


BMJ Open E-mental health mindfulness-based and skills-based 'CoPE It' intervention to reduce psychological distress in times of COVID-19: study protocol for a bicentre longitudinal study

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To cite: Bäuerle A, Graf J, Jansen C, *et al.* E-mental health mindfulness-based and skills-based 'CoPE It' intervention to reduce psychological distress in times of COVID-19: study protocol for a bicentre longitudinal study. *BMJ Open* 2020;**10**:e039646. doi:10.1136/bmjopen-2020-039646

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-039646>).

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Received 21 April 2020

Revised 24 July 2020

Accepted 29 July 2020



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ABSTRACT

Introduction The SARS-CoV-2 (COVID-19) pandemic poses immense challenges for national and international healthcare systems. Especially in times of social isolation and governmental restrictions, mental health should not be neglected. Innovative approaches are required to support psychologically burdened people. The e-mental health intervention 'CoPE It' has been developed to offer manualised and evidence-based psychotherapeutic support adapted to COVID-19-related issues in order to overcome psychological distress. In our study, we aim to assess the efficacy of the e-mental health intervention 'CoPE It' in terms of reducing distress (primary outcome), depression and anxiety symptoms as well as improving self-efficacy, quality of life and mindfulness (secondary outcomes). Furthermore, we want to evaluate the programme's usability, feasibility and participants' satisfaction with 'CoPE It' (tertiary outcome).

Methods and analysis The e-mental health intervention 'CoPE It' consists of four 30 min modules, conducted every other day, involving psychotherapeutic techniques of mindfulness-based stress reduction and cognitive-behavioural therapy. The widely applied and previously established content has been adapted to the context of the COVID-19 pandemic by experts in psychosomatic medicine and stress prevention. In our longitudinal study, adult participants—with adequate German language and computer skills, and who have provided informed consent—will be recruited via emergency support hotlines in Germany. Flyers will be distributed, and online channels will be used. Participants will complete a baseline assessment (T0), a postintervention assessment (T1) and assessments 1 and 3 months later (T2 and T3, respectively). We will perform repeated measures analysis of covariance, mixed linear models, standard analyses of variance and regression, and correlation coefficients. In case of binary outcome variables, either mixed logistic regression or χ^2 tests will be used.

Ethics and dissemination The Ethics Committees of the University of Duisburg-Essen (20-9243-BO) and University of Tübingen (469/2020BO) approved the study. Results will be published in peer-reviewed journals and conference presentations.

Strengths and limitations of this study

- Innovative approach to confront mental health aspects of COVID-19 pandemic.
- The e-mental health intervention was developed using evidence-based and theory-based approaches.
- No randomised controlled study design.

Trial registration number DRKS00021301.

INTRODUCTION

The first cases of the novel SARS-CoV-2 virus (COVID-19) were reported in the metropolis city of Wuhan, China, in December 2019.¹ After 3 months of alarming reports from Asia, especially China, the virus has now reached most countries in the world. On 11 March 2020, the WHO officially classified the spread of the virus as the first pandemic since H1N1 in 2009/2010.² In Europe, Spain, Italy and England are particularly affected by the virus and have reported thousands of deaths due to COVID-19.³ In Germany, more than 170 000 infections have been reported, but comparatively few deaths are occurring.³ So far, little is known about which medications and vaccinations could be used to combat the virus effectively. Therefore, governmental priorities are focused on actions to 'flatten the curve' and stop the spread of the virus. As in many other countries, the German government has put in place restrictions which affect people's personal lives, imposed contact prohibitions to enforce physical distancing and put many people in private quarantine. These actions—while necessary to slow down the spread of

the virus—also constitute tremendous obstacles for the economy, public life and every single person.

Mental health in times of COVID-19

Previous studies investigating the psychological impact of social isolation indicate that different stressors cause fear and frustration during quarantine, such as the fear of infection, boredom or inadequate information.⁴ The psychological impact caused by the COVID-19 pandemic on people's mental health has been investigated in several studies.^{5–11} In fact, one study conducted during the initial stage of the COVID-19 pandemic in China showed that 53.8% of respondents rated the psychological impact of the pandemic as moderate or severe; 16.5% reported moderate to severe depressive symptoms; 28.8% reported moderate to severe anxiety symptoms; and 8.1% reported moderate to severe stress levels.⁶ Moreover, a longitudinal study investigating the mental health burden of the general population in China revealed that perceived psychological impact of the pandemic, depressive symptoms, anxiety symptoms and stress levels persist for up to 1 month after the outbreak of the virus.⁷ Furthermore, psychiatric patients are deprived of their usual care services and treatment while the pandemic is ongoing, and are more anxious, depressed and stressed than the general population.⁸ Existing literature regarding the emotional burden of healthcare workers caring for patients with COVID-19 indicates heightened levels of anxiety, depression and stress but a lack of psychological support.⁹ In fact, 14.5% of the participants screened positive for anxiety, 8.9% for depression, 6.6% for stress and 7.7% for post-traumatic stress disorder.⁹ These findings highlight the importance of supporting people during the COVID-19 pandemic and maintaining their mental health. Especially after weeks of lockdown, people need support when returning to work.¹⁰ In contrast, a recent study emphasised the difficulties faced by workers in accessing psychological or medical help during the ongoing pandemic due to the lockdown and the lack of psychological first aid interventions.¹¹

E-mental health approaches

Considering the psychological impact of the ongoing COVID-19 pandemic and the lack of psychological support available, innovative and situation-based approaches to foster psychological well-being are urgently needed.¹² Supportive approaches need to be anonymous, low threshold and freely accessible.¹³ The benefits of e-mental health approaches have been discussed in depth in the mental health community before, and given the current situation, they have never been as evident. Offering manualised support to many people simultaneously, anonymously and in a low-threshold manner constitutes a great resource in times of COVID-19. Compared with the effects of face-to-face interventions in several mental and somatic disorders, online interventions lead to comparably efficient outcomes.^{14 15} Various eHealth approaches from different medical fields have

already been implemented into medical care during the COVID-19 pandemic.^{16–18} They offer great advantages in terms of patient-professional communication and provide timely symptom management. Rehabilitation programmes which support patients with the SARS-CoV-2 virus in maintaining their physical fitness during individual quarantine have been reported by one centre in Japan.¹⁶ A multi-institutional study investigating potential benefits and pitfalls of telemedicine in outpatient neuro-oncological care during COVID-19 showed that telemedicine is a powerful and possibly preferable tool for the future.¹⁷ Moreover, different clinics in the USA reported a reduction in medical visits per day in primary care practices, due to the use of virtual practices.¹⁸ Furthermore, patients from those clinics had an almost universally positive response to those changes.¹⁸

Accordingly, there is an urgent need to implement e-mental health interventions for the general community to address the mental burden of the current COVID-19 crisis. It is necessary to promptly start adopting e-mental health interventions in order to cope with the mental health symptoms due to the coronavirus outbreak.¹⁹ Therefore, developing as well as establishing e-mental health interventions to efficiently confront increased mental health burdens and a lack of appropriate emotional support in times of COVID-19 is urgently needed.

Objectives and research questions

'Coping with Corona: Extended Psychosomatic care in Essen' (CoPE) is a structured clinical approach to support psychologically burdened people in Essen, Germany.²⁰ As an integral part of the 'CoPE' concept, the e-mental health intervention 'CoPE It' offers a web-based, self-guided approach to provide support to counteract psychological strain, which is directly or indirectly caused by the coronavirus.²¹ The objective of this study is to assess the efficacy of the e-mental health intervention 'CoPE It' in a longitudinal study design. To that end, our primary research question is:

1. Does the e-mental health intervention 'CoPE It' reduce participants' distress?

Secondary objectives refer to further aspects regarding the efficacy of 'CoPE It'. To that end, we developed two research questions:

1. Does the e-mental health intervention 'CoPE It' reduce anxiety and depression symptoms among participants?
2. Does the e-mental health intervention 'CoPE It' increase self-efficacy, quality of life and mindfulness among participants?

Tertiary objectives refer to further evaluation of 'CoPE It' with respect to the usability of and participants' satisfaction with 'CoPE It'. To that end, we developed two research questions:

1. How do participants evaluate the usability of the 'CoPE It' intervention?
2. How satisfied are participants with the 'CoPE It' intervention?

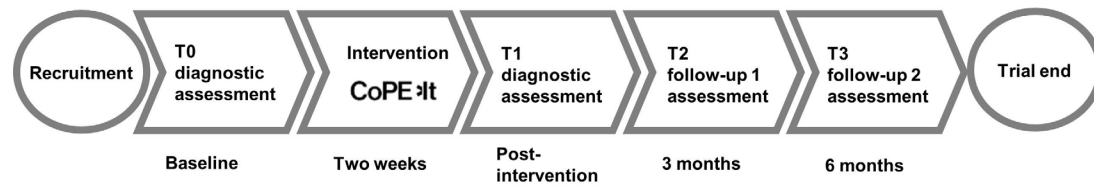


Figure 1 Trial flow.

In times of severe restrictions on social life, the benefits of e-mental health interventions are excellent, innovative resources which are currently more necessary than ever before. Such telemedical approaches need to be implemented in public health strategies in order to support many people simultaneously and effectively.²²

METHODS AND ANALYSIS

Study design

Our bicentre longitudinal study is designed to offer the low-threshold, web-based ‘CoPE It’ intervention for psychologically burdened individuals in times of COVID-19, and to investigate its efficacy. The trial flow is shown in [figure 1](#). Before participation, informed consent must be given. Participants need to create an account with their own credentials. Once username and password have been created on *cope-corona.de*, participants will complete the online baseline assessment (T0) and receive access to the first module. The postintervention, as well as the follow-up assessments, will take place after completing the intervention (T1) and both 1 and 3 months later (T2 and T3, respectively). During the intervention, each patient will receive a notification stating that a new module is accessible. To encourage participants to keep up with the study those who have been inactive for 4 days will receive an additional notification to motivate them to continue ‘CoPE It’. The intervention is considered to be completed when all four modules have been conducted.

Participant eligibility and recruitment

We applied a number of eligibility criteria. Participants will be included provided that they have a good command of the German language, internet access and basic computer skills, are at least 18 years of age and have given their informed consent (see online supplementary material 1). Participants will be recruited through the CoPE hotline, other emergency support hotlines in Germany, via the distribution of flyers and from the publicly accessible website as well as social media. Their informed consent will be given when they provide their online confirmation of the study conditions in advance of the first assessment.

The ‘CoPE It’ e-mental health intervention

‘CoPE It’ is a self-guided e-mental health intervention, which participants can use on their own personal computers, smartphones or tablets.²¹ ‘CoPE It’ addresses current findings on mental health issues and support approaches during the COVID-19 pandemic.^{6–8 23–26} Therefore, the web-based

intervention aims to reduce psychological distress by enhancing adaptive coping strategies, self-efficacy, daily routine, sleep quality, and activating individual resources as well as physical exercises. ‘CoPE It’ is based on evidence-based methods of cognitive-behavioural therapy and mindfulness-based stress reduction,^{27–29} and it has been adapted to the context of the COVID-19 pandemic by an expert panel for psychosomatic medicine and stress prevention from the University of Duisburg-Essen and University of Tübingen. Previous research showed the efficacy of cognitive-behavioural therapy on mental health outcomes (eg, post-traumatic distress, depression, poor sleep quality) after natural disasters.^{30–33} Furthermore, evidence exists that mindfulness-based stress reduction for people affected by man-made disasters relieves the negative outcomes of such events.^{34–37}

By combining both skills training and mindfulness practices, ‘CoPE It’ can address the different needs of psychologically burdened people in times of COVID-19. The four modules of ‘CoPE It’ contain different media, including psychoeducational videos, audio-guided mindfulness exercises and interactive skills training to enhance the acquisition of knowledge about specific topics (eg, rituals and routines, resources, stress management and self-compassion). [Table 1](#) gives an overview of the contents of the modules of ‘CoPE It’.²¹ The intervention consists of four 30 min modules offered every other day after one module has been finished. After each module, participants receive an individual summary of the finished module with what they have achieved, a mindfulness exercise schedule and motivational quotes. Additional mindfulness exercises, which can be performed at home, should be integrated into participants’ daily routines. To enhance this integration the participants will receive regular mindfulness notifications. An example exercise from the ‘CoPE It’ training is the ABC model (A—activating event; B—beliefs; C—consequences) which is introduced in module 2. It is a technique to overcome irrational beliefs, which was pioneered by Albert Ellis.³⁸ The idea and the aim of the ABC model is explained to the participant using tutorial videos. In a first step, the participant fills in an exercise sheet about his/her own ABC model. In a second step, the participants can select cognitive self-effective affirmation (=skills) to overcome irrational beliefs and to enhance their stress management competence.

Primary outcome measures

The schedule of the different assessments, each lasting between 10 and 25 min, is summarised in [table 2](#). Data will

Table 1 COVID-19-adapted topics, contents and exercises from 'CoPE It'

Topic	Skills training	Mindfulness	
Module 1	<ul style="list-style-type: none"> ▶ The rationale of the skills and mindfulness training Rituals and routines 	<ul style="list-style-type: none"> ▶ Planning a daily routine in times of COVID-19 ▶ Activating personal contacts ▶ Enhancing sleep routine 	Mindful breathing
Module 2	<ul style="list-style-type: none"> ▶ Coping with distress in times of COVID-19 Stress management 	<ul style="list-style-type: none"> ▶ Stress management model ▶ Encouraging quotes ▶ Self-effective skills 	Mindful experiencing
Module 3	<ul style="list-style-type: none"> ▶ Individual resources ▶ Resource management strategies 	<ul style="list-style-type: none"> ▶ Activating individual resources in times of COVID-19 ▶ Searching for possible enjoyable activities ▶ Activity skills 	Mindful compassion
Module 4	<ul style="list-style-type: none"> ▶ Skills box to handle psychological burdens in the times of COVID-19 	<ul style="list-style-type: none"> ▶ Individual skills for emotional emergencies ▶ My psychological emergency kit ▶ Reminder skills 	Mindful body awareness

be collected through an online survey tool, which is integrated directly in the 'CoPE It' platform. As the primary outcome, we chose psychological distress at T1, which will be assessed using the German version of the Perceived Stress Questionnaire (PSQ).³⁹

Secondary outcome measures

Depressive and anxiety symptoms will be assessed using the German version of the Patient Health Questionnaire Depression Scale and the Generalized Anxiety Disorder Scale-7.^{40 41} To assess self-efficacy, we plan to use

the German version of the General Self-Efficacy Scale (GSE),⁴² while to assess mindfulness, we propose to use the German version of the Freiburg Mindfulness Inventory.⁴³ Lastly, to assess participants' quality of life, we plan to use the German version of the 5-item European Quality of Life 5 Dimensions 3 Level Version questionnaire.⁴⁴

Evaluation of the 'CoPE It' e-mental health intervention

The usability of and participants' satisfaction with 'CoPE It' will be evaluated via assessment of a modified German version of the 10-item System Usability Scale,⁴⁵ the German

Table 2 Assessment schedule

Measures	T0: baseline	T1: post-intervention	T2 and T3: follow-up at 3 and 6 months
Primary outcome			
PSQ-20	x	x	x
Secondary outcomes			
PHQ-8	x	x	x
GAD-7	x	x	x
GSE	x	x	x
FMI	x	x	x
EQ-5D-3L	x	x	x
Evaluation of 'CoPE It'			
SUS		x	
CSQ-I		x	
Self-generated evaluation items		x	
Attitudes towards e-mental health			
APOI	x		
Demographics	x		
COVID-19-related data	x	x	x

APOI, Attitudes towards Psychological Online Interventions; CSQ-I, Client Satisfaction Questionnaire adapted to Internet-based interventions; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; FMI, Freiburg Mindfulness Inventory; GAD-7, Generalized Anxiety Disorder Scale-7; GSE, General Self-Efficacy Scale; PHQ-8, Patient Health Questionnaire Depression Scale; PSQ-20, Perceived Stress Questionnaire; SUS, System Usability Scale.

version of the Client Satisfaction Questionnaire adapted to Internet-based interventions⁴⁶ as well as custom-made items. Data concerning adherence to the training (eg, last login and time needed for modules) will be collected via back-end functions of the ‘CoPE It’ system.

Attitudes towards e-mental health, demographics and COVID-19-related data

The participants’ attitudes towards e-mental health interventions will be assessed using the Attitudes towards Psychological Online Interventions (APOI) instrument.⁴⁷ Demographic data (eg, gender, age, family status and employment status) and data regarding COVID-19 (eg, utilisation of health services during the pandemic, contact with COVID-19 history variables, knowledge about COVID-19, personal restrictions due to COVID-19, personal measures taken against COVID-19) will be collected. Variables on COVID-19 used in this study were adapted and translated from the ‘National University of Singapore COVID-19 questionnaire’ validated in the initial phase of COVID-19.⁶ This questionnaire has already been used in a longitudinal landmark study investigating mental health during COVID-19.⁷ The instrument is to our knowledge the most complete one for our purposes. It was translated and adapted by our working group into German language. The data will be assessed via the ‘CoPE It’ online survey application before the participants start the intervention (T0).

Sample size calculation and statistical analyses

Our design requires the computation of a repeated measures analysis of covariance (ANCOVA) with T0 and T1 as a within-subject factor and a number of covariates to condition on in order to control for potential confounds. We will add age, gender, the participants’ education, their health status, prior mental illness, as well as attitudes towards e-mental health interventions, assessed with the APOI as covariates.⁴⁷ For such a design, we found that we need a sample size of 110 complete cases given a T0–T1 difference of $d=0.30$, a desired power of ~80%, at an alpha level of 0.05 (see online supplementary material 2 for power analyses). We furthermore expect a dropout rate of up to 50%, as it is realistic for online interventions.⁴⁸ Assuming that some participants will not finish the first assessment and thus not start with ‘CoPE It’,⁴⁹ we plan to recruit $110 \text{ required} + 110 + 20 = n = 240$ participants at T0.

We will perform standard tests of normality and homogeneity as well as different descriptive analyses of socio-demographic data. The primary statistical analyses will be *F*-tests for repeated measures AN(C)OVAs (ie, with two-sided *p* values and 95% CIs). The primary analysis will be in the intention-to-treat population, with imputation of missing data in the case of dropouts. *Intention to treat* will be defined as all patients for whom the PSQ-20 scale is available at baseline. Additionally, it is expected that patient age and sex will be documented, and these variables will be used to impute missing values. Imputation will be computed using the SPSS (IBM: Version 26)

module for multiple imputations with ‘monotone missing pattern’ (as we will use complete data for sex, age and baseline). The number of imputations will be 3000, and the seed will be set to the date of analysis (ddmmyy). Furthermore, it is expected that endpoint measurements might be obtained from at least a subsample of dropouts, which might improve the accuracy of imputation procedures. An interim analysis is not planned. Secondary analyses include mixed models for overall change in distress; anxiety, depression, self-efficacy; mindfulness; and quality of life including age, gender, the participants’ education, their health status, prior mental illness, as well as attitudes towards e-mental health intervention; the analyses will use T0 as covariate and T1, T2 and T3 as dependent observations with a predefined analysis: interaction of group with contrasts estimation of adjusted mean and 95% CI. Furthermore, secondary endpoints will be analysed using a χ^2 test and logistic regression for binary outcomes, *t*-tests, and linear models for continuous outcomes. We will additionally investigate potential moderators of our effect, such as, for example, baseline depression or demographic variables and overall stance towards online interventions. Here, we will resort to mixed linear models, standard analyses of variance and regression, and correlation coefficients. In case of binary outcome variables, either mixed logistic regression or χ^2 tests will be used.

Patient and public involvement

Neither patients nor the public were involved in the development of this study design, but the CoPE concept was developed in close cooperation with the department of health of the city of Essen.²⁰

Ethics and dissemination

The Ethics Committee of the Medical Faculty of the University of Duisburg-Essen approved the study (20-9243-BO). Results will be published in peer-reviewed journals and conference presentations. Key findings will also be published on the publicly accessible website and disseminated via the various media.

Trial status

Trial start date: 23 April 2020; currently not recruiting ($n_{\text{current}}=0$ as of 21 April 2020).

DISCUSSION

In our study, we propose to evaluate the effectiveness of the highly topical e-mental health intervention ‘CoPE It’ to support psychologically burdened people in times of COVID-19. The data of previously published studies which investigated mental health during the COVID-19 pandemic clearly showed an increased mental health burden.^{5–11} The lack of a daily routine and COVID-19-related fears and uncertainties may affect psychological well-being including depression, anxiety, sleep disorders, aggression, drug abuse or even suicidal behaviour.⁴ Today’s healthcare systems, public health strategists and

policy-makers must respond to these needs. Structured approaches are needed. Our preliminary findings from a longitudinal assessment will suggest whether the self-guided e-mental health intervention ‘CoPE It’ is an efficient approach to support burdened people in times of COVID-19. One limitation of the study is that the adapted variables regarding COVID-19 were not validated in German language. The German translation and adaptation of the ‘National University of Singapore COVID-19 questionnaire’ were based on expert consensus and were not validated a priori. A further limitation of the study is its naturalistic design without any control group. Considering the current situation, we think it is important to offer all people support who indicate interest in participation. Therefore, we did not establish a control group who has no access to ‘CoPE It’. Furthermore, a lack of resources, potential difficulties in recruiting participants and ethical considerations expressed by the responsible ethics committee led to the decision not to apply a randomised control design. Nevertheless, it is not possible to establish the efficacy of ‘CoPE It’ definitively without applying a randomised control design. Adequate and feasible support for mentally stressed people in times of the COVID-19 pandemic is important and urgently needed. Telemedical approaches represent a suitable solution here. The ‘CoPE It’ e-mental health intervention is based on evidence-based content and offers a low-threshold approach to support those in need. To our knowledge, ‘CoPE It’ is the first manualised, self-guided e-mental health intervention for German-speaking people which adopts existing findings on mental health issues during the COVID-19 pandemic and is based on evidence-based techniques.

Contributors AB and JG contributed equally to designing the study, developing the intervention, administering the trial and preparing the manuscript. EMS and MT initiated the study and contributed to designing the study, developing the intervention, procuring funding and preparing the manuscript. CJ developed the information technology structure for the study and intervention as well as contributing to preparing the manuscript. MH, VM, AS, BW, ND and FJ contributed to designing the study, developing the intervention and helping with the manuscript. All authors have read and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The Ethics Committee of the Medical Faculty of the University of Duisburg-Essen approved the study (20-9243-B0).

Provenance and peer review Not commissioned; externally peer reviewed.

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