mathbf{0}, \lambda\boldsymbol{S} + \lambda_0\boldsymbol{S}_0)$$
$$\lambda, \lambda_0, \tau, \sigma_k \sim \Gamma(0.05, 0.005)$$

In this model, vague gamma priors are used for the smoothing term $\lambda$ and between-study heterogeneity variance $\tau^2$ captured by the random trial intercept (see Wood, 2016). The same prior is also used for the stratified error variance.

*One-Stage Network Meta-Analysis Model*

Let $y_{ijk}$ denote the depression score of some individual *i* in group *j* of trial *k*, where *j=b* represents the baseline arm, and *j=t* the intervention arm in *k*. In our network meta-

analysis model, we adjust by including $p$=1, ..., $P$ baseline covariates into the model. The results in the following formula:

$$\mu_{ijk} = \begin{cases} \alpha_k + \sum_{p=1}^{P} \gamma \left( X_{p,ijk} - \bar{X}_{\bullet p,k} \right) & : j = b \\ \alpha_k + \delta_k + \sum_{p=1}^{P} \gamma_p \left( X_{p,ijk} - \bar{X}_{\bullet p,k} \right) & : j \neq b \end{cases} \quad (4)$$

$$y_{ijk} \sim \mathcal{N}(\mu_{ijk}, \sigma_k^2)$$
$$\delta \sim MVN(\boldsymbol{d}, \boldsymbol{\Sigma}); \; d_1 = 0$$
$$\alpha_k, \delta_k, \gamma_p \sim \mathcal{N}(0{,}1 \times 10^4)$$

Where ***d*** represents a vector containing the (in our case 3) effect sizes in comparison to the reference treatment implicated by our network. Since one included study was a multi-arm trial, we account for this dependency in our data within $\boldsymbol{\Sigma}$ (in our case, the first and second effect are part of the same multi-arm trial):

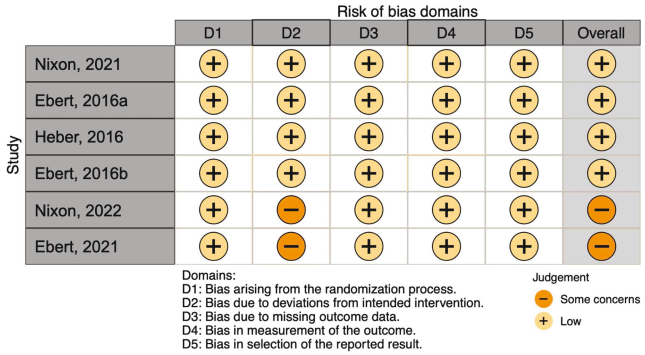
$$= \begin{bmatrix} \tau^2 & \rho\tau^2 & 0 & \cdots & 0 \\ \rho\tau^2 & \tau^2 & 0 & \cdots & 0 \\ 0 & 0 & \tau^2 & \cdots & 0 \\ \vdots & \vdots & \vdots & \ddots & 0 \\ 0 & 0 & 0 & 0 & \tau^2 \end{bmatrix} \quad (5)$$

$$\tau \sim \mathcal{HC}(0{,}5), \; \rho = 0.5.$$

## References

Wood, S. N. (2016). Just Another Gibbs Additive Modeler: Interfacing JAGS and mgcv. *Journal of Statistical Software*, *75*(7), 1–15. https://doi.org/10.18637/jss.v075.i07

**S6.** Risk of bias rating.




*Note*. For domain 4 ("bias in measurement of the outcome"), signaling questions 4.4 ("could assessment have been influenced by knowledge of the intervention?") and 4.5 ("likely that

assessment was influenced by knowledge of the intervention?") were not considered for self-reports. This was done because blinding is typically not possible in psychological interventions, and because previous meta-analyses indicate that self-reports do not create an upward bias in effect estimates of depression psychotherapies compared to (blinded or unblinded) clinician raters (Cuijpers et al., 2010).

## References

Cuijpers, P., Li, J., Hofmann, S. G., & Andersson, G. (2010). Self-reported versus clinician-rated symptoms of depression as outcome measures in psychotherapy research on depression: a meta-analysis. *Clinical psychology review*, *30*(6), 768-778.

**S7.** References of the included studies.


- **Ebert, 2016a:** Ebert, D. D., Lehr, D., Heber, E., Riper, H., Cuijpers, P., & Berking, M. (2016a). Internet-and mobile-based stress management for employees with adherence-focused guidance: Efficacy and mechanism of change. *Scandinavian Journal of Work, Environment & Health*, 382–394.

- **Ebert, 2016b:** Ebert, D. D., Heber, E., Berking, M., Riper, H., Cuijpers, P., Funk, B., & Lehr, D. (2016). Self-guided internet-based and mobile-based stress management for employees: Results of a randomised controlled trial. *Occupational and Environmental Medicine*, *73*(5), 315–323.

- **Ebert, 2021:** Ebert, D. D., Franke, M., Zarski, A.-C., Berking, M., Riper, H., Cuijpers, P., Funk, B., & Lehr, D. (2021). Effectiveness and Moderators of an Internet-Based Mobile-Supported Stress Management Intervention as a Universal Prevention Approach: Randomized Controlled Trial. *Journal of Medical Internet Research*, *23*(12), e22107.

- **Heber, 2016:** Heber, E., Lehr, D., Ebert, D. D., Berking, M., & Riper, H. (2016). Web-based and mobile stress management intervention for employees: A randomized controlled trial. *Journal of Medical Internet Research*, *18*(1), e5112.

- **Nixon, 2021:** Nixon, P., Boss, L., Heber, E., Ebert, D. D., & Lehr, D. (2021). A three-armed randomised controlled trial investigating the comparative impact of guidance on the efficacy of a web-based stress management intervention and health impairing and promoting mechanisms of prevention. *BMC Public Health*, *21*(1), 1–18.

- **Nixon, 2022:** Nixon, P., Ebert, D. D., Boss, L., Angerer, P., Dragano, N., & Lehr, D. (2022). Efficacy of a web-based stress management intervention for employees experiencing adverse working conditions and occupational self-efficacy as mediator: A randomized controlled trial. *Journal of Medical Internet Research*. https://doi.org/10.2196/40488

**S8.** Depressive symptom severity at post-test and follow-up.

| | | Overall | | | Control | | | Intervention | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Time | *M* | *SD* | *n* | *M* | *SD* | *n* | *M* | *SD* | *n* |
| **Nixon, 2021** | | | | | | | | | | |
| - Common Metrics | Post-Test | 62.40 | 6.54 | 312 | 65.35 | 6.30 | 103 | 60.95 | 6.16 | 209 |
| | Follow-Up | 62.12 | 7.15 | 312 | 65.34 | 6.29 | 103 | 60.53 | 7.03 | 209 |
| - CES-D | Post-Test | 22.88 | 8.58 | 312 | 26.75 | 8.71 | 103 | 20.97 | 7.86 | 209 |
| | Follow-Up | 22.73 | 8.97 | 312 | 26.78 | 8.57 | 103 | 20.73 | 8.48 | 209 |
| **Ebert, 2016a** | | | | | | | | | | |
| - Common Metrics | Post-Test | 61.92 | 7.39 | 174 | 63.34 | 7.32 | 95 | 60.21 | 7.15 | 79 |
| | Follow-Up | 60.73 | 8.20 | 174 | 63.68 | 7.84 | 95 | 57.17 | 7.17 | 79 |
| - CES-D | Post-Test | 22.54 | 9.04 | 174 | 24.32 | 9.22 | 95 | 20.40 | 8.37 | 79 |
| | Follow-Up | 21.34 | 9.84 | 174 | 24.96 | 9.83 | 95 | 16.99 | 7.91 | 79 |
| **Heber, 2016** | | | | | | | | | | |
| - Common Metrics | Post-Test | 60.05 | 8.76 | 178 | 62.93 | 7.39 | 90 | 57.11 | 9.09 | 88 |
| | Follow-Up | 58.67 | 8.77 | 178 | 62.58 | 7.51 | 90 | 54.68 | 8.16 | 88 |
| - CES-D | Post-Test | 20.69 | 10.15 | 178 | 23.79 | 9.36 | 90 | 17.51 | 9.98 | 88 |
| | Follow-Up | 19.14 | 9.60 | 178 | 23.44 | 8.94 | 90 | 14.74 | 8.19 | 88 |
| **Ebert, 2016b** | | | | | | | | | | |
| - Common Metrics | Post-Test | 60.68 | 8.20 | 181 | 63.98 | 6.56 | 86 | 57.69 | 8.41 | 95 |
| | Follow-Up | 59.03 | 9.36 | 181 | 62.06 | 8.41 | 86 | 56.30 | 9.38 | 95 |
| - CES-D | Post-Test | 21.26 | 9.60 | 181 | 24.94 | 8.73 | 86 | 17.94 | 9.17 | 95 |
| | Follow-Up | 19.69 | 10.39 | 181 | 23.03 | 10.09 | 86 | 16.68 | 9.76 | 95 |
| **Nixon, 2022** | | | | | | | | | | |
| - Common Metrics | Post-Test | 64.12 | 7.34 | 160 | 66.37 | 6.82 | 84 | 61.64 | 7.13 | 76 |
| | Follow-Up | 63.02 | 8.80 | 160 | 64.69 | 8.70 | 84 | 61.18 | 8.57 | 76 |
| - CES-D | Post-Test | 25.26 | 9.72 | 160 | 28.11 | 9.55 | 84 | 22.11 | 8.94 | 76 |
| | Follow-Up | 24.24 | 10.92 | 160 | 26.37 | 11.17 | 84 | 21.89 | 10.17 | 76 |
| **Ebert, 2021** | | | | | | | | | | |
| - Common Metrics | Post-Test | 57.53 | 9.16 | 230 | 60.82 | 9.05 | 114 | 54.18 | 8.01 | 116 |
| | Follow-Up | 57.06 | 9.28 | 230 | 60.60 | 8.67 | 114 | 53.45 | 8.46 | 116 |
| - CES-D | Post-Test | 18.03 | 9.83 | 230 | 21.72 | 10.23 | 114 | 14.26 | 7.81 | 116 |
| | Follow-Up | 17.52 | 9.66 | 230 | 21.33 | 9.98 | 114 | 13.64 | 7.58 | 116 |
| **All Trials** | | | | | | | | | | |
| - Common Metrics | Post-Test | 61.30 | 8.50 | 1235 | 63.74 | 8.45 | 574 | 58.98 | 7.90 | 661 |
| | Follow-Up | 60.27 | 8.49 | 1235 | 63.01 | 8.08 | 574 | 57.66 | 8.07 | 661 |
| - CES-D | Post-Test | 22.08 | 10.07 | 1235 | 25.12 | 10.31 | 574 | 19.18 | 8.95 | 661 |
| | Follow-Up | 20.87 | 9.94 | 1235 | 24.15 | 9.91 | 574 | 17.76 | 8.96 | 661 |

*Note*: Values are based on the multiply imputed data.

**S9.** Pooled intervention effects on depressive symptom severity, minimally important improvement, and reliable deterioration (two-stage model).

| | Effect Size (95% CrI) | *NNT* (95% CrI) | $\tau$ (95% CrI) |
|---|---|---|---|
| Depressive Symptom Severity | | | |
| - Post-Test (*d*) | -0.68 [-0.86; -0.50] | 7.00 [6.08; 8.68] | 0.11 [0.00; 0.36] |
| - Follow-Up (*d*) | -0.79 [-1.03; -0.55] | 5.42 [4.67; 6.91] | 0.17 [0.00; 0.49] |
| Minimally Important Improvement | | | |
| - Post-Test (*OR*) | 4.46 [2.83; 6.39] | 2.99 [2.38; 4.54] | 0.16 [0.00; 0.62] |
| - Follow-Up (*OR*) | 4.27 [2.34; 6.62] | 2.94 [2.28; 5.22] | 0.30 [0.00; 0.94] |
| Reliable Deterioration | | | |
| - Post-Test (*OR*) | 0.43 [0.00; 1.52] | 26.42 [14.52; -31.04][a] | 1.00 [0.00; 3.67] |
| - Follow-Up (*OR*) | 0.21 [0.00; 1.08] | 15.36 [11.91; -172.95][b] | 0.84 [0.00; 4.17] |

[a] *NNB* 14.52 to $\infty$ to *NNH* 31.04
[b] *NNB* 11.91 to $\infty$ to *NNH* 172.95

**S10.** Pooled intervention effects on depressive symptom severity, minimally important improvement, and reliable deterioration (one-stage model, $\tau \sim \mathcal{HC}(0,3)$).

| | Effect Size (95% CrI) | *NNT* (95% CrI) | $\tau$ (95% CrI) |
|---|---|---|---|
| Depressive Symptom Severity | | | |
| - Post-Test (*d*) | -0.67 [-0.90; -0.48] | 7.05 [5.96; 8.95] | 0.13 [0.00; 0.39] |
| - Follow-Up (*d*) | -0.74 [-0.97; -0.51] | 5.65 [4.83; 7.40] | 0.15 [0.00; 0.45] |
| Minimally Important Improvement | | | |
| - Post-Test (*OR*) | 4.78 [3.00; 7.09] | 2.85 [2.25; 4.26] | 0.18 [0.00; 0.71] |
| - Follow-Up (*OR*) | 4.64 [2.29; 7.52] | 2.78 [2.15; 5.35] | 0.36 [0.00; 1.18] |
| Reliable Deterioration | | | |
| - Post-Test (*OR*) | 0.17 [0.00; 0.73] | 17.61 [14.53; 57.46] | 1.79 [0.00; 4.89] |
| - Follow-Up (*OR*) | 0.09 [0.00; 0.30] | 13.26 [11.91; 17.44] | 0.93 [0.00; 4.03] |

**S11.** Pooled intervention effects on depressive symptom severity, minimally important improvement, and reliable deterioration (two-stage model, $\tau \sim \mathcal{HC}(0,3)$).

| | Effect Size (95% CrI) | *NNT* (95% CrI) | $\tau$ (95% CrI) |
|---|---|---|---|
| Depressive Symptom Severity | | | |
| - Post-Test (*d*) | -0.68 [-0.86; -0.49] | 7.00 [6.10; 8.83] | 0.11 [0.00; 0.36] |
| - Follow-Up (*d*) | -0.79 [-1.02; -0.54] | 5.41 [4.69; 7.01] | 0.17 [0.00; 0.49] |
| Minimally Important Improvement | | | |
| - Post-Test (*OR*) | 4.46 [2.87; 6.38] | 2.99 [2.38; 4.46] | 0.16 [0.00; 0.59] |
| - Follow-Up (*OR*) | 4.29 [2.36; 6.58] | 2.93 [2.28; 5.17] | 0.30 [0.00; 0.91] |
| Reliable Deterioration | | | |
| - Post-Test (*OR*) | 0.45 [0.00; 1.43] | 27.07 [14.52; -37.37][a] | 0.88 [0.00; 3.12] |
| - Follow-Up (*OR*) | 0.21 [0.00; 0.93] | 15.42 [11.91; 182.81] | 0.73 [0.00; 3.27] |

[a] *NNB* 14.52 to ∞ to *NNH* 37.37

**S12.** Pooled intervention effects on minimally important improvement when defined as ⅓ symptom decrease.

| | Odds Ratio (95% CrI) | NNT (95% CrI) | $\tau$ (95% CrI) |
|---|---|---|---|
| Post-Test | | | |
| - One-Stage Model | 4.87 [3.09; 7.11] | 2.74 [3.95; 2.22] | 0.18 [0.00; 0.73] |
| - Two-Stage Model | 4.45 [3.01; 6.28] | 2.91 [4.06; 2.36] | 0.16 [0.00; 0.59] |
| Follow-Up | | | |
| - One-Stage Model | 4.79 [1.98; 8.26] | 2.69 [6.35; 2.08] | 0.44 [0.00; 1.41] |
| - Two-Stage Model | 4.34 [2.36; 6.91] | 2.86 [4.96; 2.23] | 0.34 [0.00; 1.00] |

**S13.** Minimally important change (MIC) and marginal odds ratios at post-test and follow-up.

| Trial | Group | *n* | Post-Test | | | Follow-Up | | |
|---|---|---|---|---|---|---|---|---|
| | | | MIC | % | *OR* | MIC | % | *OR* |
| **Nixon, 2021** | CG | 103 | 13 | 12.62 | 4.29 | 19 | 18.45 | 3.03 |
| | IG | 209 | 80 | 38.28 | - | 85 | 40.67 | - |
| **Ebert, 2016a** | CG | 95 | 17 | 17.89 | 3.47 | 18 | 18.95 | 5.66 |

| Trial | Group | *n* | Post-Test | | | Follow-Up | | |
|---|---|---|---|---|---|---|---|---|
| | | | MIC | % | *OR* | MIC | % | *OR* |
| | IG | 79 | 34 | 43.04 | - | 45 | 56.96 | - |
| **Heber, 2016** | CG | 90 | 18 | 20.00 | 4.00 | 20 | 22.22 | 6.12 |
| | IG | 88 | 44 | 50.00 | - | 56 | 63.64 | - |
| **Ebert, 2016b** | CG | 86 | 15 | 17.44 | 5.26 | 23 | 26.74 | 3.77 |
| | IG | 95 | 50 | 52.63 | - | 55 | 57.89 | - |
| **Nixon, 2022** | CG | 84 | 14 | 16.67 | 2.92 | 24 | 28.57 | 1.63 |
| | IG | 76 | 28 | 36.84 | - | 30 | 39.47 | - |
| **Ebert, 2021** | CG | 116 | 44 | 37.93 | 3.03 | 45 | 38.79 | 3.42 |
| | IG | 114 | 74 | 64.91 | - | 78 | 68.42 | - |
| **Overall** | CG | 574 | 121 | 21.08 | 3.31 | 149 | 25.96 | 3.19 |
| | IG | 661 | 310 | 46.90 | - | 349 | 52.80 | - |

*Note*: Aggregated count data based on the multiply imputed data; CG=control group; IG=intervention group.

**S14.** Reliable deterioration (RD) and marginal odds ratios at post-test and follow-up.

| Trial | Group | *n* | Post-Test | | | Follow-Up | | |
|---|---|---|---|---|---|---|---|---|
| | | | RD | % | *OR* | RD | % | *OR* |
| **Nixon, 2021** | CG | 103 | 7 | 6.80 | 0.41 | 12 | 11.65 | 0.26 |
| | IG | 209 | 6 | 2.87 | - | 7 | 3.35 | - |
| **Ebert, 2016a** | CG | 95 | 3 | 3.16 | 0.39 | 5 | 5.26 | 0.47 |
| | IG | 79 | 1 | 1.27 | - | 2 | 2.53 | - |
| **Heber, 2016** | CG | 90 | 6 | 6.67 | 0.33 | 3 | 3.33 | 0.14[a] |
| | IG | 88 | 2 | 2.27 | - | 0 | 0.00 | - |
| **Ebert, 2016b** | CG | 86 | 5 | 5.81 | 0.35 | 6 | 6.98 | 0.14 |
| | IG | 95 | 2 | 2.11 | - | 1 | 1.05 | - |
| **Nixon, 2022** | CG | 84 | 7 | 8.33 | 1.12 | 12 | 14.29 | 0.25 |
| | IG | 76 | 7 | 9.21 | - | 3 | 3.95 | - |
| **Ebert, 2021** | CG | 116 | 10 | 8.62 | 0.09 | 10 | 8.62 | 0.09 |
| | IG | 114 | 1 | 0.88 | - | 1 | 0.88 | - |
| **Overall** | CG | 574 | 38 | 6.62 | 0.42 | 48 | 8.36 | 0.24 |
| | IG | 661 | 19 | 2.87 | - | 14 | 2.12 | - |

*Note*: Aggregated count data based on the multiply imputed data; CG=control group; IG=intervention group; [a] Zero-cell correction applied.

**S15.** Smoothing parameter $\lambda$ of all GAMs.

| Model | $\lambda$ | 95% CrI |
|---|---|---|
| Overall | 0.54 | [0.00; 210.56] |
| Responders | 1.09 | [0.01; 213.67] |
| Non-Responders | 3.48 | [0.01; 367.88] |

**S16.** Effect estimates by guidance type (IPD network meta-analysis).

| | Unguided | Adherence-Focused | Full Guidance |
|---|---|---|---|
| Unguided | -0.57 [-1.09; -0.06] | . | . |
| Adherence-Focused | 0.09 [-0.57; 0.73] | -0.48 [-1.00; 0.03] | . |
| Full Guided | -0.25 [-1.30; 0.82] | -0.34 [-1.40; 0.72] | -0.82 [-1.75; 0.11] |

*Note*: waitlist control used as reference condition.

**S17.** User satisfaction.

| CSQ-8 Item | Guidance Format | *M* | *SD* | Agreement[a] *N* | % |
|---|---|---|---|---|---|
| *Quality of the training* [b] | Overall | 3.50 | 0.66 | 547 | 94.64 |
| | Unguided | 3.45 | 0.70 | 257 | 93.45 |
| | Guided | 3.54 | 0.61 | 290 | 95.71 |
| *Received the training I wanted* [c] | Overall | 3.21 | 0.72 | 507 | 87.72 |
| | Unguided | 3.16 | 0.75 | 236 | 85.82 |
| | Guided | 3.26 | 0.68 | 271 | 89.44 |
| *Training met my needs* [d] | Overall | 3.19 | 0.73 | 503 | 87.02 |
| | Unguided | 3.16 | 0.75 | 238 | 86.55 |
| | Guided | 3.22 | 0.70 | 265 | 87.46 |
| *Would recommend training to a friend* [e] | Overall | 3.51 | 0.76 | 517 | 89.45 |
| | Unguided | 3.43 | 0.83 | 238 | 86.55 |
| | Guided | 3.59 | 0.67 | 279 | 92.08 |
| *Received the amount of help I wanted* [f] | Overall | 3.21 | 0.78 | 489 | 84.60 |
| | Unguided | 3.16 | 0.80 | 230 | 83.64 |
| | Guided | 3.25 | 0.76 | 259 | 85.48 |

| CSQ-8 Item | Guidance Format | *M* | *SD* | Agreement[a] *N* | % |
|---|---|---|---|---|---|
| *Training helped me to deal more effectively with my problem* [g] | Overall | 3.22 | 0.79 | 491 | 84.95 |
| | Unguided | 3.14 | 0.80 | 227 | 82.55 |
| | Guided | 3.29 | 0.77 | 264 | 87.13 |
| *Generally satisfied with the training* [h] | Overall | 3.49 | 0.72 | 529 | 91.52 |
| | Unguided | 3.41 | 0.77 | 248 | 90.18 |
| | Guided | 3.56 | 0.67 | 281 | 92.74 |
| *Would use training again* [i] | Overall | 3.45 | 0.84 | 505 | 87.37 |
| | Unguided | 3.37 | 0.90 | 233 | 84.73 |
| | Guided | 3.52 | 0.78 | 272 | 89.77 |

[a] Responded with ≥3; [b] Excellent (4); Good (3); Fair (2); Poor (1); [c] No, definitely not (1); No, not really (2); Yes, generally (3); Yes, definitely (4); [d] Almost all of my needs have been met (4); Most of my needs have been met (3); Only a few of my needs have been met; (2); None of my needs have been met (1); [e] No, definitely not (1); No, I don't think so (2); Yes, I think so (3); Yes, definitely (4); [f] Quite dissatisfied (1); Indifferent or mildly dissatisfied (2); Mostly satisfied (3); Very satisfied (4); [g] Yes, it helped a great deal (4); Yes, it helped somewhat (3); No, it really didn't help (2); No, it seemed to make things worse (1); [h] Very satisfied (4); Mostly satisfied (3); Indifferent of mildly dissatisfied (2); Quite dissatisfied (1); [i] No, definitely not (1); No, I don't think so (2); Yes, I think so (3); Yes, definitely (4).

# 3. General Discussion

In the third chapter of this dissertation, the results of the three studies are summarised in relation to the seven research questions, with a focus on key findings and their implications. Core aspects of each study are discussed, providing greater depth than the corresponding discussion sections of the respective publications.

## 3.1 Summary of Main Findings

Experiencing stress can pose a considerable health risk for employees and is associated with numerous adverse health consequences on both physical and psychological levels. Digital SMIs offer compelling advantages in terms of accessibility, scalability, and cost-effectiveness, and research has consistently demonstrated their efficacy in achieving sustainable stress reduction in employees. In designing a digital SMI, various components, including the format of provided guidance, can be adjusted to a considerable extent, allowing for a tailored approach that meets diverse individual needs and preferences while minimising costs. The choice of a specific guidance format is directly linked to the required resources and is presumed to impact the intervention's efficacy in improving health outcomes. Despite this presumption, direct comparisons between different guidance formats are lacking regarding their efficacy in achieving sustainable stress reduction. Furthermore, there is limited evidence regarding mechanisms of change in digital SMIs, with no available studies investigating relevant pathways influencing the efficacy on depression. Additional gaps in research remain concerning the efficacy of a digital SMI for employees exposed to adverse working conditions, and which factors might contribute to changes in health outcomes in such contexts. While several single trials have demonstrated the efficacy of digital SMIs in achieving sustainable reductions in depression, a systematic analysis of these findings is still lacking. Moreover, no studies have examined whether different guidance formats in a digital SMI are associated with varying effects on depression.

Against this background, three studies were conducted within this dissertation to address the seven research questions.

## Study 1: Comparative Efficacy of Guidance Formats in a Digital Stress Management Intervention and Health Mechanisms

### Research Question 1: Does the efficacy of a digital stress management intervention in reducing stress differ between adherence-focused guidance and self-help, and how do adherence and acceptability compare?

To investigate the comparative efficacy of different guidance formats in the digital SMI GET.ON "Fit im Stress", 404 employees with elevated stress levels were included in Study 1 and randomised into three different conditions: AFG ($n$=135), SH ($n$=134), and WLC ($n$=135). Data were collected at three different points in time during the study: baseline (T1), post-intervention (T2), and six-month follow-up (T3). The primary outcome was perceived stress, measured with PSS-10 (Cohen et al., 1983; Michalsen et al., 2012), and secondary outcomes were further health- and work-related measures including depression, assessed with CES-D (Hautzinger & Bailer, 1992; Lehr et al., 2008).

Regarding the primary outcome, results from analyses of covariance (ANCOVA) revealed a significant stress reduction in both intervention conditions, AFG and SH, compared to WLC at T2, $F_{2,400}$=36.08, $P$<.001, with large effect sizes for AFG, $d$=0.83, 95% $CI$ [0.58, 1.08], Δ5.46, and SH, $d$=0.88, 95% $CI$ [0.63, 1.13], Δ5.15, and at T3, $F_{2,400}$=37.04, $P$<.001, again with large effect sizes for AFG, $d$=0.85, 95% $CI$ [0.60, 1.10], Δ5.78, and SH, $d$=0.91, 95% $CI$ [0.66, 1.16], Δ5.41. Significant between group effects were also revealed for secondary outcomes in both intervention conditions, AFG and SH, compared to WLC. This includes depressive symptoms that were significantly lower after participation for both AFG and SH compared to WLC at T2, $F_{2,400}$=28.64, $P$<.001, and T3, $F_{2,400}$=23.6, $P$<.001. Interestingly, no significant between group effects could be found for AFG and SH, neither for the primary nor secondary outcomes. Adherence operationalised as the number of completed modules was significantly higher in AFG, $M$=5.9, $SD$=2.01, compared to SH, $M$=5.17, $SD$=2.38. No differences between the two intervention conditions were found regarding user satisfaction with the intervention.

In summary, the efficacy of the digital SMI GET.ON "Fit im Stress" in reducing stress in employees did not differ between the two examined guidance formats, AFG and SH, although adherence was higher in AFG, with both formats showing comparable acceptability among participants.

**Research Question 2: Do perceived stress and resilience mediate the effects of a digital stress management intervention on depression?**

To examine how the digital SMI GET.ON "Fit im Stress" impacts depression, secondary analyses of Study 1 involved a parallel mediation analysis. In the mediation model, two pathways were considered. On one hand, a health promoting path was assumed, operationalised as resilience measured using CD-RISC (Campbell-Sills & Stein, 2007). On the other hand, a health impairing path was considered, operationalised as perceived stress and assessed with PSS-10 (Cohen et al., 1983; Michalsen et al., 2012). For the analysis, post-intervention scores (T2) were included in the model to examine the impact on later depressive symptoms, measured with CES-D (Hautzinger & Bailer, 1992; Lehr et al., 2008), at the six-month follow-up (T3).

Results identified perceived stress as a significant mediator in the relationship between participation and depressive outcomes, $a_1b_1$=−0.77, 95% *CI* [−1.26, −0.34], and resilience as a second significant mediator, $a_2b_2$ =−0.62, 95% *CI* [−1.05, −0.26]. After incorporating both mediators into the model, the direct effect of GET.ON "Fit im Stress" on depression remained significant, $c'$=−1.08, 95% *CI* [−1.95, −0.21].

In conclusion, the intervention unfolded its effect on depression through two distinct pathways: by enhancing resilience ('the good') and reducing perceived stress ('the bad').

**Study 2: Digital Stress Management for Employees in Adverse Working Conditions: Efficacy and Mediators**

**Research Question 3: Is a digital stress management intervention effective in reducing stress in employees facing adverse working conditions?**

To examine the efficacy of the digital SMI GET.ON "Fit im Stress" in the face of adverse working conditions, 262 employees with elevated levels of stress (PSS-10 ≥22) and an ERI score >0.715 were included in Study 2 and randomised into either the intervention group (IG; *n*=132) or WLC (*n*=132). Data were assessed at three measurement points: baseline (T1), after seven weeks when the intervention was completed (T2), and at a six-month follow-up (T3). The primary outcome was perceived stress, measured using PSS-10 (Cohen et al., 1983; Michalsen et al., 2012), while secondary outcomes included work- and mental health-related outcomes. ANCOVAs were conducted to detect between group differences.

For the primary outcome, results revealed significantly higher stress reductions in the IG compared to the WLC at both T2, $F_{259,1}$=46.14, $P$<.001, $d$=0.87, 95% $CI$ [0.61, 1.12], Δ5.00, and T3, $F_{259,1}$=24.82, $P$<.001, $d$=0.65, 95% $CI$ [0.41, 0.90], Δ4.19. Regarding secondary outcomes, a significant improvement was observed in most measures for the IG compared to the WLC, including occupational self-efficacy at T2, $F_{259,1}$=10.65, $P$<.01, $d$=0.38, 95% $CI$ [0.13, 0.62], Δ2.18. Furthermore, regarding working conditions, a significant between group effect was found for rewards at T2, $d$=0.28, 95% $CI$ [0.04, 0.52], $P$<.05, whereas no such effect was found for efforts, $d$=0.05, 95% $CI$ [–0.19, 0.30], $P$>.05.

To conclude, participation in the digital SMI GET.ON "Fit im Stress" was associated with reduced stress levels in employees facing adverse working conditions, showing significant improvements in perceived stress and several secondary outcomes compared to controls.

**Research Question 4: Does occupational self-efficacy mediate the effects of a digital stress management intervention on perceived stress?**

Several mediation analyses were conducted in Study 2 to elucidate the associations between participation in GET.ON "Fit im Stress", the personal resource of occupational self-efficacy, and the outcome of perceived stress. The independent variable (X) was the study condition (coded as 0=WLC and 1=IG), and the dependent variable was perceived stress at T3, measured using PSS-10 (Cohen et al., 1983; Michalsen et al., 2012). The mediators included in the analyses, were occupational self-efficacy, measured using OSS-SF (Rigotti et al., 2008), and efforts and rewards, measured using ERI (Siegrist et al., 2009), assessed at T2. To test indirect effects, 95% bias-corrected confidence intervals based on 10,000 bootstrap samples were calculated.

The first model posited occupational self-efficacy as the sole mediator (M). Results from a simple mediation analysis revealed that the study group (X), i.e., participation in the intervention, was significantly associated with increased occupational self-efficacy (M), $b$=2.18, $P$<.002. Furthermore, the intervention (X) had an impact on perceived stress (Y) through occupational self-efficacy (M), $b$=–0.44, $P$<.001. The 95% bias-corrected confidence interval indicated that the indirect effect was significant, $b$=0.95, 95% $CI$ [–1.73, –0.32], $P$<.001. In conclusion, occupational self-efficacy was found to be a significant mediator in this model.

In subsequent models, occupational self-efficacy ($M_1$) continued to serve as a significant mediator. When occupational self-efficacy ($M_1$) and efforts ($M_2$) were examined simultaneously, the study group (X) had a significant effect on occupational self-efficacy ($M_1$), $b$=2.18, $P$<.01, which in turn was associated with lower stress levels (Y), $b$=–0.44, $P$<.001. The indirect effect of the intervention (X) on perceived stress (Y) through occupational self-efficacy ($M_1$) was significant, $b$=–0.14, 95% *CI* [–0.25, –0.05], $P$<.001. Similarly, when the two factors occupational self-efficacy ($M_1$) and rewards ($M_2$) were explored as potential mediators, the study group (X) again had a significant effect on occupational self-efficacy ($M_1$), $b$=2.18, $P$<.01, which led to a significant indirect effect on perceived stress (Y), $b$=–0.12, 95% *CI* [–0.22, –0.04], $P$<.001. Again, a significant indirect effect of the intervention (X) on stress (Y) through occupational self-efficacy ($M_1$) was observed, $b$=–0.12, 95% *CI* [–0.22, –0.04], $P$<.001.

Finally, the model integrating all three mediators within one framework ($M_1$: occupational self-efficacy, $M_2$: efforts, $M_3$: rewards) further supported the mediating role of occupational self-efficacy ($M_1$). The study group (X) had a significant effect on occupational self-efficacy ($M_1$), $b$=2.18, $P$<.01, which, in turn, significantly predicted perceived stress (Y), $b$=–0.38, $P$<.001 and rewards ($M_3$), $b$=0.18, $P$<.001, but not efforts ($M_2$). The indirect effect of the intervention (X) on perceived stress (Y) through occupational self-efficacy ($M_1$) was significant, $b$=–0.04, 95% *CI* [–0.10, 0.01], $P$<.001. Sensitivity analyses, incorporating data from study completers only, corroborated the results for all models and validated the robustness of these findings.

In summary, occupational self-efficacy significantly mediated the effects of the digital SMI GET.ON “Fit im Stress” on perceived stress through both direct and indirect pathways, highlighting the role of this personal resource for effective occupational health management and underscoring its relevance in managing stress in employees.

**Research Question 5: Do efforts and rewards mediate the effects of a digital stress management intervention on perceived stress?**

To explore the role of efforts and rewards as mediators, several mediation analyses were conducted to examine their impact on the associations between participation in GET.ON “Fit im Stress” and perceived stress. In all analyses, the independent variable (X) was the study condition (coded as 0=WLC and 1=IG), and the dependent variable was perceived stress at T3, measured using PSS-10 (Cohen et al., 1983; Michalsen et al., 2012). Next to occupational self-

efficacy, measured with OSS-SF (Rigotti et al., 2008), efforts and rewards, assessed using ERI (Siegrist et al., 2009) at T2, were included as mediators. To assess indirect effects, 95% bias-corrected confidence intervals were computed using 10,000 bootstrap samples.

In the model examining occupational self-efficacy ($M_1$) and the role of efforts ($M_2$), the study group (X) had no significant effect on efforts ($M_2$), $b$=–0.18, $P$>.05. Although efforts ($M_2$) significantly predicted perceived stress (Y), $b$=0.53, $P$<.01, the indirect effect of the intervention (X) on perceived stress (Y) through efforts ($M_2$) was not significant, $b$=–0.01, 95% *CI* [–0.06, 0.02], $P$>.05. While efforts had a significant impact on perceived stress, this factor did not mediate the effects of GET.ON "Fit im Stress" on perceived stress.

After replacing efforts with rewards as second mediator ($M_2$) in this model, along with occupational self-efficacy ($M_1$), the study group (X) did not significantly predict rewards ($M_2$), $b$=0.64, $P$>.05. Despite this, rewards ($M_2$) had a significant effect on perceived stress (Y), $b$=–0.37, $P$<.01. However, the indirect effect of the intervention (X) on perceived stress (Y) through rewards ($M_2$) was not significant, $b$=–0.04, 95% *CI* [–0.10, 0.01], $P$>.05. Similarly to efforts, rewards significantly predicted perceived stress, yet this factor did not mediate the effects on GET.ON "Fit im Stress" on stress in employees.

Finally, the fourth model, integrating all investigated mediators ($M_1$: occupational self-efficacy, $M_2$: efforts, $M_3$: rewards), corroborated these findings. The study group (X) did not significantly predict either efforts ($M_2$) or rewards ($M_3$). The indirect effect of the intervention (X) on perceived stress (Y) was not significant through efforts ($M_2$), $b$=–0.01, 95% *CI* [–0.05, 0.02], $P$>.05, or rewards ($M_3$), $b$=–0.03, 95% *CI* [–0.09, 0.01], $P$>.05. However, a significant indirect effect of the intervention (X) on perceived stress (Y) was found through occupational self-efficacy ($M_1$) and rewards ($M_3$), $b$=–0.02 95% *CI* [–0.05, –0.01], $P$<.001.

Overall, working conditions, operationalised as the external factors of efforts and rewards, did not significantly mediate the effects of GET.ON "Fit im Stress" on perceived stress in employees. While both efforts and rewards exhibited significant direct effects on perceived stress, neither served as a significant mediator in the relationship between the intervention and perceived stress. The impact of the intervention on reducing perceived stress was mediated by occupational self-efficacy, particularly when combined with rewards, but not through efforts or rewards in isolation. This suggests that the efficacy of GET.ON "Fit im Stress" might be closely associated with changes in individual occupational self-efficacy and its interaction with workplace rewards, highlighting the importance of considering both personal and external factors when implementing occupational health strategies.

### Study 3: Indirect Treatment: Efficacy of a Digital Stress Management Intervention for Depression

**Research Question 6: Is a digital stress management intervention effective in reducing depressive symptom severity in employees with clinically relevant depression?**

To investigate if GET.ON "Fit im Stress" can reduce depressive symptom severity in employees, in Study 3, a meta-analysis on IPD from 1235 participants across six RCTs with clinically relevant depression was conducted. The one-stage model analysis revealed significantly lower levels of depressive symptom severity, measured with CES-D (Hautzinger & Bailer, 1992; Lehr et al., 2008), at T2 (post-intervention) for subjects in the IG compared to WLC, *d*=–0.65, 95% *CrI* [–0.84, –0.48], resulting in a *NNT* of 7.19, 95% *CrI* [6.18, 8.93]. Sensitivity analyses using a two-stage approach corroborated these results, further underscoring their robustness. The odds ratio (OR) for achieving a minimally important improvement in depressive symptom severity, based on the pooled effect, was 4.85, 95% *CrI* [2.89, 7.45], with a *NNT* of 2.82, 95% *CrI* [2.20, 4.43]. Pooled intervention effects on depressive symptom severity were sustained at T3 (follow-up), *d*=–0.74, 95% *CrI* [–1.01, –0.48], with a *NNT* of 5.61, 95% *CrI* [4.71, 7.67], as well as on the minimally important improvements thereof, *d*=–4.94, 95% *CrI* [2.23, 8.50], with a *NNT* of 2.67, 95% *CrI* [2.04, 5.55]. Furthermore, the one-stage model analysis revealed lower rates of reliable symptom deterioration in the IG, *OR*=0.19, 95% *CrI* [0. 0.75], with a *NNT* 18.07, 95% *CrI* [14.52, 62.39], while this effect was not found using the two-stage model, *OR*=0.43, 95% *CrI* [0, 1.52].

This study also focused on the dose-response relationship and revealed a roughly linear association between the number of completed sessions (i.e., adherence) and depressive symptom severity, assessed with CES-D, at T2. Every additional completed session corresponded to a reduction of 0.63 points on the CES-D scale at T2, β=–0.631, 95% *CrI* [–0.93, –0.329], $\tau_0$=0.29, underscoring the importance of adherence. When only non-responders were investigated, a non-linear association was found with no additional benefit after completing the fourth intervention module.

In conclusion, participation in the digital SMI GET.ON "Fit im Stress" was associated with reduced depressive symptom severity in clinical samples, demonstrating significant and robust effects sustained over time in both short- and long-term outcomes compared to controls, highlighting its potential as indirect intervention for depression.

**Research Question 7: Does the efficacy of a digital stress management intervention in reducing depressive symptom severity differ between full guidance, adherence-focused guidance, and self-help?**

To expand the results gained in Study 1 regarding differences in the efficacy of different guidance formats utilised in GET.ON "Fit im Stress", in Study 3, a first systematic evaluation was conducted to examine the impact of guidance on depressive symptom severity. To detect potential differences, a network IPD meta-analysis was employed to compare full guidance, AFG, and SH. The posterior probabilities of clinically significant benefits were also estimated.

Findings suggested the beneficial effect highest for full guidance, *d*=–0.82, 95% *CrI* [–1.75, 0.11], followed by SH, *d*=–0.57, 95% *CrI* [–1.09, –0.06], and AFG, *d*=–0.48, 95% *CrI* [–1.00, 0.03]. Notably, conclusions regarding additional benefits should be drawn cautiously, as the wide *CrIs* include zero. When comparing full guidance to SH, the effect was estimated at *d*=–0.25, 95% *CrI* [–1.30, 0.82]. There is a 35% posterior probability that the effects of full guidance and SH are clinically equivalent, suggesting a potentially modest benefit. Comparing full guidance to AFG resulted in effect estimates of *d*=0.09, 95% *CrI* [–0.57, 0.73], with a 60% posterior probability that AFG provides no clinically relevant added benefit, indicating that this guidance format might not be substantially more effective than the SH version of the intervention.

In summary, the efficacy of GET.ON "Fit im Stress" in reducing depressive symptom severity does not substantially differ between full guidance, AFG, or SH. While full guidance may offer some additional benefits, findings do not provide robust evidence supporting a substantial difference in the efficacy of different guidance formats. With few participants utilising the options available within AFG, the findings suggest that this format may provide negligible additional benefits. However, further research is needed to strengthen the evidence and better understand the role of guidance in enhancing the efficacy of digital SMIs for depression.

### 3.2 Synthesis of Research

All three studies within this dissertation contribute to a better understanding of the efficacy of the digital SMI GET.ON "Fit im Stress" and influencing factors, offering valuable new insights.

Study 1 was the first trial investigating the comparative efficacy of a digital SMI within a three-armed RCT. The results demonstrated large effect sizes for both guidance formats, AFG and SH, compared to WLC at post-intervention (T2), AFG: *d*=0.83, Δ5.46; SH: *d*=0.88, Δ5.15, and

six-month follow-up (T3), AFG: *d*=0.85, Δ5.78; SH: *d*=0.91, Δ5.41. Additionally, the study aimed to investigate how positive effects can be achieved through participation regarding depression, as this has not been researched previously. The findings of this study provide initial evidence on head-to-head comparisons between two guidance formats within one digital SMI, as well as on the pathways that influence intervention effects.

This study represents the first head-to-head comparison of different guidance formats within one trial; thus, no previous research is available to compare the efficacy to. In the context of existing research, the detected effect sizes in Study 1 were larger than those found previously, including a meta-analysis based on 26 studies resulting in an overall effect size of *d*=0.43 (Heber et al., 2017). The findings of this study are furthermore in line with large effect sizes found in trials investigating the same guidance formats AFG (Ebert, Lehr, et al., 2016) and SH (Ebert, Heber, et al., 2016) within the digital SMI GET.ON "Fit im Stress" separately, with significant effects compared to WLC at post-intervention (T2), AFG: *d*=0.79, Δ4.54; SH: *d*=0.96, Δ5.3, and six-month follow-up (T3), AFG: *d*=0.85, Δ5.19; SH: *d*=0.65, Δ4.3. Against the background of substantial heterogeneity in studies evaluating the efficacy of digital SMIs (Phillips et al., 2019), Study 1 provides new insights into the relative efficacy of different guidance formats within the same intervention framework.

The head-to-head comparison conducted in Study 1 revealed that the intervention was effective irrespective of the guidance format, showing no significant differences between AFG and SH. Despite this, adherence, operationalised as the number of completed modules, was slightly better for AFG (*M*=5.90) compared to SH (*M*=5.17). This suggests that while both formats are equally effective, participants may demonstrate more engagement with AFG despite only few participants making use of available assistance within this format. Participants' preferences further highlight this trend, as, when directly asked, most expressed a preference for regular feedback by an e-coach if they were to participate in a similar training in the future, with AFG being the second most preferred option, and SH being the least favored. These preferences align with findings from a previous RCT on a digital intervention for problematic drinking, demonstrating slightly better adherence for AFG (*M*=3.0) compared to SH (*M*=2.5) (Boß et al., 2018), and a pooled analysis, reporting a higher number of completed modules for AFG (*M*=5.6) compared to SH (*M*=4.4) (Zarski et al., 2016). Despite the preference for more intensive guidance, as mentioned, only a small percentage of participants utilised the options available within AFG. In the present study, only 28% requested feedback, which is consistent with previous findings where only 10% and 5% of participants requested feedback in studies

on digital SMIs for problematic drinking (Boß et al., 2018) and subthreshold depression (Ebert, Buntrock, et al., 2018).

The systematic evaluations from the IPD meta-analysis conducted in Study 3 provided further insights into the differences between the guidance formats with depression as outcome. They indicate a 60% probability that AFG may not significantly enhance the efficacy of GET.ON "Fit im Stress", relative to a lower probability of 35% for full guidance. However, it should be noted that the wide confidence intervals suggest uncertainty regarding the precise effect size estimates. Additionally, Study 3 revealed a linear association between adherence, measured by the number of completed intervention modules, and the outcome, depressive symptom severity. This highlights the critical importance of adherence for both providers and users, emphasising that consistent engagement with the entire intervention is vital for effectively and sustainably achieving changes in health outcomes. Prior to this dissertation, it was widely assumed that providing guidance would enhance the efficacy of digital SMIs (Baumeister et al., 2014; Carolan et al., 2017; Heber et al., 2017). However, the findings from the head-to-head comparison and systematic evaluation within this dissertation challenge this assumption, showing that GET.ON "Fit im Stress" was equally effective across different guidance formats. Nonetheless, adherence was significantly better in AFG compared to SH, although the low utilisation rates of AFG, in all to date available studies, highlight the need for further research to better understand and optimise user engagement.

In Study 2, the previous findings of positive effects on stress levels were replicated by offering GET.ON "Fit im Stress" with AFG to a high-risk population of employees exposed to adverse working conditions. The results demonstrated practically meaningful moderate to large effect sizes for the IG compared to the WLC at post-treatment (T2), $d$=0.87, Δ5.00, and six-month follow-up (T3), $d$=0.65, Δ4.19. This study represents an initial investigation into the efficacy of a digital SMI among employees, considering working conditions as environmental factors. Therefore, the results provide unique evidence in addressing whether a person-centered digital SMI can facilitate positive health effects despite adverse working conditions. In comparison to the AFG condition in Study 1, the effect sizes for the same guidance format were smaller at follow-up in this sample. This comparison raises important questions for future research, particularly concerning which type of intervention is not only most effective but also sustainable for individuals experiencing a high ERI imbalance in the workplace. This could serve as a fruitful starting point to explore the integration of person-focused SMIs, as examined within this dissertation, with organisation-focused interventions, with an umbrella review underscoring the importance of acknowledging the impact of systemic workplace issues on

health and emphasising that occupational interventions should not be limited to individual-level changes (Rugulies et al., 2023).

The results in Study 3 represent the first systematic evaluation of GET.ON "Fit im Stress" as an indirect treatment for depression, based on a newly developed paradigm (Cuijpers, 2021), demonstrating moderate to large effect sizes at post-intervention (T2), $d$=0.65, and follow-up (T3), $d$=0.74. These findings highlight the potential of GET.ON "Fit im Stress" to effectively reduce depressive symptom severity in clinical samples. Given the distinct nature of this study, comparative evidence on the efficacy of digital SMIs as indirect treatment for depression and other health outcomes remains limited. Despite the limited body of research, Study 1 was a promising starting point for conducting Study 3 by identifying stress reduction as a key mechanism influencing the intervention's effects on depression. Furthermore, the findings from Study 3 align with broader research demonstrating that individuals with high levels of stress and depressive symptom severity benefited significantly from participating in a digital SMI with great reductions of both stress levels ($d$=0.86) and depression scores ($d$=0.69) (Weisel et al., 2018), next to a previous meta-analysis including 26 trials on digital SMIs that reported a significant effect on depression ($d$=0.34) (Heber et al., 2017), which was smaller relative to the findings of the present study. In this comparison, it should be acknowledged that the meta-analysis included a variety of digital SMIs, while the present IPD meta-analysis focused exclusively on RCTs examining GET.ON "Fit im Stress". This focus reduces the heterogeneity and enhances the robustness of the findings, highlighting the potential of this specific digital SMI in reducing depressive symptoms and therefore being utilised as indirect intervention. The design of the intervention itself may also provide an explanation for the higher effect sizes found in this study, as GET.ON "Fit im Stress" is grounded in a robust theoretical framework based on transactional model of stress (Lazarus & Folkman, 1984), incorporating two main components: problem-solving and emotion regulation. These components are commonly used in depression treatment and have demonstrated efficacy in face-to-face settings, potentially yielding larger effect sizes. Additionally, the intervention's focus on a limited number of core modules is associated with better outcomes (Richardson & Rothstein, 2008).

In summary, the three studies within this dissertation contribute to a deeper understanding of the efficacy of GET.ON "Fit im Stress" across different guidance formats. By investigating the comparative efficacy of different guidance formats, exploring mechanisms of change, assessing outcomes in a high-risk population, and evaluating the intervention as indirect treatment for depression, the studies offer valuable and comprehensive insights.

### 3.3 Strengths and Limitations

The studies in this dissertation demonstrate several conceptual and methodological strengths. Each of the three studies was conducted and published in adherence to the highest scientific standards, following Consolidated Standards of Reporting Trials (Schulz et al., 2010). All studies addressed gaps in research concerning the efficacy of digital SMIs. Notably, Study 1 was the first to conduct a direct head-to-head comparison between different guidance formats within a digital SMI. Study 2 pioneered the utilisation of a digital SMI within a high-risk population experiencing adverse working conditions. Lastly, Study 3 represented the first empirical test of the newly developed paradigm utilising a digital SMI as an indirect treatment for depression. The robustness of the findings in each study was further confirmed through additional sensitivity analyses. User safety was rigorously prioritised in all three studies by calculating reliable change and reporting deterioration rates. Multiple assessments were conducted across all studies to examine effects at post-intervention and at follow-up, allowing for conclusions on the sustainability of the findings. Altogether, a practical strength lies in the essential insights gained into the comparative efficacy of guidance formats, mechanisms of change, environmental factors, and the use of the intervention an as indirect intervention. These insights are crucial for the effective design and implementation of a digital SMI to effectively promote health.

In Studies 1 and 2, additional mediation analyses were performed to explore mechanisms of change, enhancing the understanding of not only ‘whether’ the digital SMI is effective, but also ‘how’ these effects are achieved. The importance and the necessity of studies examining mechanisms of change have been emphasised to deepen our understanding of efficacy (Drozd et al., 2013; Mogoașe et al., 2017). Study 1 focused on the intervention’s impact on depressive symptoms, as the utilisation of SMIs is regarded as a strategy to prevent depression. Study 2 addressed a previously identified gap in research on occupational self-efficacy (Ebert, Lehr, et al., 2016) and uniquely considered environmental factors, operationalised as ERI (Siegrist et al., 2009).

Additionally, Studies 1 and 2 replicated earlier findings on GET.ON “Fit im Stress” regarding stress and other health- and work-related outcomes (Ebert et al., 2021; Ebert, Heber, et al., 2016; Ebert, Lehr, et al., 2016; Heber et al., 2016). These replications strengthen the validity and reliability of the findings by confirming the consistency and robustness of the observed effects, thereby enhancing the overall credibility and trustworthiness of the outcomes. This is further underscored by the IPD meta-analysis conducted in Study 3.

Study 3 represented the first systematic evaluation of the efficacy of a digital SMI on depression, a growing health concern in both general and working populations. This study demonstrated conceptual strength through employing IPD meta-analysis, which is considered the gold standard of evidence synthesis (Stewart & Tierney, 2002). This approach allowed for more sophisticated analyses; while reducing heterogeneity due to the intervention and guidance formats being standardised across the single trials, thereby increasing the internal validity of the results. Further methodological strengths lie in employing the anchor-based approach to calculate response rates, as recommended (Cook et al., 2018; Devji et al., 2021; Haase et al., 2022). Another strength of Study 3 are the compelling positive effects achieved within clinical samples, as only subjects with clinically relevant depression were included.

All three studies included in this dissertation have several limitations. Data were gathered from populations recruited from the open community. This may limit the generalisability of the results, as individuals self-selected to participate, potentially inflating intrinsic motivation to improve health outcomes and amplify the effects of a digital SMI (Phillips et al., 2019). As a result, caution is needed when drawing conclusions about the broader uptake of a digital SMI, particularly in occupational populations, as the findings may not accurately reflect the potential motivation levels and resource access in these groups. Moreover, an inclusion criterion across all studies was an elevated stress level, assessed with PSS-10 (Cohen, 1994). This criterion might have led to larger improvements compared to populations with lower stress levels; thus, the generalisability to those individuals might be limited. Standardising this criterion in the studies is, however, a methodological strength, as it allows for better comparability of the findings across studies.

A limitation that needs to be considered in Study 1 and the subsequent IPD meta-analysis in Study 3 is the low utilisation rate of the investigated guidance format, AFG. Both studies indicated no additional benefit for AFG compared to SH, although adherence appeared to be slightly better for AFG. The uncertainty around the found effect sizes for AFG highlights the need for future studies to further explore differences between guidance formats in digital SMIs particularly regarding their efficacy, adherence, and acceptance. These findings also open avenues for investigating optimal strategies for promoting engagement with different types of guidance formats within digital SMIs, including factors that drive users to actively seek support.

In Study 2, the persisting adverse effects of efforts, as measured with ERI (Siegrist et al., 2009), suggest that the individual-focused digital SMI GET.ON “Fit im Stress” may not fully address the factors that could potentially influence environmental factors at work. It remains an open question whether an organisational-focused intervention SMI could be more effective in

significantly reducing efforts and their impact on employees' well-being by targeting the workplace directly. Moreover, the modules in the intervention were developed based on Lazarus' transactional model of stress (Lazarus & Folkman, 1984), with problem-solving and emotion regulation as core components. Therefore, the findings of the studies cannot be generalised to digital SMIs with different theoretical foundations.

A methodological limitation in Study 3 involves the identification of individuals with clinically relevant depression through cut-off scores, since no diagnostic interviews were conducted to select participants. For this reason, future studies should include participants with formally diagnosed depression to validate the promising results.

In conclusion, the strengths and limitations of the three conducted studies in this dissertation highlight critical considerations for future research and raise several new questions for subsequent trials.

### 3.4 Implications and Future Directions

The studies conducted within this dissertation offer valuable insights into the efficacy of the digital SMI GET.ON "Fit im Stress" in mitigating the adverse effects of stress on employee health, offering several avenues for future research in this domain.

Study 1 provided the first direct comparison of different guidance formats within a single trial on GET.ON "Fit im Stress" and revealed that the intervention could achieve sustainable effects with limited resources. Furthermore, mediation analyses underscored the importance of interventions addressing both processes: health impairing (i.e., reducing 'the bad') and health promoting (i.e., strengthening 'the good'), suggesting a balanced approach in intervention design. The comparative analysis of AFG and SH conducted in this study provides a good foundation for exploring factors that may enhance the utilisation rate. This aligns with the current body of research on digital interventions employing AFG for problematic drinking (Boß et al., 2018), stress management (Ebert, Lehr, et al., 2016; Zarski et al., 2016), and cannabis use reduction (Baumgartner et al., 2021). These studies underscore the necessity for more nuanced investigations, as it remains unclear how AFG, as a distinctive guidance format, needs to differ from other guidance formats to reach its full potential and to optimise outcomes. Future studies could examine whether targeted promotion of AFG or enhancements in the format itself could improve engagement with this type of guidance. Based on Study 1, a prospective study could, for instance, conduct a three-armed RCT with intervention groups that actively promote AFG versus those that do not, assessing utilisation metrics such as login frequency, number of

inquired feedback, feedback interactions, and rates of module completion. This direct comparison would facilitate testing the assumption that participants in previous studies, including Study 1 conducted within this dissertation, may not have been fully aware of the opportunities inherent in their assigned guidance format (Boß et al., 2018; Ebert, Buntrock, et al., 2018).

Study 2 demonstrated first positive and sustainable effects of a digital SMI on reducing stress levels in employees exposed to adverse working conditions. These findings suggest that implementing a digital SMI can be beneficial despite challenges in the work environment, highlighting the potential for interventions to positively impact employee well-being irrespective of external work conditions. Particularly, occupational self-efficacy was identified as a relevant personal resource, emphasising its importance in developing SMIs for employees. While the findings revealed indirect effects of the intervention on perceived stress through occupational self-efficacy and rewards, such effects could not be demonstrated for efforts. Future research could therefore test the assumption that these findings indicate a need for more personal support for employees facing adverse working conditions to achieve more pronounced effects on workplace factors such as efforts. A similar study could be conducted utilising full guidance instead of AFG, as in Study 2, to examine how this change might impact efficacy on working conditions and to identify the most effective strategy. Future studies should also explore whether the nature of the topics influences the efficacy. In Study 2, participants chose their focus, addressing either personal or work-related issues, depending on personal preferences. An avenue for future research is to understand if and how the chosen issues participants work on might influence the outcome or acceptance of the intervention and if differences can be found for personal- or work-related topics. In addition to this, more nuanced studies are needed to compare organisational-focused versus individual-focused digital SMIs or their combinations. Specifically, future studies should perform head-to-head comparisons to identify which approach, or which combination, yields the most significant benefits for employees facing adverse working conditions. Critical aspects future studies should address in these comparisons are, for example, communication strategies to enhance the acceptance and uptake of digital interventions in the workplace to harness their full potential (Philippi et al., 2021).

Study 3 presented the initial systematic evaluation of GET.ON “Fit im Stress” within clinical samples, demonstrating positive effects of a digital SMI on depression for the first time. This study holds considerable implications for both research and practice in mental health since it represents the first systematic exploration of the novel paradigm proposing the use of indirect

interventions (Cuijpers, 2021). The relevance of this study lies in its potential to transform how digital SMIs are perceived and utilised, particularly in clinical populations. From both conceptual and methodological perspectives, future evaluations of the efficacy of digital SMIs on depression should pre-specify depression as the primary outcome, rather than focusing on perceived stress, which was the primary outcome in the RCTs included in Study 3. Additionally, head-to-head comparisons between indirect and direct treatment approaches within single trials would provide valuable insights into their relative efficacy and uptake. Following this initial demonstration of positive effects, it is essential to further examine the paradigm of indirect treatments and to test the assumption that this novel approach appeals to individuals who are hesitant to seek traditional forms of help, particularly by not overtly addressing issues associated with depression initially, as underscored before (Cuijpers, 2021). In the treatment of depression, several moderators have been identified that impact the efficacy of digital interventions. Along with clinical factors such as the severity and chronicity of depressive symptoms and demographic variables such as age and education levels, a recent systematic review has highlighted additional factors such as motivation and the extent of engagement with the intervention (Sextl-Plötz et al., 2024). These findings should be considered in future studies conducting moderator analyses that aim to determine whether these previously identified factors are also relevant in the utilisation of digital SMIs as indirect treatment for depression.

In conclusion, the findings of the three studies offer valuable insights into the efficacy of the digital SMI GET.ON “Fit im Stress” in employees and underscore the need for further research to optimise its implementation and address the challenges posed by adverse working conditions.

### 3.5 General Conclusion

The combined findings from the three studies conducted within this dissertation demonstrated the efficacy of GET.ON “Fit im Stress” in reducing stress and alleviating depressive symptom severity in employees, irrespective of the utilised guidance format or adverse working conditions. Specifically, Study 1 demonstrated that participation in GET.ON “Fit im Stress” was associated with sustainable positive effects regarding stress levels in employees and further secondary health outcomes, regardless of the guidance format. Moreover, the study highlighted the importance of addressing both health impairing (i.e., stress reducing) and health promoting (i.e., resilience building) processes in intervention design.

Study 2 extended the existing body of research on the efficacy of digital SMIs by considering the impact of the work environment, demonstrating positive outcomes in a high-risk population

facing adverse working conditions. Additionally, the study underscored the importance of considering occupational self-efficacy in the design and implementation of an occupational digital SMI, while noting the limited effects of the intervention on working conditions directly.

Study 3 provided important implications for the indirect treatment of depression through a digital SMI. This study is the first to show that participation in a digital SMI could effectively reduce depressive symptom severity, with outcomes comparable to direct interventions for depression. Furthermore, all three studies highlighted the importance of user safety and satisfaction in implementing digital SMIs. GET.ON “Fit im Stress” was found to be appealing to both first-time users and participants with prior experience in digital health interventions.

Collectively, the studies underscored the potential of GET.ON “Fit im Stress” to provide effective and sustainable health promotion solutions in the workplace. They also identified avenues for future research focusing on optimising digital SMIs and addressing the complex interactions between personal and environmental factors in occupational health.

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