

**Coping with a pandemic: Findings on efficacy and predictors of treatment outcome
in an internet-based self-help intervention for COVID-19 related psychological distress**

Cumulative doctoral thesis presented to the faculty of Human Sciences of the University of Bern
for the degree of Doctorate in Psychology

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Summary

The ongoing COVID-19 pandemic represents a non-normative life event and is associated with various pandemic-related stressors. Research at the onset of the COVID-19 pandemic indicated an increase in psychological distress in the general population. However, over the course of the COVID-19 pandemic, findings increasingly showed that, on average, the general population appeared to recover from psychological distress. Nonetheless, a substantial minority appears to have become and remained psychologically distressed by the COVID-19 pandemic. Internet-based self-help interventions might be promising in the treatment of this COVID-19 related psychological distress. Against this background, the aim of this doctoral thesis is to investigate the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress. In addition, by exploring predictors of treatment outcome, the aim is to identify who might benefit from such an intervention. For this purpose, three articles are presented. The first article presents the study protocol of the ROCO project, in which the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress was evaluated in a randomized controlled trial (RCT). In the second article, the main results of this RCT are reported and in the third article, in a secondary analysis, predictors of treatment outcome were explored. Results indicate that the intervention was not effective in reducing depressive symptoms but led to a significant increase in emotion regulation skills and resilience. In addition, with regard to depressive symptoms, young adults in particular seem to benefit from the intervention, and with regard to resilience, individuals with higher pre-existing resources seem to particularly benefit. In this doctoral thesis, the articles are embedded in both the underlying theoretical framework and the current state of research. Moreover, results are summarized, discussed, and implications for coping with possible future pandemics are derived.

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1 General introduction

Following the emergence of the first cases of pneumonia of unknown cause in December 2019 in Wuhan, China, the novel coronavirus disease 2019 (COVID-19) rapidly spread globally. Accordingly, on March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a *pandemic* (Wiersinga et al., 2020). As of December 21, 2021, over 270 million COVID-19 cases have been confirmed worldwide (World Health Organization, 2021). In response to the COVID-19 pandemic, countries around the world implemented preventive measures to reduce infection transmission (Desvars-Larrive et al., 2020; Haug et al., 2020). Measures included, for example, contact and travel restrictions, adjustments in education and employment (e.g., online teaching and home office), and limited access to recreational activities (Desvars-Larrive et al., 2020).

Due to psychological consequences known from previous pandemics, experts warned of a "tsunami" of mental illnesses already at the beginning of the COVID-19 outbreak (Royal College of Psychiatrists, 2020; World Health Organization, 2020). In accordance, the psychological impact of pandemics came into focus.

1.1 Psychological impact of pandemics

A pandemic can be defined as an *outbreak* of a disease (usually an infectious disease) that spreads globally (Grennan, 2019). An outbreak is thereby understood as a significantly higher incidence of a disease in a community or region than would be expected (Grennan, 2019). Pandemics are classified as *biological disasters*, which in turn are considered *non-normative life events* (Schwarzer & Luszczynska, 2013). *Life events* have been defined as events that considerably change the current life circumstances of a person and therefore, have a

psychological impact on that person (Olaya Guzmán & Essau, 2011). It can be distinguished between normative and non-normative life events. *Normative life events* are events that are expected to happen to many individuals throughout lifespan such as school and job transitions, marriage, childbirth, or death of parents, whereas non-normative life events are unexpected and less frequent events such as accidents, diseases, or human-made and natural disasters (Schwarzer & Luszczynska, 2013). According to Schwarzer and Luszczynska (2013) there are three subcategories of natural disasters: (1) *hydro-meteorological disasters* such as hurricanes, droughts, and avalanches (2) *geophysical disasters* such as earthquakes, tsunamis, and volcanic eruptions, and (3) biological disasters such as pandemics, epidemics, and insect infestations. As opposed to hydro-meteorological and geophysical disasters, biological disasters are more likely to unfold over weeks, months, and even years, requiring measures disrupting normal routines over extended time periods (Hsieh et al., 2021). Epidemics and pandemics in particular also tend to be dynamic events as they often are characterized by so-called waves. So far there exists no standard definition of an epidemic or pandemic wave, however a wave could be described as a phase of increasing numbers of disease infections ending in a distinct peak followed by a decline in disease infections (Ayala et al., 2021; Salyer et al., 2021). As a result of these waves, measures and restrictions imposed by the government are usually also adjusted. Accordingly, psychological reactions may also change in the course of an epidemic/pandemic depending on the number of infections and existing restrictions (Taylor, 2021a).

According to Taylor (2021a) pandemics are associated with several stressors. Stressors of a pandemic can arise both from the disease itself and from preventive measures and restrictions. Specific pandemic-related stressors are for example: (1) the loss of close persons, (2) potential or actual loss of employment or income as a consequence of restrictions or economic crisis, (3)

traumatic experiences such as exposure to death, domestic abuse, or life-threatening courses of disease, (4) exposure to infection, (5) after-effects of infection such as fatigue, (6) discontinuation of important rituals such as funerals and weddings because of restrictions, and (7) social isolation due to restrictions (Sher, 2020; Taylor, 2021a, 2021b). In addition to these specific pandemic-related stressors, pandemics are accompanied by various uncertainties such as uncertainty about the menace of a disease outbreak, effectiveness of preventative measures, infection status, or duration of a pandemic (Taylor, 2021a, 2021b). Previous studies indicate that uncertainty appears to be a strong stressor (Greco & Roger, 2003; Yang et al., 2018). Eventually, such pandemic-related stressors may lead to various mental health problems.

1.2 Previous pandemics and mental health

Pandemics have occurred at fairly regular intervals in the course of human history. Early recorded pandemics include the Antonine Plague in the late 2nd century, the Justinian Plague in the mid-sixth century, and the Black Death in the 14th century (Huremović, 2019). Though, the most famous example is the Spanish flu (1918-1920) which infected more than one-third of the world's population (Grennan, 2019; Huremović, 2019). However, the psychological impact of these pandemics has never been empirically examined. A more recent example is the Severe Acute Respiratory Syndrome (SARS) pandemic in 2002/2003 (Grennan, 2019; Huremović, 2019). In the context of the SARS pandemic, psychological sequelae were studied in SARS-infected individuals, healthcare professionals, and the general population (e.g., Lau et al., 2005; Maunder et al., 2003). In their review Gardner and Moallef (2015) found that previously SARS-infected individuals showed psychological distress throughout recovery up to 51 months post-infection. Likewise, increased stress, depressive, and anxiety symptoms were reported in

healthcare professionals exposed to SARS (Maunder, 2004; McAlonan et al., 2007; Poon et al., 2004). However, psychological effects were not only observed in directly SARS-affected persons. Lau et al. (2005) reported that approximately 48% of the study population consisting of Hong Kong residents reported that their mental health had worsened because of SARS and approximately 40% reported that the level of stress-related to family and work increased. Accordingly, other study results also suggest high levels of psychological distress such as depressive symptoms or higher suicide rates during the SARS pandemic in the general population (Chan et al., 2006; Yu et al., 2005; Yueqin et al., 2003). Comparable findings related to psychological distress in healthcare professionals and the general population were also reported in few studies examining the psychological consequences of the H1N1 ("swine flu") pandemic in 2009/2010 (e.g., Goulia et al., 2010; Gu et al., 2015).

However, the body of research on mental health during previous pandemics (and epidemics) is small compared to the body of research on mental health during the COVID-19 pandemic. For example, Maalouf et al. (2021) showed that far more publications on mental health outcomes were published just one year after the COVID-19 outbreak than during the H1N1 pandemic and Ebola epidemic (2014-2016) combined.

1.3 The COVID-19 pandemic and mental health

Compared to previous epidemics and pandemics of the 21st century the magnitude of the COVID-19 pandemic is substantial. This is reflected, among other things, in the comparably high number of registered deaths, but also in the global affectedness (Maalouf et al., 2021). Therefore, as previously mentioned, concerns about the *trajectory* of mental health among infected individuals, health care workers, and the general population were expressed at the onset of the

COVID-19 pandemic. As previously mentioned, there has been a high level of research interest in the psychological consequences of the COVID-19 pandemic. Less than a year after the first COVID-19 case was officially reported, 3070 documents on mental health aspects of the COVID-19 pandemic had already been published (Maalouf et al., 2021).

In the early stages of the COVID-19 pandemic increased levels of psychological distress were reported in the general population (Ettman et al., 2020; Luo et al., 2020; Qiu et al., 2020; Wang et al., 2020; Xiong et al., 2020). For example, in a systematic review and meta-analysis by Luo et al. (2020), pooled prevalence of anxiety and depression symptoms in the general population were 33% (95% *confidence interval* (CI): 28%-38%) and 28% (95% CI: 23%-32%), respectively. In accordance, a comparison of two large nationally representative surveys performed before and at the beginning of the COVID-19 outbreak in the US revealed a three-fold increase of depressive symptoms (Ettman et al., 2020). Longitudinal studies support the assumption that levels of psychological distress in the general population increased at the onset of the COVID-19 pandemic (McGinty, Presskreischer, Han, et al., 2020; Pierce et al., 2020). Both Pierce et al. (2020) and McGinty, Presskreischer, Han, et al. (2020) compared pre-pandemic levels of psychological distress with the general population's levels of psychological distress during the COVID-19 pandemic based on existing cohort studies in the UK and the US, respectively. The population prevalence of psychological distress among UK adults increased from 18.9% (95% CI: 17.8–20.0%) in 2018-2019 to 27.3% (95% CI: 26.3-28.2%) in April 2020 (Pierce et al., 2020). Likewise, in the US, the population prevalence of psychological distress among adults increased from 3.9% (95% CI: 3.6-4.2%) in 2018 to 13.6% (95% CI: 11.1-16.5%) in April 2020 (McGinty, Presskreischer, Han, et al., 2020).

In other longitudinal studies, changes in psychological distress were observed among the general population over the course of the COVID-19 pandemic (Daly & Robinson, 2021; Daly et al., 2020; Ettman et al., 2022; McGinty, Presskreischer, Anderson, et al., 2020; Robinson et al., 2021). According to the study results of McGinty, Presskreischer, Anderson, et al. (2020) the prevalence of psychological distress reported by US adults did not significantly change between April (14.2%; 95% CI: 11.3-17.7%) and July 2020 (13%; 95% CI: 10.1-16.5%). Consistent with these findings, Daly et al. (2020) found that psychological distress remained elevated among UK adults in May and June 2020, after an initial increase of psychological distress of 13.5% (95% CI: 11.8-15.1%) from 2017-2019 to April 2020. However, even though levels of psychological distress did not return to pre-COVID-19 levels, psychological distress declined 5.8% (95% CI: -7.4 to -4.3%) from April 2020 to June 2020 (Daly et al., 2020). A study in the US, showed a comparable trend regarding psychological distress: psychological distress increased from March to April 2020 at the onset of the COVID-19 pandemic and subsequently declined to levels observed in March by June 2020 (Daly & Robinson, 2021). This observation of an initial increase in psychological distress followed by a decrease is further supported by a meta-analysis of 65 longitudinal cohort studies (Robinson et al., 2021). Results of this meta-analysis point towards a significant increase of psychological distress during March to April 2020 and a subsequent decline of psychological distress to near pre-pandemic levels in May to July 2020. However, for depressive symptoms, the increase tended to be greater and the decrease less pronounced over time, such that elevated depressive symptoms persisted beyond the onset of the COVID-19 pandemic (Robinson et al., 2021). In this line, in a recently published study, the prevalence of elevated depressive symptoms persisted from 27.8% (95% CI: 24.9 – 30.9%) in March-April 2020 to 32.8% (95% CI: 29.1-36.8%) in March-April 2021 (Ettman et al., 2022).

Therefore, the impact of the COVID-19 pandemic could be more pronounced and long-lasting in terms of depressive symptoms. However, because the COVID-19 pandemic is still ongoing, no conclusions can yet be drawn regarding long-term effects.

The studies discussed so far reported overall prevalence levels. This approach has been criticized for assuming a homogeneous response to the COVID-19 pandemic across the population (Shevlin et al., 2021). Therefore, some studies aimed to identify different trajectories of psychological distress during the COVID-19 pandemic (Ahrens et al., 2021; Iob et al., 2020; Shevlin et al., 2021). In two studies, short-term trajectories were analyzed. Using *latent growth modelling* (LGM) Iob et al. (2020) found three trajectories for depressive symptoms over a 6-week period: (1) low depressive symptom trajectory (60.0%): participants with persistent minimal depressive symptoms (2) moderate depressive symptom trajectory (29.0%): participants with persistent moderate depressive symptoms, and (3) severe depressive symptom trajectory (11%): participants with persistent severe depressive symptoms. Also using LGM, Ahrens et al. (2021) found three trajectories of mental health over the first eight weeks of lockdown in Germany: (1) recovered trajectory (9.0%): participants showing deterioration of mental health in the first three weeks, followed by quick improvement (2) resilient trajectory (82.6%): participants showing improved mental health over time, and (3) delayed dysfunction trajectory (8.4%): participants showing significant deterioration of mental health after four weeks. In one study, trajectories of anxiety and depression between March 2020 and July 2020 were reported (Shevlin et al., 2021). Whereas the overall prevalence of anxiety and depression remained stable, using LGM different trajectories were found: (1) resilient trajectory (56.6%): participants with persistent low anxiety and depression (2) chronic trajectory (6.3%): participants with persistent high anxiety and depression, (3) adaptive trajectory (8.6%): participants with moderate anxiety

and depression at the beginning, followed by improvement, (4) deteriorating trajectory (11.6%): participants with moderate anxiety and depression at the beginning, followed by deterioration, and (5) vulnerable trajectory (16.9%): participants with low-moderate anxiety and depression at the beginning, followed by deterioration (Shevlin et al., 2021). Overall, these findings indicate that the psychological response to the COVID-19 pandemic is not homogeneous across the population. Furthermore, a majority of participants showed resilient trajectories of mental health. This finding aligns with previous research, suggesting that *resilience*, defined as either maintaining mental health or recovering ("bouncing back") from psychological distress, is the most common response to stressful life events. Nevertheless, a substantial proportion within the population consistently showed trajectories of chronic psychological distress or delayed onset of psychological distress (Bonanno, 2004; Galatzer-Levy et al., 2018; Goldmann & Galea, 2014). The previously discussed studies indicate that such trajectories are also observed during the COVID-19 pandemic.

In conclusion, an increase in psychological distress was observed in the general population during the first months of the COVID-19 pandemic. However, in the following months, the majority of studies showed on average an improvement of mental health. Although, the general population tends to show resilience in the face of the COVID-19 pandemic, mental health of a substantial minority was negatively affected, and especially depressive symptoms might be more persistent. In accordance, not all affected persons might recover without treatment. Therefore, mental health interventions mitigating detrimental effects of the COVID-19 pandemic on mental health are needed.

1.4 Internet-based interventions for COVID-19 related psychological distress

Due to the expected increase in the number of individuals requiring psychological support, the need for easily accessible and scalable interventions became apparent. Moreover, in the beginning of the COVID-19 pandemic, when strict lockdowns and social distancing restrictions were common, alternatives to face-to-face therapy were needed. Therefore, the use of internet-based self-help interventions was recommended (Taylor, 2021a; Wang et al., 2020; Wind et al., 2020). Internet-based self-help interventions have been found to be effective in the treatment of various psychological problems (Andersson & Titov, 2014; Cuijpers et al., 2011). While *guided internet-based self-help interventions* provide scheduled online support from a therapist, *unguided internet-based self-help interventions* are completely automated and participants are self-reliant (Berger et al., 2020). Guided internet-based self-help interventions have been shown to be as effective as face-to-face therapy (Andersson et al., 2019; Carlbring et al., 2018). Moreover, they generally yield higher effect sizes than unguided internet-based self-help interventions (Baumeister et al., 2014; Richards & Richardson, 2012). However, since guided internet-based self-help interventions rely on human resources, they are less scalable than unguided internet-based self-help interventions which still are effective (Baumeister et al., 2014; Richards & Richardson, 2012). Another possible approach in regard to guidance is the use of *guidance on demand*. Guidance on demand implies that support is provided only on demand by a participant. Therefore, human resources might be less strained. So far, evidence suggests that internet-based self-help interventions with guidance on demand are effective (Krieger et al., 2019; Rheker et al., 2015). However, in one study an internet-based self-help intervention with guidance on demand did not yield higher effects than an unguided version of the same internet-based self-help intervention (Rheker et al., 2015).

In addition, suggestions were made regarding the content of interventions targeting COVID-19-related psychological distress. *Cognitive behavioral therapy* (CBT) techniques such as identifying and restructuring thought patterns, relaxation exercises, activity scheduling, and promotion of *emotion regulation skills* were recommended (Ahrens et al., 2021; Halder, 2020; Wang et al., 2020).

To date, only few *randomized controlled trials* (RCT's) investigating internet-based self-help interventions targeting COVID-19 related psychological distress have been published. In a small RCT, Wei et al. (2020) evaluated the efficacy of a 2-week internet-based self-help intervention for patients diagnosed with COVID-19. The intervention consisted of breath relaxation training, mindfulness, and self-soothing skills and significantly reduced symptoms of anxiety and depression (Wei et al., 2020). Furthermore, in three RCT's, internet-based self-help interventions targeting COVID-19 related psychological distress in the general population were evaluated (Al-Alawi et al., 2021; Aminoff et al., 2021; Wahlund et al., 2021). In their pragmatic RCT, Al-Alawi et al. (2021) compared a 6-week intervention consisting of weekly online therapy sessions with a certified psychotherapist with a 6-week internet-based self-help intervention consisting of a weekly newsletter based on CBT and *acceptance and commitment therapy* (ACT). They found preliminary evidence that both interventions reduced levels of anxiety and depression. However, the reduction was higher for online therapy sessions (Al-Alawi et al., 2021). In another RCT, Wahlund et al. (2021) evaluated the efficacy of an internet-based self-help intervention for dysfunctional worry related to COVID-19. The 3-week CBT intervention led to a significant reduction of COVID-19 related worry as well as to an improvement in other outcomes such as mood, insomnia, daily functioning, and intolerance of uncertainty (Wahlund et al., 2021). Moreover, in a pilot RCT, Aminoff et al. (2021) evaluated

the efficacy of a tailored internet-based self-help intervention for COVID-19 related psychological distress. Based on a screening and clinical interview, 7 out of 16 modules were selected for each participant. The guided 7-week CBT intervention significantly reduced depressive symptoms and other outcomes such as anxiety and stress symptoms (Aminoff et al., 2021).

In conclusion, preliminary evidence suggests that internet-based self-help interventions are effective in reducing COVID-19 related psychological distress in the general population. However, the available evidence is still limited.

1.5 The ROCO project

Against this background, the ROCO project was initiated under the direction of Prof. Dr. Hansjörg Znoj and Prof. Dr. Thomas Berger. In the ROCO project the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress called “ROCO” was evaluated in an RCT. The acronym ROCO stands for Resilience and Optimism during COVID-19. A total of 107 participants with at least mild depressive symptoms were randomized to either an intervention condition with direct access to the 3-week internet-based self-help intervention plus *care as usual* (CAU) or to a waiting control condition consisting of CAU only. Participants in the waiting control condition received access to the internet-based self-help intervention after the 3-week waiting period. The primary outcome measure were depressive symptoms and secondary outcome measures included stress and anxiety symptoms, resilience, emotion regulation skills, health-related quality of life, embitterment, loneliness, optimism, and self-efficacy. Outcome measures were assessed pre- and post-treatment and at a 6- and 18-week follow-up using online self-report questionnaires.

The ROCO intervention, was developed and adapted based on an internet-based self-help intervention for adjustment problems after an accident (Hegy et al., 2020). The 3-week intervention consisted of six mainly CBT based modules encompassing the following contents: (1) psychoeducation about COVID-19 related psychological distress, (2) emotion regulation skills, (3) cognitive techniques, (4) resilience promotion, (5) relaxation exercises, and (6) self-care. Moreover, a guidance on demand approach was used. The ROCO intervention as well as the RCT are described in more detail in the study protocol (Brog et al., 2021).

The three articles discussed in this doctoral thesis originated from the ROCO project. The first article covers the study protocol of the ROCO project. In this article, the background and rationale, objectives, methodology (e.g., study design, study population, intervention, data collection methods, outcome measures), data management and statistical analysis plan as well as operative aspects of the ROCO project are documented. The aim of the study protocol is to make the original intent along with detailed information regarding the ROCO project accessible and transparent. This allows the scientific community to evaluate whether the procedure and reported results in subsequently published articles are consistent with the originally planned procedures and analyses (Ohtake & Childs, 2014).

In the second article, the main results of the RCT are reported. As previously mentioned, in the RCT we aimed to evaluate the efficacy of the ROCO intervention. We expected that the 3-week intervention plus CAU would lead to a greater reduction of depressive symptoms (primary outcome) and anxiety and stress symptoms (secondary outcomes) compared to CAU only. Furthermore, we expected that the 3-week intervention plus CAU would lead to greater beneficial effects on well-being, optimism, embitterment, loneliness, optimistic self-beliefs, emotion regulation skills, and resilience (secondary outcome measures) compared to CAU only.

We expected these effects to be stable in the 6-week follow-up. To answer the hypotheses, data from the post-assessment and 6-week follow-up were analyzed.

Finally, in the third article, a secondary analysis of the data of the RCT is presented. We aimed to explore predictors of treatment outcomes, which were defined as post-treatment depressive symptoms and post-treatment resilience. The following groups of predictor variables were explored: sociodemographic, psychopathological, resource-related, and treatment-related variables. For this secondary analysis, the data from participants in the intervention condition and in the waiting control condition were combined, using the data of the respective treatment phase (immediate or delayed).

2 Scientific articles

The aim of this doctoral thesis is to investigate whether an internet-based self-help intervention is an effective treatment option for COVID-19 related psychological distress and to identify who might benefit. As part of this dissertation, the following three articles are presented as manuscripts submitted to the respective journals:

Article 1:

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (2021). An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial. *Trials*, 22(1), 1-11. <https://doi.org/10.1186/s13063-021-05089-9>

Article 2:

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (2022). Effects of an internet-based self-help intervention for psychological distress due to COVID-19: Results of a randomized controlled trial. *Internet Interventions*, 27, 100492. <https://doi.org/10.1016/j.invent.2021.100492>

Article 3:

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (under review). Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress. Submitted to *Frontiers in public health*.

2.1 Manuscript of Article 1

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (2021). An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial. *Trials*, 22(1), 1-11. <https://doi.org/10.1186/s13063-021-05089-9>

**An internet-based self-help intervention for people with psychological distress due to
COVID-19: study protocol for a randomized controlled trial**

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Abstract

Background: The Coronavirus-19 (COVID-19) has reached pandemic status and is affecting countries all over the world. The COVID-19 pandemic is accompanied by various stressors that require adjustment in everyday life and possibly changes in personal future prospects. While some individuals cope well with these challenges, some develop psychological distress including depressive symptoms, anxiety, or stress. Internet-based self-help interventions have proven to be effective in the treatment of various mental disorders such as depression and anxiety. Based on that, we developed an internet-based self-help program for individuals with psychological distress due to the situation surrounding the COVID-19 pandemic. The 3-week self-help program consists of 6 modules comprising texts, videos, figures, and exercises. Participants can request guidance within the self-help program (guidance on demand). The primary aim of this study is to evaluate the efficacy and feasibility of the self-help program compared to a waiting control condition. **Methods:** The design is a parallel group randomized controlled trial. Participants are allocated to a 3-week self-help intervention plus care as usual or a 3-week waiting period with only care as usual. There are follow-ups after 6 weeks and 18 weeks. At least 80 participants with COVID-19 pandemic related psychological distress will be recruited. Primary outcome are depressive symptoms. Secondary outcomes include anxiety and chronic stress, suicidal experiences and behaviour, health-related quality of life, generalized optimism and pessimism, embitterment, optimistic self-beliefs, emotion regulation skills, loneliness, resilience, and the satisfaction with and usability of the self-help program. **Discussion:** To the best of our knowledge, this is one of the first studies investigating the efficacy of an internet-based self-help program for psychological distress due to the situation surrounding the COVID-19 pandemic. Thus, the results of this study may give further insight into the use of internet-based self-help

programs in pandemic-related psychological distress. **Trial registration:** ClinicalTrials.gov, NCT04380909. Retrospectively registered on 8 May 2020, <https://clinicaltrials.gov/ct2/show/NCT04380909>

Keywords: Anxiety, Coronavirus, COVID-19, Depression, Internet-based self-help, Psychological distress, Randomized controlled trial, Stress

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	An internet-based self-help intervention for people with psychological distress due to COVID-19: study protocol for a randomized controlled trial.
Trial registration {2a and 2b}.	ClinicalTrials.gov, NCT04380909, Retrospectively registered on 8 May 2020
Protocol version {3}	2021 January 28, Version 3
Funding {4}	The study is entirely funded by the University of Bern.
Author details {5a}	NB ¹ , JH ¹ , TB ¹ , and HZ ¹ ¹ Department of Psychology, University of Bern
Name and contact information for the trial sponsor {5b}	Trial Sponsor: University of Bern Contact name: Prof. Dr. HZ Address: Fabrikstrasse 8, 3012 Bern, Switzerland

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Role of sponsor {5c}	The funding body (University of Bern) played no role in the design of the study, the collection, analysis and interpretation of data or in writing the manuscript. However, the trial sponsor is the principal investigator of the study (sponsor investigator).

Introduction

Background and rationale {6a}

The Coronavirus-19 (COVID-19) has reached pandemic status and is affecting countries all over the world. Health systems are facing major challenges: In addition to the risks for physical health, the COVID-19 pandemic also represents a burden for mental health [1]. Pandemic related stressors such as quarantine, social isolation/distancing, unemployment, financial losses, caregiver stress and confrontation with illness and death can have a negative impact on mental health [1]. For example, in a study on the severe acute respiratory syndrome (SARS) pandemic, approximately 40% of the study population experienced increased stress related to work, finances and family and 16% showed signs of posttraumatic stress [2]. Preliminary research on the psychological impact of the COVID-19 pandemic indicates increased levels of psychological distress in the general population [3, 4]. Symptoms of anxiety,

depression, and self-reported stress are suggested psychological reactions to the COVID-19 pandemic [5, 6].

Although pandemics comprise a multitude of stressors that may strain mental health, not everybody is experiencing psychological distress in response. Moreover, individuals might differ in the amount and kind of stressors they are exposed to, and therefore, some individuals might be at higher risk for mental health problems [7]. Some of the stressors that occur during a pandemic can be considered critical life events (e.g., death of loved ones and job loss) and require adjustment to changed life circumstances [8]. A lack of adjustment can lead to psychological distress, for example expressed in a change of one's psychological condition. This can include experiencing depressive and anxiety symptoms [9]. Furthermore, maladaptive adjustment to critical life events might eventually lead to full-blown mental disorders like adjustment disorders (AjD) or depression [10-12].

Some recommendations for interventions targeting psychological distress due to the COVID-19 pandemic have been made: Firstly, cognitive behavioural therapy (CBT), in particular the restructuring of thought patterns and cognitive thinking traps, as well as activity planning and relaxation techniques are considered suitable interventions [6, 13]. Secondly, digital aids such as internet-based self-help interventions are encouraged, as they do not require physical contact and are easily scalable [6, 14, 15].

The efficacy of internet-based self-help interventions for various psychological problems is established [16, 17]. However, internet-based interventions can differ in their design, especially in the degree of therapist support that they offer. While some internet-based interventions offer contact with a therapist (guided self-help) other interventions are completely automated (unguided self-help). Moreover, guided self-help interventions can differ in the

intensity of provided contact. On the one hand, guided self-help programs yield higher effect-sizes and have higher retention rates than unguided self-help programs [18, 19]. On the other hand, unguided self-help programs have the advantage that they are less costly and better scalable [20]. One promising approach, possibly combining the benefits of both guided and unguided self-help programs, is the use of guidance on demand [21]. Guidance on demand implies that support from a therapist is only established when requested by a participant. An internet-based self-help program for increased self-criticism with guidance on demand showed promising results [22]. Nonetheless, an internet-based self-help program for symptoms of anxiety and/or depression based on problem-solving therapy with guidance on demand had the same effect as the unguided version of the same program [23]. Likewise, an internet-based self-help program for tinnitus-related distress based on CBT with guidance on demand did not differ in its effectiveness from the unguided version of that program [24].

To the best of our knowledge, there is no study that has evaluated an internet-based self-help intervention for psychological distress due to COVID-19 in the general population yet. However, an internet-based self-help intervention for patients diagnosed with COVID-19 experiencing psychological distress has been evaluated in a small randomized controlled trial (RCT) [25]. The internet-based self-help intervention consisted of audio-recorded instructions focusing on relaxation, self-care and a rising sense of security, which were uploaded online. Over a 2-week period, participants in the intervention group listened to the instructions via their mobile phone and performed a daily task, which took about 50 minutes. The intervention addressed COVID-19 patients with mild-to-moderate depression and/or anxiety symptoms. The average age of the 26 participants was 44.7 years; 62% were male and 38% were female. 92% of the participants experienced at least mild depression symptoms and 62% experienced at least

mild anxiety symptoms. Participants in the intervention group showed a significant reduction in depression and anxiety symptoms compared to the control group [25].

Against this background, we developed an internet-based self-help intervention with guidance on demand called ROCO. This intervention specifically addresses individuals experiencing psychological distress due to the COVID-19 pandemic. Hence, the study aims to evaluate the efficacy and feasibility of the internet-based self-help program ROCO for people with psychological distress due to the COVID-19 pandemic.

Objectives {7}

The specific objectives of the study are:

- (1) To evaluate the effects of the internet-based self-help program compared with awaiting control condition on:
 - the primary outcome depressive symptoms
 - secondary outcomes such as anxiety and stress symptoms, well-being, embitterment, and loneliness
- (2) To evaluate the acceptance and user-friendliness of the internet-based self-help program and drawing conclusions for further developments of the program.
- (3) To exploratory search for predictors, moderators and mediators for the efficacy of the program:
 - e.g., optimism, age, severity of depressive symptoms and frequency of use of the program

Trial design {8}

The study is a parallel group RCT comparing an internet-based self-help intervention combined with care as usual (CAU) to a waiting control condition with only CAU. The study flowchart is displayed in Figure 1. Participants in the waiting control condition receive access to the intervention 3 weeks after the baseline questionnaire. Eligible participants are randomly allocated to one of the two conditions in a 1:1 allocation ratio.

The aim of the RCT is to show the superiority of the internet-based self-help intervention combined with CAU to only CAU at the 3-week post assessment. Additionally, there will be 2 follow-up measurements after 6, respectively 18 weeks after the baseline questionnaire. Since at the time of the follow-up measurements both groups have used the internet-based self-help intervention, the groups can no longer be compared. However, we use these follow-up measurements to assess the sustainability of potential treatment gains, i.e. to examine whether the short-term effects of the internet-based self-help intervention are maintained within groups. In addition, the follow-up measurements will be used to explore predictors of the sustainability of potential treatment effects.

Methods: Participants, interventions and outcomes

Study setting {9}

The single study center is located at the University of Bern, Switzerland. All data is collected online using questionnaires programmed in Qualtrics [28]. Data is collected in German-speaking areas (i.e., Switzerland, Germany, Austria, and Liechtenstein).

Eligibility criteria {10}

All interested persons must provide full written informed consent and are required to complete a baseline-screening questionnaire prior to randomization to assess eligibility.

Inclusion criteria are:

1. To be at least 18 years old
2. To exceed a cut-off value of 4 points on the brief Patient Health Questionnaire (PHQ-9) [29]
3. To be able to specify an emergency address in the event of an acute crisis
4. To have access to the internet
5. To understand and master the German language to the degree that one understands the content and instructions of the study

Exclusion criteria are:

1. The presence of suicidal tendencies (Score ≥ 8 on the Suicide Behavior Questionnaire Revised (SBQ-R) [30])
2. A known diagnosis of a psychotic or bipolar disorder

Who will take informed consent? {26a}

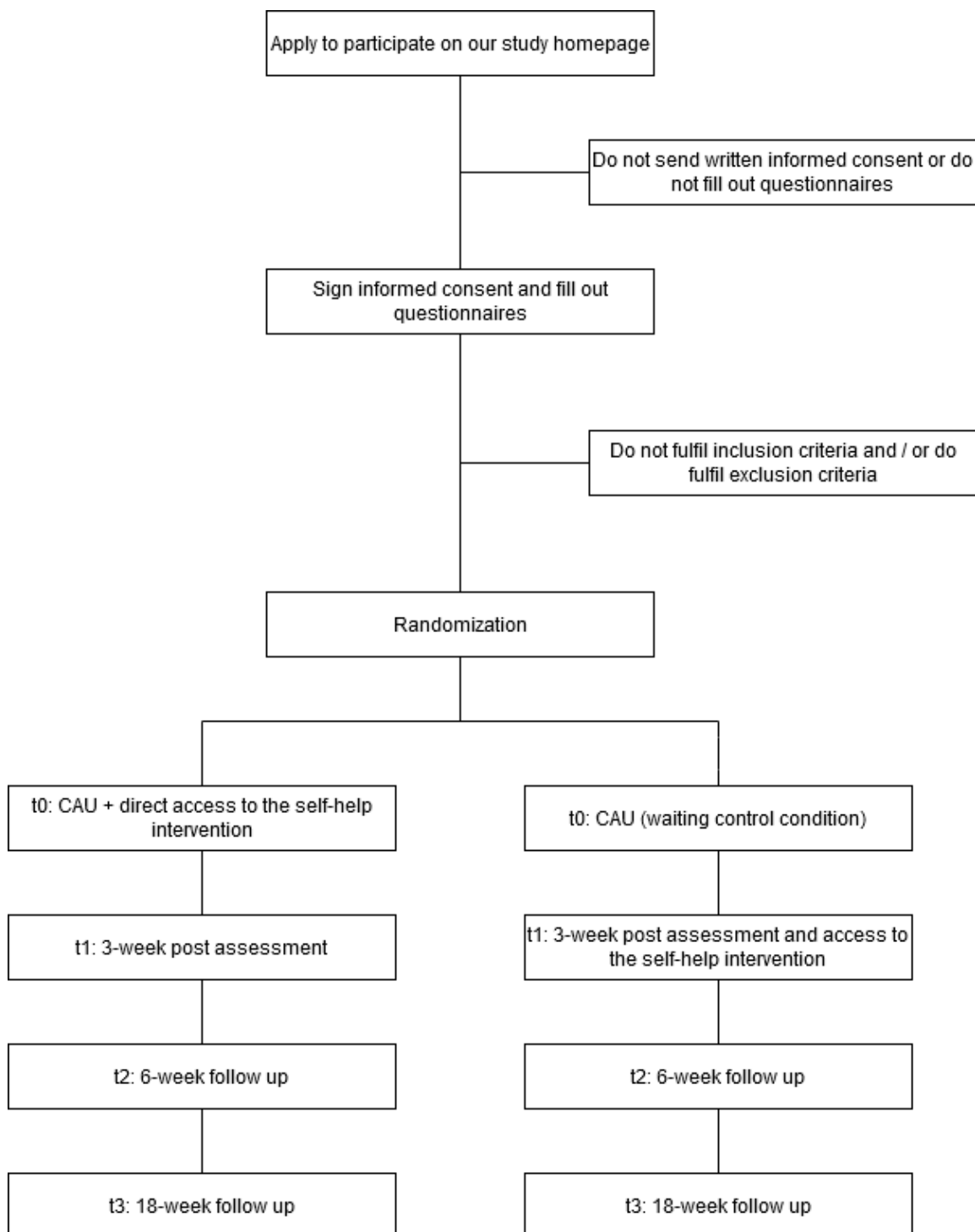
Individuals interested in participating in the study can provide their e-mail address on the study homepage. Subsequently, they receive an e-mail with the detailed study information and the informed consent form. They are also asked to watch a video on the study homepage in which the study information is explained orally by the principal investigator. Individuals have the possibility to ask the study team questions about the study via e-mail. Written informed consent is obtained from individuals willing to participate in the study by the Principal Investigator.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable as no ancillary studies are performed.

Figure 1

Flowchart of the study design



Interventions

Explanation for the choice of comparators {6b}

The efficacy of the intervention is to be established. This is why we have chosen a waiting control condition as comparator. However, both the participants in the waiting control condition as well as in the intervention condition receive CAU, whereby CAU can range from no treatment at all to psychotherapy and/or drug therapy. Participants in the waiting control condition receive access to the internet-based self-help program after a waiting period of 3 weeks. We decided to give participants in the waiting control condition access to the program after only 3 weeks since, due to the pressing situation surrounding the COVID-19 pandemic, we wanted to give all participants access to psychological support as fast as possible. However, this has the implication that only short-term effects of the intervention can be assessed.

Intervention description {11a}

The intervention is a 3-week internet-based self-help program with guidance on demand called ROCO. The self-help program consists of 6 thematic modules including texts, videos, graphics, exercises and for each module a weekly task. The 6 thematic modules are supplemented by an introduction and a conclusion. For a detailed description, see Table 1. Furthermore, the self-help program comprises a page with information on what to do in an acute crisis, including a list with emergency contacts, as well as a page named Toolbox, where the weekly tasks are listed. Participants also can track their symptoms on a page named Mood-Tracker.

Participants are encouraged to work through two of the 6 thematic modules per week. One module takes between 40 to 80 minutes to complete. However, participants can determine

Table 1

Outline of the content of the internet-based self-help program ROCO

Introduction	Information about the self-help program
1. Identifying consequences and challenges	Information about psychological distress/adjustment problems due to the COVID-19 pandemic, assessment of the current state (bodily sensations, positive and negative feelings), resource-oriented weekly task
2. Understanding own feelings	Information about feelings such as anxiety, helplessness, anger, sense of shame and sadness, strategies to cope with these feelings, acceptance-oriented weekly task
3. Changing the perspective	Information about the influence of thoughts, automatic thoughts, rumination and irrational beliefs, exercises to challenge own thinking patterns, weekly task on rumination
4. Strengthening resilience	Information about resilience and three possible ways of gaining resilience, namely coping, joie de vivre and optimism, exercises to promote these, resource-oriented weekly task
5. Finding rest	Information about sleep, sleep hygiene and relaxation techniques, progressive muscle relaxation as a weekly task
6. Taking care of oneself	Information about the concept of posttraumatic growth and the importance of pleasure, exercises of gratitude and mindfulness, resource-oriented weekly task
Conclusion	Information about the importance of practicing and transferring what has been learnt to daily life

the timing and order of the modules themselves. The first module includes information about possible psychological consequences and challenges concerning the situation surrounding COVID-19. In the second module participants receive information concerning ways to deal with difficult feelings that may arise due to the current situation. The third module focuses on restructuring thought patterns and cognitive thinking traps and the fourth module on promoting resilience and coping skills. The fifth module consists of information about sleep hygiene and relaxation techniques. Finally, the last module addresses self-care and personal growth.

As the self-help program offers guidance on demand, participants have the possibility to contact a psychologist, but there is no scheduled contact per se. Participants can require guidance via chat function in the self-help program. They are informed that a psychologist will answer their request within 3 working days. Otherwise, the self-help program is unguided.

Criteria for discontinuing or modifying allocated interventions {11b}

Since internet-based self-help is not suited as a treatment for acute suicidality, participants reporting an acute crisis during treatment are referred to an appropriate treatment. This will be recorded and reported as an adverse event.

Strategies to improve adherence to interventions {11c}

Participants have the possibility to enable reminders within the self-help program. They can choose whether the reminder is sent via e-mail or text message after a certain time of inactivity. In the reminder, participants are encouraged to log into the self-help program again. We have further adopted a guidance on demand approach, since some form of support appears to increase adherence [19].

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants receiving the intervention, as well as participants in the waiting control condition are allowed to start any concomitant treatment at any time during the trial. However, participants must indicate at each measurement time whether they use concomitant psychological or psychiatric treatment (e.g., psychotherapy or drug therapy).

Provisions for post-trial care {30}

The University of Bern will provide insurance for any harm suffered as a result from this trial.

Outcomes {12}

All assessments are carried out online via self-observation questionnaires. The baseline measurement is at t0, the post-measurement t1 is at 3 weeks, the first follow-up measurement t2 is at 6 weeks, and the second follow-up measurement t3 is at 18 weeks after the baseline. Validated German versions of the questionnaires are used. For an overview of all outcome measures and corresponding measurement time points see Figure 2.

Primary outcome measure

Patient Health Questionnaire (PHQ-9). The primary outcome measure is the score of the PHQ-9 [29]. The PHQ-9 is a 9-item measure assessing the severity of depressive symptoms. All 9 DSM-IV criteria for depression are scored on a scale from 0 = not at all to 5 = nearly every day. A score of 5 represents a mild depression, a score of 10 a moderate depression, a score of 15 a moderately severe depression and a score of 20 a severe depression [31]. The PHQ-9 showed good internal consistency (Cronbach's alpha between 0.86 and 0.89) [32, 33].

Secondary outcome measures

Depression Anxiety Stress Scale (DASS-21). The DASS-21 is a short-form of the DASS and is used to assess depressive mood, anxiety, and chronic stress during the past week [34]. The DASS-21 consists of 21 items which are answered on a scale from 0 = did not apply to me at all to 3 = applied to me very much or most of the time. The internal consistencies of the scores for depressive mood, for anxiety and for chronic stress (Cronbach's alpha = 0.88, 0.76 and 0.86) lie between satisfactory and good [35].

Suicide Behavior Questionnaire Revised (SBQ-R). The SBQ-R assesses suicidal experiences and behaviour [30]. The SBQ-R consists of 4 items which are not scaled equally. A total score of the 4 items is calculated. The total score can range from 3 to 18 whereas a score greater than or equal to 8 is considered the most useful cut-off score for suicide risk in a clinical sample [30]. This SBQ-R cut-off is also used as an indication for suicidal tendencies (safety outcome). The internal consistency of the SBQ-R is satisfactory (Cronbach's alpha = 0.72) [36].

12-Item Short-Form Health Survey (SF-12). The SF-12 assesses health-related quality of life and is the short version of the Medical Outcomes Study 36-Item Short-Form Health Survey [37]. The SF-12 consists of 12 items with varying answer format. There are two versions of the SF-12, one assessing the health-related quality of life over the past week and one assessing it over the past 4 weeks. In this study, the latter is used. From the 12 items of the SF-12, a Physical Component Score and a Mental Component Score can be calculated. The internal consistency of the subscales exceeds the recommended Cronbach's alpha level of 0.70 [38].

Life Orientation Test Revised (LOT-R). The LOT-R is a 10-item scale assessing generalized optimism and pessimism [39]. The items are answered on a scale from 0 = strongly disagree to 4 = strongly agree. 3 items form the score for pessimism and 3 items the score for

optimism, whereas 4 items are unscored as they are filler items. The internal consistency is satisfactory with a Cronbach's alpha of 0.69 for optimism and 0.68 for pessimism [40].

Bern Embitterment Inventory (BEI). The BEI is an 18-item questionnaire assessing embitterment, whereby embitterment can be understood as the feeling of being disadvantaged by others and fate [41, 42]. The items are answered on a scale from 0 = I do not agree to 4 = I agree. The internal consistency for the total embitterment score is good (Cronbach's alpha 0.89) [41]. In this study, the 6-item short version of the BEI is used [43].

General Self-Efficacy Scale (GSE). The GSE is a 10-item questionnaire assessing optimistic self-beliefs [44]. The items are answered on a scale from 1 = not at all true to 4 = exactly true. The internal consistency (Cronbach's alpha) for the total score ranges between .76 and .90 [44].

Self-report Measure for the assessment of emotion regulation skills (SEK-27). The SEK-27 assesses adaptive ways of coping with negative emotions [45]. The 27 items are answered on a scale from 0 = never to 4 = (almost) always. Two versions of the SEK-27 are available: a trait version assessing the coping with negative emotions in general and a prolonged state version assessing the coping with negative emotions over the last week. In this study, the latter is used. A total scale as well as the subscales attention, bodily awareness, clarity, understanding, regulation, acceptance, resilience, self-support and goal-oriented readiness for confrontation can be formed. The total scale of the prolonged state version has an excellent internal consistency (Cronbach's alpha = 0.90). The internal consistency of the subscales of the prolonged state version ranges from 0.72 to 0.81 [46].

UCLA Loneliness Scale (ULS). The ULS is a measure assessing one's subjective feeling of loneliness [47]. The items are answered on a scale from 1 = never to 4 = often. The

original version of the ULS consists of 20 items and has an internal consistency (Cronbach's alpha) ranging from 0.82 to 0.92 [47]. In this study, a 9-item version of the ULS is used.

Connor-Davidson Resilience Scale (CD-RISC). The CD-RISC assesses resilience [48]. Items are answered on a scale from 0 = not true at all to 4 = true nearly all of the time. In this study, the 10-item version of the CD-RISC is used. The 10-item version has a good internal consistency (Cronbach's alpha) of 0.84 [49].

Client Satisfaction Questionnaire-8 (CSQ-8). The CSQ-8 assesses the satisfaction of the participants with the intervention [50]. The CSQ-8 consists of 8 items which are answered on a scale from 1 = poor to 4 = excellent. Since the CSQ-8 measures the satisfaction with the intervention, it can only be used after the intervention phase. THE CSQ-8 has an excellent internal consistency (Cronbach's alpha) ranging from 0.87 to 0.93 [51].

System Usability Scale (SUS). The SUS is used to assess the usability of a system such as mobile devices, websites, and applications [52]. The 10 items of the SUS are answered on a scale from 1 = strongly disagree to 5 = strongly agree. A score between 0 and 100 can be calculated, indicating the usability of a system, in this case the internet-based self-help program. Since the SUS measures the system usability of the internet-based self-help program, it can only be used after the intervention phase. The English version of the SUS has an excellent internal consistency (Cronbach's alpha) ranging from = 0.91 to 0.92 [53, 54].

Predictors and moderators

Demographic variables. Demographic variables include sex, age, country of residence, civil status, housing situation, current childcare situation, education, employment situation (before and during COVID-19 pandemic), income (before and during COVID-19 pandemic), current everyday working life, psychiatric medical history, concomitant

psychological/psychiatric treatment, and COVID-19 specific questions (e.g., belonging to a risk group, own illness, or instances of deceased family members due to the pandemic).

Adherence. The intensity and frequency of use of the self-help program is measured by indicators collected within the self-help program such as percentage of accessed pages or number of logins.

Sample size {14}

To specify the sample size needed for the different analyses, we conducted a power analysis based on a probability level of 0.05 and a power of 0.80 with G*Power [55] for a repeated-measures ANOVA with a within-between-interaction. To test the efficacy of the self-help program compared to the control condition, we expected a small-to-medium between group effect size of $d = 0.35$ and a correlation between the factors of at least $r = 0.4$. The expected effect size is based on the results of meta-analyses on the effectiveness of unguided internet-based self-help programs targeting depressive symptoms [17, 56]. We decided to base the expected effect size on unguided internet-based self-help programs as it is yet to be determined if a guidance on demand approach yields higher effect sizes than unguided self-help [23, 24]. Power analysis indicated a necessary sample size of 80 individuals. In consideration of a possible attrition rate between 5.4% to 45.5% at post-assessment, we aim to recruit between 80 and 120 participants at baseline [17].

Participant timeline {13}

See Figure 2.

Recruitment {15}

Participants are recruited from the general population via the study web page. This study web page is advertised on various websites, internet forums and social media. The study web

Figure 2

SPRIT figure, schedule of enrolment, interventions, and assessments

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			
			Intervention / Waiting period			
TIMEPOINT	t_0	0	0	t_1	t_2	t_3
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
<i>ROCO direct access</i>			↔			
<i>Waiting control group</i>				↔		
ASSESSMENTS:						
Primary outcome measure						
Patient Health Questionnaire (PHQ-9)	X			X	X	X
Secondary outcome measures						
Depression Anxiety Stress Scale (DASS-21)	X			X	X	X
Suicide Behavior Questionnaire Revised (SBQ-R)	X			X	X	X
12-Item Short-Form Health Survey (SF-12)	X			X	X	X
Life Orientation Test Revised (LOT-R)	X			X	X	X
Bern Embitterment Inventory (BEI)	X			X	X	X
General Self-Efficacy Scale (GSE)	X			X	X	X
Self-report Measure for the assessment of emotion regulation skills (SEK-27)	X			X	X	X
UCLA Loneliness Scale (ULS)	X			X	X	X
Connor-Davidson Resilience Scale (CD-RISC)	X			X	X	X
Client Satisfaction Questionnaire-8 (CSQ-8)				X	X	
System Usability Scale (SUS)				X	X	
Predictors and mediators						
Demographic variables	X					
Concomitant psychological/psychiatric treatment	X			X	X	X
Adherence			↔	↔		

page includes information about the self-help program and the study. People interested in participating can leave their e-mail address on the study homepage and will then be sent the detailed participant information per e-mail.

Assignment of interventions: allocation

Sequence generation {16a}

Eligible participants will be randomly allocated to either the intervention or the waiting control condition with a 1:1 allocation ratio as per a computer generated randomization schedule using randomly permuted block sizes by Randomization.com [57].

Concealment mechanism {16b}

The allocation schedule was generated by an independent researcher and is unknown to the investigators. Allocation takes place after the baseline assessment has been completed. Since the allocated condition is not known until the interested individual has been recruited into the trial, allocation concealment is ensured

Implementation {16c}

All interested individuals who give written informed consent for participation and who fulfil all the inclusion criteria and none of the exclusion criteria will be randomized. Staff members responsible for recruitment and data management will ask the independent researcher to randomize respective individuals. In return, the independent researcher informs the staff members per e-mail about the allocation. Finally, the staff members inform the individual about the assigned condition per e-mail.

Assignment of interventions: Blinding

Who will be blinded {17a}

The staff members are not blinded to the allocation. However, all assessments are performed online with self-report questionnaires. Since participants either receive direct access to the self-help program or have a waiting period, participants are neither blinded to their allocation.

Procedure for unblinding if needed {17b}

Not applicable since no blinding is performed.

Data collection and management

Plans for assessment and collection of outcomes {18a}

All data is assessed online by means of questionnaires programmed in Qualtrics [28]. In addition, data on the use of the self-help program (e.g., number of logins or processed pages) is collected within the self-help program.

Plans to promote participant retention and complete follow-up {18b}

The participants are asked by e-mail to complete the online questionnaires. If participants fail to complete a questionnaire, they will be reminded by e-mail to do so: For post measurement, they will be reminded after 5 and 10 days and for follow-up measurements after 7 and 14 days. All participants are asked to complete the online questionnaire at each point of measurement, regardless of protocol adherence or any previously uncompleted online questionnaires.

Data management {19}

Data quality is ensured through several mechanisms, including referential data rules, valid values, range checks and consistency checks. The option to choose a value from a list of valid codes and a description of the meaning of the code will be available where applicable.

Checks are applied at the time of data entry into a specific field. All data collected is stored on a firewall-encrypted back-upped server of the University of Bern with strictly regulated access only for researchers directly involved in the study.

Confidentiality {27}

All data concerning participant information will be stored in locked file cabinets only accessible for staff members. All collected data will only be traceable by a code. All files containing names or other personal identifiers, such as the informed consent forms, will be stored separately from data containing this code number.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable since no biological specimens are used.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

We will use linear mixed models with time (pre versus post-intervention measures) as a within-group-factor and study condition (immediate access versus control condition) as a between-group-factor to evaluate the efficacy of the internet-based self-help intervention. This primary analysis will be performed using the data from the baseline and the 3-week post assessment. To analyze the stability of the short-term effects of the internet-based self-help intervention, we will conduct within-group analyses using repeated measures ANOVA (pre-intervention, post-intervention and follow-up measures) and paired t-tests when comparing only two time points.

Moreover, we will exploratory analyze possible predictors, mediators and moderators for the relationship between the internet-based self-help program and the outcomes. The significance level is set at 5%. Analyses will be conducted using SPSS and R.

Interim analyses {21b}

Not applicable since no interim analyses are planned.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Not applicable since no additional analyses such as subgroup analyses are planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Statistical analyses will be carried out according to the intention-to-treat approach and therefore will include all randomized participants. The extent of missing data will be analyzed. We will explore missing data patterns and determine the type of missing data (missing completely at random, missing at random, not missing at random). We will use multiple imputation to substitute missing values and will conduct sensitivity analyses for both the datasets with and without the imputed data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

There are no plans for granting public access to the full protocol, participant-level dataset and statistical code.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

There is no trial steering committee. The composition of the coordinating center is as follows:

- Principal Investigator: HZ

- Design and conduct of the study
- Publication of study reports
- Preparation of protocol and revisions and Case Report Forms
- Co-Principal Investigator: TB
 - Design and conduct of the study
 - Publication of study reports
 - Preparation of protocol and revisions and Case Report Forms
- PhD students: NB and JH
 - Supporting the Principal and Co-principal Investigator in all the above responsibilities
 - Data entry and management
 - Recruitment of participants

Composition of the data monitoring committee, its role and reporting structure {21a}

As to the best of our knowledge, the internet-based self-help program in itself does not bear risks for the participants. Therefore, a data monitoring committee is not required. The principal Investigator, the co-principal investigator and the PhD students warrant for data and participant safety.

Adverse event reporting and harms {22}

In this trial, adverse events are defined as unintended negative developments in the participants, which may occur at the time of the use of the internet-based self-help program, but do not have to be causally related to its use. Those unintended negative developments in the participants include acute suicidality and hospitalization. Such adverse events and the corresponding actions taken will be documented in the case report form.

Frequency and plans for auditing trial conduct {23}

The research management of the Faculty of Human Sciences at the University of Bern, an independent research control unit, warrants the auditing. There will be on site monitoring visits on a regular basis. The monitoring visits are documented in a monitoring report form. The data monitoring committee controls study procedures such as the site progress and enrollment, obtaining participant informed consent, randomization, or the reporting of adverse events.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Important protocol amendments will be reported to the relevant parties (i.e., the Cantonal Ethics committee Bern, the trial participants and trial registries) by e-mail. Substantial amendments are only implemented after approval of the Cantonal Ethics committee Bern. All non-substantial amendments are communicated to the Cantonal Ethics committee Bern within the Annual Safety Report.

Dissemination plans {31a}

Trial participants and the general population are informed about the results of the study by means of a results report.

Discussion

The internet-based self-help program ROCO is, to the best of our knowledge, one of the first internet-based self-help programs specifically developed for the treatment of psychological distress due to the situation surrounding the COVID-19 pandemic. The results will give insight into the efficacy and acceptance of an internet-based self-help program in the context of COVID-19 pandemic related psychological distress. Moreover, the results will contribute to the further adaption of the self-help program. In light of possible multiple waves and future pandemics, it is

important to investigate the effectiveness of such psychological interventions as mental health resources might be strained.

Limitations of this study include that only short-term effects of the internet-based self-help program can be determined, since the waiting control condition already receives access to the self-help program after 3 weeks.

Trial status

Trial start date: May 2020.

Currently recruiting (N = 99, January 2021)

Approximate date when recruitment will be completed: April 2021.

Version 3: 28. January 2021

Abbreviations

AjD: adjustment disorder; BEI: Bern Embitterment Inventory; CAU: care as usual; CBT: cognitive behavioural therapy; CD-RISC: Connor-Davidson-Resilience Scale; COVID-19: Coronavirus 19; CSQ-8: Client Satisfaction Questionnaire-8; DASS-21: Depression Anxiety Stress Scale; GSE: General Self-Efficacy Scale; LOT-R: Life Orientation Test Revised; PHQ-9: Patient Health Questionnaire; RCT: randomized controlled trial; SARS: severe acute respiratory syndrome; SBQ-R: Suicide Behavior Questionnaire Revised; SEK-27: Self-report Measure for the assessment of emotion regulation skills; SF-12: 12-Item Short-Form Health Survey; SUS: System Usability Scale; ULS: UCLA loneliness Scale

Declarations

Acknowledgements

We thank Céline Bieri for supporting the data management and organization of e-mail schedules.

Authors' contributions {31b}

NB participated in the design of the study and the development and programming of the self-help program and drafted the manuscript. JH participated in the design of the study and the development and programming of the self-help program. TB and HZ participated in the design of the study and HZ conceived the study. All authors read and approved the final manuscript.

Funding {4}

This study is entirely funded by the University of Bern. The funding body (University of Bern) played no role in the design of the study, the collection, analysis and interpretation of data or in writing the manuscript. However, the trial sponsor is the principal investigator of the study (sponsor investigator).

Availability of data and materials {29}

The Principal Investigator, the Co-Principal Investigator and the PhD students have access to the full data sets. All data collected is stored on a firewall-encrypted back-upped server of the University of Bern with strictly regulated access only for researchers directly involved in the study.

Ethics approval and consent to participate {24}

Ethical approval has been obtained by the Cantonal Ethics Committee Bern (BASEC2020-00990). The study is registered with ClinicalTrials.gov (NCT04380909). Informed consent will be obtained from all participants in this study.

Consent for publication {32}

Not applicable.

Competing interests {28}

The authors declare that they have no competing interests.

Authors' information (optional)

None.

Rights and permission

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2.2 Manuscript of Article 2

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**Effects of an internet-based self-help intervention for psychological distress due to
COVID-19: results of a randomized controlled trial**

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Abstract

Background: The COVID-19 pandemic and its far-reaching impact on physical and mental health generate high demand and, accordingly, a great need for treatment opportunities that promote well-being and manage psychological distress. Internet-based interventions are particularly suitable for this purpose. They are easily scalable, readily accessible, and the online format allows for adherence to social distancing. For this reason, we developed an internet-based self-help intervention called ROCO to address psychological distress due to the COVID-19 pandemic. This randomized controlled trial aimed to examine the efficacy of the ROCO intervention. **Methods:** A total of 107 German-speaking adults with at least mild depressive symptoms were randomized either to the intervention group with direct access to the three-week ROCO intervention plus care as usual or the waiting control group receiving care as usual. Primary outcome (depressive symptoms) and secondary outcomes (stress, anxiety, resilience, emotion regulation, health-related quality of life, embitterment, loneliness, optimism, and self-efficacy) were assessed pre- and post-treatment and at a 6-week follow-up using self-report questionnaires (e.g., Patient Health Questionnaire-9 for depressive symptoms). **Results:** The average age was 40.36 years (SD = 14.59) and 81.3% of participants were female. The intervention did not significantly reduce primary depressive symptoms (between-group effect size: $d = 0.04$) and secondary outcomes such as anxiety and stress symptoms (between-group effect size: $d = -0.19$). However, the intervention led to a significant increase in emotion regulation skills (between-group effect size $d = 0.35$) and resilience (between-group effect size $d = 0.38$). **Conclusions:** The internet-based self-help intervention cannot be recommended for the purpose of reducing depressive symptoms. However, the increase in emotion regulation skills and resilience suggest that the intervention may be suitable for preventive purposes, like

improving overall coping with psychological distress or potential stressors. Future research is needed to examine for whom and how the intervention is most effective.

Keywords: Coronavirus, COVID-19, Depression, Internet-based self-help, Psychological distress

Introduction

In December 2019, the first cases of pneumonia of unknown origin occurred in Wuhan, China. On March 11, 2020, the World Health Organization (WHO) declared the outbreak of the novel coronavirus disease 2019 (COVID-19) as a global pandemic, and as of July 2020, more than 10 million COVID-19 cases were reported worldwide (Wiersinga et al., 2020). In addition to the threat to physical health, the COVID-19 outbreak may also negatively affect mental health. Research at the onset of the COVID-19 pandemic has already indicated that symptoms of depression, anxiety, and self-reported stress have increased in the general population (Rajkumar, 2020; Wang et al., 2020). Meanwhile, various studies point towards an increase in depression and anxiety symptoms in the general population (Luo et al., 2020; Xiong et al., 2020). Moreover, in a study comparing the prevalence of depression symptoms before and during the COVID-19 pandemic in the U.S. general population, more than a tripling of the prevalence was found (Ettman et al., 2020). A continuation of this rise in the level of depression symptoms can be expected, since ongoing restrictions such as social distancing measures lead to isolation and loneliness (Beutel et al., 2017; Dozois, 2020). Preliminary evidence supports this assumption (de Quervain et al., 2020). An online survey in Switzerland showed an increase in psychological distress from the first to the second COVID-19 wave in the general population. For example, during the first COVID-19 wave in April 2020, 9% of respondents reported severe depression symptoms, compared to 18% during the second COVID-19 wave in November 2020 (de Quervain et al., 2020). However, due to the method of data collection, these results should be considered with caution.

Since the COVID-19 pandemic appears to be associated with high levels of psychological distress in the general population, measures should be taken to diminish and prevent further

negative mental health impacts. Accordingly, considering the potential increase in demand for psychological support and a continued requirement for social distancing, easily accessible psychological interventions aiming to reduce COVID-19 related psychological distress are urgently needed (Luo et al., 2020; Xiong et al., 2020).

Information on the development and implementation of psychological interventions during the COVID-19 pandemic is still scarce. However, cognitive behavioral therapy (CBT) focusing on identifying and restructuring thought patterns and traps, relaxation techniques, and activity scheduling has been recommended (Halder, 2020; Wang et al., 2020). Furthermore, digital aids such as internet-based self-help interventions were found to be particularly suitable for the treatment of psychological distress under the given circumstances since they do not require direct on-site contact and are easily scalable (Halder, 2020; Soklaridis et al., 2020; Wang et al., 2020; Wind et al., 2020). Internet-based self-help interventions have proven to be an effective treatment option for various psychological problems, such as depressive symptoms (Andersson & Titov, 2014; Cuijpers et al., 2011).

To date, only a few studies have addressed psychological interventions targeting COVID-19 related psychological distress. In randomized controlled trials (RCT's), so far primarily psychological interventions for patients diagnosed with COVID-19 have been evaluated (Liu et al., 2020; Sotoudeh et al., 2020; Wei et al., 2020). For example, in an RCT, progressive muscle relaxation training over a period of 5 days effectively reduced anxiety and improved sleep quality in patients diagnosed with COVID-19 (Liu et al., 2020). Likewise, in a small RCT, a four-session face-to-face crisis intervention including relaxation, cognitive and metacognitive techniques, and techniques to increase resilience significantly reduced stress, anxiety, and depression in patients diagnosed with COVID-19 (Sotoudeh et al., 2020). With respect to

internet-based self-help interventions for COVID-19 related psychological distress, Wei et al. (2020) evaluated the efficacy of an internet-based self-help intervention for patients diagnosed with COVID-19 experiencing psychological distress in a small RCT. The 2-week intervention consisting of breath relaxation training, mindfulness, and self-soothing skills has proven to reduce symptoms of anxiety and depression (Wei et al., 2020). Moreover, three studies evaluated internet-based self-help interventions targeting COVID-19 related psychological distress in the general population. In their pragmatic RCT, Al-Alawi et al. (2021) found preliminary evidence that a 6-week internet-based intervention consisting of weekly online sessions based on CBT and acceptance and commitment therapy (ACT) with a certified psychotherapist significantly reduced symptoms of anxiety and depression. In addition, the control group receiving an internet-based self-help intervention (weekly newsletter based on CBT and ACT) also showed improvement in anxiety and depression. However, the online therapy sessions were found to be superior (Al-Alawi et al., 2021). Wahlund et al. (2021) evaluated a 3-week internet-based self-help intervention for dysfunctional worry related to COVID-19. The CBT-based intervention significantly reduced COVID-19 related worry and improved other outcomes such as mood and insomnia (Wahlund et al., 2021). In a pilot RCT, Aminoff et al. (2021) evaluated a tailored internet-based CBT intervention for psychological distress associated with the COVID-19 pandemic. During the 7-week intervention, participants worked on 7 out of 16 modules selected for them based on a screening and clinical interview. Participants received support from a therapist. The intervention significantly reduced depression and other outcomes such as anxiety and stress symptoms (Aminoff et al., 2021).

Based on this background, we conducted an RCT to evaluate the efficacy of an internet-based self-help intervention for psychological distress due to COVID-19 in the general

population. The intervention condition was compared to a waiting control condition with both conditions receiving care as usual (CAU). We hypothesized that the 3-week intervention called “ROCO” would lead to greater reduction of depression symptoms (primary outcome measure) and anxiety and stress symptoms (secondary outcome measures). Furthermore, we hypothesized that the intervention in addition to CAU would lead to greater beneficial effects on well-being, optimism, embitterment, loneliness, optimistic self-beliefs, emotion regulation skills, and resilience (secondary outcome measures) compared to CAU alone. We expected the effects to be stable in the 6-week follow-up.

Methods

Study design

In this parallel group RCT, an immediate treatment group receiving direct access to the 3-week internet-based self-help intervention was compared with a waiting control group. Both groups received CAU. Participants in the waiting control group were given access to the internet-based self-help intervention after 3 weeks. The immediate treatment group was followed up 6 weeks after randomization to evaluate the maintenance of potential treatment effects. We aimed to be able to detect small-to-medium between-group effect sizes of $d = 0.35$, since smaller effect sizes were considered clinically irrelevant (Donker et al., 2009). A power analysis with an α error level of 0.05 and a power ($1-\beta$) of 0.80 indicated a necessary sample size of at least 40 participants per group.

The Ethics Committee of the Canton of Bern approved the protocol of this study, and the trial was registered on ClinicalTrials.gov (NCT04380909). However, there is a slight deviation from the study protocol, as data from a second, 18-week, follow-up will be published at a later time due to the pressing nature of the topic (Brog et al., 2021).

Participants

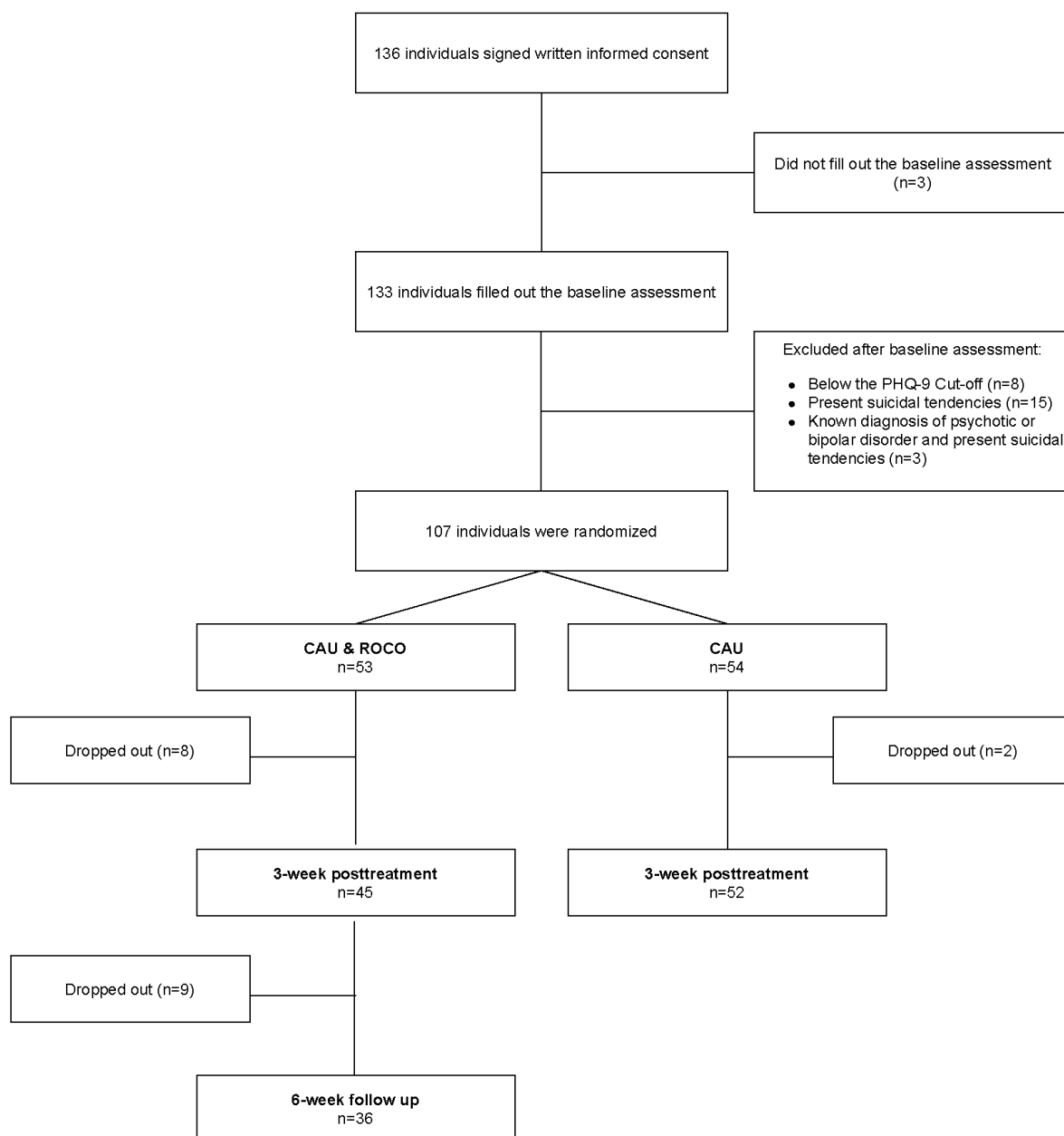
Recruitment of German-speaking participants took place between April 2020 and February 2021, mainly through newspaper articles and internet self-help forums. All interested participants first visited our study website (<https://selfhelp.psy.unibe.ch/roco/>). Participants who registered on the study website subsequently received the study information. After returning a written informed consent form signed by the participant, participants were asked to complete an online baseline assessment. The online baseline assessment consisted of the outcome measure questionnaires, questions concerning socio-demographic variables, previous or present psychological treatment, and ongoing medication intake for psychological problems. Eligibility for participation in the study was determined based on this baseline assessment.

Criteria for inclusion were (a) to be at least 18 years old, (b) to have access to the internet, (c) to have sufficient knowledge of the German language, (d) to be able to specify an emergency address in the event of an acute crisis, and (e) to exceed a cut-off value of 4 points on the Patient Health Questionnaire (PHQ-9: Löwe et al., 2002), which is interpreted as the presence of mild depressive symptoms. Criteria for exclusion were (a) the presence of suicidal tendencies (Score ≥ 8 on the Suicide Behavior Questionnaire Revised (SBQ-R); Osman et al., 2001) and (b) a known diagnosis of a psychotic or bipolar disorder.

A detailed description of the participant flow is shown in Fig. 1. A total of 26 participants had to be excluded after they filled out the baseline assessment, mainly due to present suicidal tendencies ($n = 15$) and falling below the PHQ-9 cut-off ($n = 8$). Three participants fulfilled both exclusion criteria (suicidal tendencies and known diagnosis of a psychotic or bipolar disorder). A total of 107 participants fulfilled all the inclusion criteria and none of the exclusion criteria and were randomized to one of the two study groups in a 1:1 allocation ratio.

Figure 1

Selection, randomization, and flow of participants throughout the trial



Randomization was performed using a computer-generated randomization schedule by Randomization.com (Dallal, 2007, August 3). The allocation list was concealed from the investigators and participants.

Participants were informed about their group allocation by e-mail. Participants allocated to the intermediate treatment group received an access code and registration instructions for the ROCO intervention. Three weeks after the start of the intervention the waiting period, all participants were asked to fill out an online post-assessment, consisting of the outcome measure questionnaires. After completing the post-assessment, participants in the waiting control group also were given access to the ROCO intervention. At 6 weeks after randomization, participants were asked to fill out the same outcome measure questionnaires again.

Measures

Primary outcome measure

All assessments were carried out online using self-report questionnaires. Participants filled out self-report questionnaires at pre-treatment, post-treatment (3 weeks) and follow-up (6 weeks after randomization). The primary outcome measure was the 9-item Patient Health Questionnaire (PHQ-9; Löwe et al., 2002), assessing the severity of depressive symptoms. The 9 items of the PHQ-9 correspond to the 9 DSM-IV criteria for depression. In the current sample, Cronbach's α was 0.71.

Secondary outcome measure

Secondary outcome measures include the Depression Anxiety Stress Scale (DASS-21; Lovibond & Lovibond, 1995) and the 12-Item Short-Form Health Survey (SF-12; Ware Jr et al., 1996). The DASS-21 assesses depressive mood, anxiety, and stress and is often used as measure of general psychological distress (Breedvelt et al., 2020). To address general psychological

distress, we report the composite scale of the 21-item measure (Cronbach's $\alpha = 0.87$). To assess quality of life the SF-12 was used. The 12-item measure consists of two subscales, a Physical Component Score and a Mental Component Score. The SF-12 is widely used and has a good test-retest reliability (Gandek et al., 1998).

Further secondary outcome measures are the 10-item Life Orientation Test Revised (LOT-R; Glaesmer et al., 2008), the 6-item version of the Bern Embitterment Inventory (BEI; Znoj & Schnyder, 2014), and the 10-item General Self-Efficacy Scale (GSE; Jerusalem & Schwarzer, 2003). The LOT-R assesses generalized optimism (Cronbach's $\alpha = 0.73$) and pessimism (Cronbach's $\alpha = 0.77$), while the BEI assesses embitterment, defined as the feeling of being disadvantaged by others and fate (Cronbach's $\alpha = 0.77$), and the GSE assesses optimistic self-beliefs (Cronbach's $\alpha = 0.88$).

Furthermore, emotion regulation skills were assessed using the 27-item Self-report Measure to measure emotion regulation skills (SEK-27; Berking & Znoj). For this study, the composite score is reported (Cronbach's $\alpha = 0.93$). Moreover, loneliness and resilience were assessed using the 9-item version of the UCLA Loneliness Scale (ULS; Luhmann et al., 2016) and the 10-item version of the Connor-Davidson Resilience Scale (CD-RISC; Connor & Davidson, 2003), respectively. The internal consistencies in the current sample were Cronbach's $\alpha = 0.85$ for the ULS and Cronbach's $\alpha = 0.85$ for the CD-RISC.

In addition, overall satisfaction with and usability of the internet-based self-help intervention were assessed post-treatment using the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson & Zwick, 1982) and the System Usability Scale (SUS; Brooke, 1996), respectively.

Last, the 4-item SBQ-R (Osman et al., 2001), which has been used to screen for the presence of suicidal tendencies, was also used to assess possible worsening of suicidal tendencies

during the use of the internet-based self-help intervention. However, the internal consistency of the SBQ-R was unacceptable in the current sample (Cronbach's $\alpha = 0.34$), and results concerning the SBQ-R should be considered with caution.

Description of intervention

Participants in the intervention group received access to the internet-based self-help intervention ROCO (stands for resilience and optimism during COVID-19), specifically addressing persons experiencing COVID-19 related psychological distress. ROCO is a 3-week self-help intervention consisting of 6 thematic modules. All modules contain brief texts, videos, illustrations, exercises, and a weekly task. The modules are based on cognitive behavioral therapy, focusing on (a) psychoeducation about COVID-19 related psychological distress, (b) emotion regulation skills, (c) identifying and restructuring thought patterns, (d) strengthening resilience, and (e) fostering relaxation and self-care. For a detailed description of the modules see Table 1.

The modules are preceded by an introduction and rounded off by a conclusion. The self-help intervention also comprises information on what to do in an acute crisis, including a list of emergency contacts. Furthermore, an overview of the weekly tasks can be found, as well as a symptom-tracking questionnaire, allowing participants to track their self-reported symptoms.

Participants had access to all modules at all times. However, they were encouraged to work through two of the 6 modules per week. The individual modules require 40 to 80 minutes to complete. Since participants were able to access all self-help intervention content at any time, they could thus determine the timing and order in which they worked through the self-help intervention. While working on the self-help intervention, participants had the possibility to

Table 1*Outline of the content of the internet-based self-help intervention ROCO*

Introduction	Information on the self-help intervention and its handling
1. Identifying consequences and challenges	Psychoeducation on COVID-19 related psychological distress, evaluation of the current well-being (bodily sensations, positive, and negative feelings), resource-oriented weekly task
2. Understanding own feelings	Psychoeducation on emotions such as anxiety, helplessness, anger, sense of shame, and sadness, emotion regulation skills, acceptance-oriented weekly task
3. Changing the perspective	Psychoeducation on the influence of thoughts, automatic thoughts, rumination, and irrational beliefs, restructuring thought patterns, weekly task on rumination
4. Strengthening resilience	Psychoeducation on resilience, promoting coping, joie de vivre, and optimism, resource-oriented weekly task
5. Finding rest	Psychoeducation on sleep, sleep hygiene, and relaxation techniques, progressive muscle relaxation as weekly task
6. Taking care of oneself	Psychoeducation on the concept of post-traumatic growth and the importance of indulgence, gratitude and mindfulness exercises, resource-based weekly task
Conclusion	Information on maintaining and transferring what has been learned into everyday life

enable reminders that encouraged them to log in to the self-help intervention again after a certain period of inactivity.

Furthermore, a guidance on demand approach was applied. Guidance on demand implies that support is only established when requested by a participant, but there is no scheduled contact per se. Therefore, participants could demand guidance via text-based chat function in the self-help intervention. They were informed that a psychologist would answer their request within 3 working days.

Statistical analysis

Analyses were conducted in SPSS according to an intention-to-treat principle. We conducted independent samples t tests and χ^2 tests (nominal data) to test group differences in demographic data and pre-treatment outcome measures. The efficacy of the intervention was tested with a mixed-model repeated-measures analysis of variance with time (pre-post) as a within-group factor and treatment as a between-group factor. Mixed models offer some advantages: First, in mixed models, all available data from each participant is used. Therefore, missing values are not substituted, but the parameters of the missing values are estimated. Second, mixed models account for the dependence of data and correlation of repeated measures within individuals (Bell & Fairclough, 2014; Gueorguieva & Krystal, 2004).

We computed a separate model for each outcome measure. We used a compound symmetry covariance structure since it provided the best model fit based on Bayesian Information Criteria (BIC). We calculated Cohen's d for within- and between-group effect sizes based on estimated means and the pooled standard deviations of the observed means. In order to control for the baseline measures, we computed effect sizes sensu Morris (2008) for the pre-post comparison for the intervention group and the waiting control group. We calculated a Reliable

Change Index (RCI; Jacobson & Truax, 1992) for depressive symptoms to analyze negative effects of the intervention (PHQ-9 = 4.69).

To test the stability of the effects from post-treatment to the follow-up, within-group changes in outcome scores from post-assessment to follow-up assessment were analyzed using paired t tests. Only completers were included in the analysis of follow-up data. To compare drop-outs and completers we conducted independent t tests and χ^2 tests (nominal data).

Results

Baseline Evaluation

The mean age of the 107 German-speaking participants was 40.36 years (SD = 14.59, range = 18-81 years). The majority were female ($n = 87$, 81.3%), of Swiss origin ($n = 78$, 72.9%), single ($n = 65$, 60.7%) went to university ($n = 64$, 59.8%), and were engaged in full-time ($n = 27$, 25.2%) or part-time paid work ($n = 51$, 47.5%). In total, 28 participants (26.2%) were in concurrent psychological treatment and 24 participants (22.4%) were taking medication for psychological problems. A large percentage of the participants had previous experiences with psychological treatment ($n = 68$, 63.6%). Based on the PHQ-9, the average depression score was 11.07 (SD = 4.23); 38.3% of the participants reported a mild, 39.3% a moderate, and 22.4% a severe depression. Participants initiated the participation in the study after they found the study website through a search on the internet (26.2%), after they read about the study on social media (13.1%) or in newspaper articles (16.8%), saw flyers (6.5%), and as a response to recommendations from a health professional (13.1%) or other sources such as friends or university services (23.4%).

Table 2 presents the baseline characteristics of the participants and between-group comparisons.

There was a significant between-group difference in terms of education. Persons in the treatment

group were less educated ($\chi^2_{(2)} = 8.03$, $p = 0.02$, *Cramer's V* = 0.27). The groups did not differ significantly on any of the remaining demographic characteristics or other variables. Moreover, there were no significant between-group pre-treatment differences on any of the primary or secondary outcome measures (p 's > 0.08).

Drop-out analysis and adherence to treatment

Of the 107 randomized participants, 97 (90.7%) completed the post-assessment, whereas 10 participants (9.3%) did not fill out the post-assessment (see Fig.1). There were no significant differences in terms of demographics and primary and secondary outcome measures at pre-treatment between participants who did and who did not fill out the post-assessment (p 's > 0.08). However, participants who did not fill out the post-assessment spent significantly less time in the self-help intervention ($M_{DO} = 47$ min, $SD_{DO} = 1$ h 32 min vs. $M_C = 4$ h 18 min, $SD_C = 3$ h 58 min, $t_{(27.2)} = 4.39$, $p = 0.003$, $d = 0.95$) and completed significantly less modules ($M_{DO} = 2$, $SD_{DO} = 2.07$ vs. $M_C = 4.53$, $SD_C = 2.10$, $t_{(9.7)} = 3.18$, $p = 0.004$, $d = 1.21$). A module was considered as completed if there was a timestamp (time at which the module was accessed) for the corresponding module. Since each module consisted of only one page, a timestamp indicated that the module had been consulted. Among participants who completed at least one module (48 of 53 participants in the intervention group), drop-out was 12.5%. Moreover, there was a tendency that participants who did not fill out the post-assessment were more often in the intervention group (15.1% vs. 3.7%).

Table 2

Demographics and sample characteristics at baseline for the treatment and waiting control group

	Total N = 107	Treatment group n = 53	Control group n = 54	Statistic
Age, M (SD)	40.36 (14.59)	40.68 (15.55)	40.04 (13.73)	$t_{(105)} = 0.23, p = 0.82^b$
Gender, n (%)				$\chi^2_{(1)} = 1.60, p = 0.21^a$
Male	19 (17.8)	7 (13.2)	12 (22.2)	
Female	87 (81.3)	46 (86.8)	41 (75.9)	
Non-binary	1 (0.9)	-	1 (1.9)	
Current marital status, n (%)				$\chi^2_{(1)} = 0.24, p = 0.63^a$
Single	65 (60.7)	36 (67.9)	29 (53.7)	
Married / Civil Union	30 (28.0)	15 (28.3)	15 (27.8)	
Divorced / Civil Union annulled	11 (1.3)	2 (3.8)	9 (16.7)	
Widowed / Civil partner died	1 (0.9)	-	1 (1.9)	
Education, n (%)				$\chi^2_{(2)} = 8.03, p = 0.02^a$
Compulsory School	3 (2.8)	2 (3.8)	1 (1.9)	
Apprenticeship	21 (19.6)	16 (30.2)	5 (9.3)	
Secondary II	19 (17.8)	9 (17.0)	10 (18.6)	
University	64 (59.8)	26 (49.0)	38 (70.4)	
Employment, n (%)				$\chi^2_{(3)} = 0.86, p = 0.84^a$
Full-time paid work	27 (25.2)	14 (26.4)	13 (24.1)	
Part-time paid work	51 (47.5)	24 (45.3)	27 (50.0)	
Unemployed	3 (2.8)	2 (3.8)	1 (1.9)	
At-home parent	4 (3.7)	3 (5.7)	1 (1.9)	
Student	13 (12.1)	5 (9.4)	8 (14.8)	
Retired	9 (8.4)	5 (9.4)	4 (7.4)	
Nationality, n (%)				$\chi^2_{(1)} = 0.46, p = 0.50^a$
Swiss	78 (72.9)	36 (67.9)	42 (77.8)	
German Speaking countries	26 (24.3)	14 (26.5)	12 (22.3)	
Other Countries	3 (2.7)	3 (5.7)	-	
Psychological Treatment, n (%)				
Past	68 (63.6)	38 (71.7)	30 (55.6)	$\chi^2_{(1)} = 3.01, p = 0.08$
Current	28 (26.2)	14 (26.4)	14 (25.9)	$\chi^2_{(1)} = 0.00, p = 0.95$
Current Medications, n (%)	24 (22.4)	14 (26.4%)	10 (18.5)	$\chi^2_{(1)} = 0.96, p = 0.33$
Depressive symptoms				
Gesamtwert, M (SD)	11.07 (4.23)	11.13 (4.36)	11.00 (4.14)	$t_{(105)} = 0.16, p = 0.88^b$
Mild, n (%)	41 (38.3)	21 (39.6)	20 (37.0)	$\chi^2_{(2)} = 1.54, p = 0.46$
Moderate, n (%)	42 (39.3)	18 (34.0)	24 (44.4)	
Severe, n (%)	24 (22.4)	14 (6.4)	10 (18.5)	

Note. ^a Chi-Square calculations include only categories with a frequency > 3. ^b Bootstrap 1000 samples.

Out of the 53 participants in the intervention group, 36 completed the follow-up questionnaires (67.9%). Drop-out at follow-up was associated with significantly lower usability ratings of the self-help intervention ($M_{DO} = 66.25$, $SD_{DO} = 11.91$ vs. $M_C = 87.5$, $SD_C = 11.91$, $t_{(6.8)} = 4.038$, $p = 0.005$, $d = 1.8$) and fewer completed modules ($M_{DO} = 2.17$, $SD_{DO} = 2.2$ vs. $M_C = 5.11$, $SD_C = 1.66$, $t_{(6)} = 3.1$, $p = 0.021$, $d = 1.6$).

On average, participants completed four of the six modules ($M = 4.15$, $SD = 2.27$, range = 0-6 modules) and 54.7% of participants completed all modules. Five participants did not log in to the self-help intervention (9.4%). The mean time spent in the self-help intervention was 3 hours and 47 minutes ($SD = 3$ h 54 min, range: 0 min – 22 h 24 min). Only three participants demanded guidance via text-based chat function and 15 messages were exchanged in total. Pre-post changes of the outcome measures did not correlate with the number of completed modules nor with usage time, with one exception: The pre-post changes in loneliness, assessed by the ULS, correlated significantly with the number of completed modules ($r_s = 0.395$, $p = 0.009$), meaning that the more modules were completed the higher the reduction in loneliness tended to be.

Overall effects at post-treatment

The observed and estimated means for the primary and secondary outcome measures are displayed in Table 3. For each outcome measure, a linear mixed model with group as a fixed factor and time as a repeated factor was calculated (see Table 3).

The primary outcome measure, the PHQ-9, was not qualified by a significant group x time interaction ($F_{(1,97.6)} = 0.048$, $p = 0.827$). Between-group effect size controlling for pre-measurement sensu Morris (2008) for depressive symptoms was $d = 0.04$.

Table 3

Observed and estimated means for primary and secondary outcome measures and within- and between-group effect sizes

Outcome	Pre-treatment		Post-treatment (observed)		Post-treatment (estimated)		Follow up (observed)		Post-treatment between group comparisons ^a	Pre-Post within group effect sizes (estimated means)	Between-group effect sizes at post-treatment (estimated means)
	<i>M</i> (SD)	<i>n</i>	<i>M</i> (SD)	<i>n</i>	<i>M</i> (SE)	<i>n</i>	<i>M</i> (SD)	<i>n</i>	<i>F</i> (<i>df</i>), <i>p</i>	<i>d</i> _{Cohen} (95% CI)	<i>d</i> _{ppc2 sensu morris}
PHQ-9											
Intervention	11.13 (4.36)	53	9.56 (3.70)	45	9.63 (0.59)	53	8.75 (5.07)	36	<i>F</i> (_{1,97.6}) = 0.048, <i>p</i> = 0.827	0.37 (-0.18-0.91)	0.04
Control	11.00 (4.14)	54	9.60 (3.89)	52	9.67 (0.56)	54				0.33 (-0.21-0.87)	
DASS-21											
Intervention	21.53 (9.23)	53	20.27 (10.84)	45	20.66 (1.39)	53	17 (10.44)	36	<i>F</i> (_{1,97.0}) = 1.732, <i>p</i> = 0.191	0.09 (-0.45-0.63)	-0.19
Control	22.37 (9.86)	54	19.33 (9.13)	52	19.66 (1.34)	54				0.29 (-0.25-0.82)	
SF-12 MH											
Intervention	31.10 (9.10)	53	36.72 (11.01)	43	36.47 (1.35)	53	38.31 (10.40)	36	<i>F</i> (_{1,98.3}) = 1.586, <i>p</i> = 0.211	0.54 (-0.01-1.09)	0.24
Control	28.81 (7.73)	54	32.23 (9.20)	52	32.14 (1.27)	54				0.39 (-0.15-0.93)	
SF-12 PH											
Intervention	53.43 (8.79)	53	50.96 (10.03)	43	51.26 (1.16)	53	51.26 (11.24)	36	<i>F</i> (_{1,96.3}) = 0.005 <i>p</i> = 0.942	-0.23 (-0.77-0.31)	0.01
Control	56.11 (6.98)	54	53.87 (6.43)	52	53.86 (1.10)	54				-0.34 (-0.87-0.20)	
LOT-R O											
Intervention	7.19 (2.73)	53	7.52 (2.62)	42	7.45 (0.38)	53	7.69 (2.86)	36	<i>F</i> (_{1,92.1}) = 0.674 <i>p</i> = 0.414	0.10 (-0.44-0.64)	0.12
Control	6.87 (2.33)	54	6.84 (2.65)	50	6.82 (0.36)	54				-0.02 (-0.55-0.51)	
LOT-R P											
Intervention	4.75 (2.76)	53	4.67 (2.39)	42	4.63 (0.39)	53	4.58 (2.31)	36	<i>F</i> (_{1,92.2}) = 0.027, <i>p</i> = 0.969	0.05 (-0.49-0.59)	-0.02
Control	4.70 (2.63)	54	4.62 (2.91)	50	4.64 (0.37)	54				0.02 (-0.51-0.56)	
BEI											
Intervention	8.75 (4.88)	53	8.45 (4.23)	42	8.52 (0.71)	53	7.61 (4.69)	36	<i>F</i> (_{1,93.1}) = 0.075, <i>p</i> = 0.785	0.05 (-0.49-0.59)	0.04
Control	10.07 (4.96)	54	9.50 (5.22)	50	9.62 (0.68)	54				0.09 (-0.45-0.62)	

ULS												
Intervention	21.26 (4.82)	53	19.88 (4.56)	43	20.12 (0.64)	53	19.28 (4.94)	36	$F_{(1,95.3)} = 2.155$	0.24 (-0.30-0.78)	0.20	
Control	20.37 (4.25)	54	20.27 (4.04)	52	20.16 (0.61)	54			$p = 0.145$	0.05 (-0.48-0.58)		
GSE												
Intervention	25.91 (4.47)	53	26.88 (4.81)	43	26.88 (0.66)	53	27.03 (5.35)	36	$F_{(1,95.5)} = 1.405$	0.21 (-0.33-0.75)	0.17	
Control	26.56 (4.72)	54	26.69 (4.47)	51	26.74 (0.63)	54			$p = 0.239$	0.04 (-0.49-0.57)		
SEK-27												
Intervention	62.64 (15.45)	53	73.33 (15.19)	42	71.68 (2.33)	53	73.92 (17.57)	36	$F_{(1,93.6)} = 5.661$	0.59 (0.04-1.14)	0.35	
Control	59.83 (16.61)	54	62.76 (16.65)	50	63.17 (2.22)	54			$p = 0.019$	0.20 (-0.33-0.74)		
CD-RISC												
Intervention	21.87 (6.62)	53	23.48 (6.43)	42	23.47 (0.92)	53	23.11 (6.51)	36	$F_{(1,92.8)} = 6.523$	0.25 (-0.30-0.79)	0.38	
Control	23.78 (5.47)	54	23.10 (6.75)	50	23.05 (0.88)	54			$p = 0.012$	-0.12 (-0.65-0.42)		
SBQ-R												
Intervention	4.92 (1.36)	53	5.18 (1.78)	45	5.15 (0.21)	53	5.36 (1.79)	36	$F_{(1,97.3)} = 0.010$,	-0.15 (-0.69-0.39)	-0.02	
Control	4.72 (1.28)	54	4.92 (1.41)	52	4.93 (0.20)	54			$p = 0.919$	-0.16 (-0.69-0.38)		

Note. M, mean; SD, standard deviation; SE, standard error; df, degrees of freedom; CI, confidence interval; PHQ-9, Patient Health Questionnaire; DASS-21, Depression Anxiety Stress Scale; SF-12 MH, Short-Form Health Survey mental health subscale, SF-12 PH, Short-Form Health Survey physical health subscale; LOT-R O, Life Orientation Test Revised optimism subscale; LOT-R P, Life Orientation Test Revised pessimism subscale; BEI, Bern Embitterment Inventory; ULS, UCLA Loneliness Scale; GSE, General Self-Efficacy Scale; SEK-27, Self-report Measure to measure emotion regulation skills; CD-RISC, Connor-Davidson Resilience Scale; SBQ-R, Suicide Behavior Questionnaire Revised. ^a Intention-to-treat analysis.

Likewise, the mixed-model analyses revealed no significant group x time interactions for the following secondary outcome measures: DASS-21, mental and physical health subscales of the SF-12, optimism and pessimism subscales of the LOT-R, BEI, ULS, and GSE (all F 's (degrees of freedom 1, 92.1-98.3) < 2.155, all p 's > 0.145). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) ranged between $d = 0.01 - 0.24$ (absolute values).

The SEK-27 as measure of emotion regulation skills and CD-RISC as measure of resilience were qualified by significant group x time interactions (CD-RISC: $F_{(1,92.8)} = 6.523$, $p = 0.012$; SEK-27: $F_{(1,93.6)} = 5.661$, $p = 0.019$). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) were small-to-medium with $d = 0.35$ (SEK-27) and $d = 0.38$ (CD-RISC). Within-group comparisons in the intervention group revealed small and medium effect sizes (CD-RISC: $d = 0.25$; SEK-27: $d = 0.59$). Within-group effect sizes in the waiting control group were $d = -0.12$ for the CD-RISC, respectively $d = 0.20$ for the SEK-27.

To explore whether concurrent psychological treatment or medication intake during the self-help intervention moderated pre-post effects on outcome measures, we included the corresponding variables in the mixed-model analyses and tested the significance of the three-way interaction between time, group, and concurrent psychological treatment or medication intake. None of the three-way interactions were significant (all p 's > 0.054) with two exceptions: both three-way interactions for the DASS-21 were significant (psychological treatment: $F_{(1,95.06)} = 4.626$, $p = 0.034$; medication intake: $F_{(1,92.40)} = 4.526$, $p = 0.036$). For both, concurrent psychological treatment and medication intake, only time x group interactions among participants receiving concurrent psychological treatment / medication became significant (psychological treatment: $F_{(1,23.4)} = 6.14$, $p = 0.021$ vs. $F_{(1,71.45)} = 0.002$, $p = 0.962$; medication

intake: $F_{(1,19.5)} = 4.647, p = 0.044$ vs. $F_{(1,72.8)} = 0.037, p = 0.848$). Between-group effect sizes controlling for pre-measurement sensu Morris (2008) were higher among those participants receiving psychological treatment or medication [psychological treatment: $d = -0.73$ vs. $d = 0.01$; medication intake: $d = -0.85$ vs. $d = 0.05$]. Participants who received both the internet-based self-help intervention and concurrent psychological treatment or medication showed worsening on the DASS-21 (see Table 4 for observed and estimated means).

Treatment satisfaction

Overall, participants were satisfied with the self-help intervention. The mean score on the CSQ-8 was 3.09 (SD = 0.61), corresponding to mostly satisfied (3). In addition, participants were very satisfied with the usability of the self-help intervention. The mean score on the SUS was 84.39 (SD = 14.01), lying between good (71.4) and excellent (85.5; Bangor et al., 2009).

Suicidal tendencies and negative effects

A linear mixed model with group as fixed factor and time as repeated factor (pre-post) was conducted for the worsening of suicidal tendencies. There was no significant group x time interaction on the SBQ-R ($F_{(1,97.3)} = 0.010, p = 0.919$). Observed and estimated means for the SBQ-R are presented in Table 3. Regarding negative effects, the RCI showed that in the intervention group, 20% of the participants deteriorated on depressive symptoms and in the waiting control group, 19.23% of the participants deteriorated on depressive symptoms.

Stability of effects

Observed means and standard deviations at the 6-week follow-up for the primary and secondary outcome measures are displayed in Table 3. Only participants in the intervention group who completed all three assessments (pre, post, and follow-up) were included. DASS-21 scores decreased significantly from post-treatment to follow-up ($t_{(35)} = 2.314, p = 0.027, d_z =$

0.38). There were no significant post-treatment to follow-up changes in the primary and the other secondary outcome measures ($t_{(35)}$'s = 0.170-1.617, p 's = 0.115-0.866).

Discussion

In this trial, the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress – ROCO – was investigated. The results show that the 3-week internet-based self-help intervention was not effective in reducing depressive, anxiety, and stress symptoms. There could be several reasons for this result: First, participants in this trial showed on average moderate depressive symptoms (primary outcome) at baseline. Meta-analyses indicate that the severity of depressive symptoms at baseline influence treatment effects (Bower et al., 2013; Fournier et al., 2010). For example, in their meta-analysis of low-threshold internet-based interventions, Bower et al. (2013) found that participants who are initially more severely depressed show larger treatment effects compared to participants with lower initial symptom severity. Similar results were reported by Fournier et al. (2010) in their meta-analysis on antidepressant medication and depression severity. The benefit of antidepressant medication increased with the severity of depressive symptoms. Such results can be explained by the fact that more severe depressive symptoms offer more room for improvement than mild or moderate depressive symptoms. Second, the ROCO intervention is rather short, with a duration of three weeks. Although internet-based interventions often are shorter compared to face-to-face therapies (van Beugen et al., 2014), it is possible that the ROCO intervention was too short to produce more and stronger changes for example in depressive symptoms. A study by Christensen et al. (2006) suggests that longer internet-based interventions are more effective in reducing depressive symptoms than shorter ones.

Table 4

Observed and estimated means for the DASS-21 and within- and between-group effect sizes, considering concurrent psychological treatment and medication intake

Outcome	Pre-treatment		Post-treatment (observed)		Post-treatment (estimated)		Post-treatment between group comparisons ^a	Pre-Post within group effect sizes (estimated means)	Between-group effect sizes at post-treatment (estimated means)
	<i>M</i> (SD)	<i>n</i>	<i>M</i> (SD)	<i>n</i>	<i>M</i> (SE)	<i>n</i>	<i>F</i> (<i>df</i>), <i>p</i>	<i>d</i> _{Cohen} (95% CI)	<i>d</i> _{ppc2 sensu morris}
DASS-21									
Concurrent psychological treatment									
Intervention	22.86 (8.51)	14	25.00 (10.58)	12	25.77 (2.69)	14	<i>F</i> (_{1,23.4}) = 6.14, <i>p</i> = 0.021	-0.31 (-1.36-0.75)	-0.73
Control	21.07 (9.68)	14	16.54 (8.59)	13	17.17 (2.64)	14		0.43 (-0.63-1.49)	
No concurrent psychological treatment									
Intervention	21.05 (9.53)	39	18.66 (10.56)	33	18.81 (1.62)	39	<i>F</i> (_{1,71.45}) = 0.002, <i>p</i> = 0.962	0.22 (-0.41-0.85)	0.01
Control	22.83 (10.00)	40	20.26 (9.22)	39	20.51 (1.54)	40		0.24 (-0.38-0.86)	
DASS-21									
Concurrent medication intake									
Intervention	25.29 (7.62)	14	27.91 (12.01)	11	27.53 (2.63)	14	<i>F</i> (_{1,19.5}) = 4.647, <i>p</i> = 0.044	-0.23 (-1.28-0.82)	-0.85
Control	31.20 (9.86)	10	25.90 (11.61)	10	25.90 (2.93)	10		0.49 (-0.77-1.75)	
No concurrent medication intake									
Intervention	20.18 (9.59)	38	17.82 (9.48)	33	18.37 (1.56)	38	<i>F</i> (_{1,72.8}) = 0.037, <i>p</i> = 0.848	0.19 (-0.45-0.83)	0.05
Control	20.51 (8.83)	43	17.93 (7.83)	41	18.40 (1.43)	43		0.25 (-0.35-0.85)	

Note. *M*, mean; SD, standard deviation; SE, standard error; df, degrees of freedom; CI, confidence interval; DASS-21, Depression Anxiety Stress Scale.

^a Intention-to-treat analysis.

However, heavy time constraints are one of the most common reasons for high attrition in internet-based interventions (Christensen et al., 2006; Christensen et al., 2009), which in turn would be an argument for shorter interventions. Third, we used the PHQ-9 to assess depressive symptoms. Although short measurement instruments such as the PHQ-9 are widely used, they also carry some risks (Titov & Andersson, 2021). Regarding the PHQ-9, for example, significantly more cases of major depression are detected when using simple cut-off scores than when using additional criteria consistent with DSM-IV. (Titov & Andersson, 2021). Therefore, the use of convenient cut-off scores for the PHQ-9 could lead to over-identification of individuals with clinically relevant depressive symptoms. Accordingly, our sample may have included individuals for whom psychological treatment would not be necessary and who, accordingly, would not benefit from such treatment (Titov & Andersson, 2021). Fourth, while several studies suggest that the COVID-19 pandemic has a lasting negative impact on mental health (Daly et al., 2020; Kikuchi et al., 2020), a study from the U.S. reports an initial increase in psychological distress at the onset of the COVID-19 pandemic that was followed by a decline in psychological distress in the months thereafter (Daly & Robinson, 2021). Such findings may indicate that although there was a substantial increase in psychological distress at the onset of the COVID-19 pandemic, there may be a decrease in psychological distress over time. A trajectory like this, which is characterized by a decline in mental health at the time of an adversity followed by a gradual improvement coming close to previous levels, is referred to as recovery in resilience research (Infurna & Luthar, 2018). Recovery is a common response to other major life stressors or potentially traumatic events (Clark & Georgellis, 2013; Galatzer-Levy et al., 2018). In accordance with this assumption of recovery, both groups in this trial show improvements in the primary outcome, depressive symptoms, over time. Within-group effect sizes are small-to-

medium (intervention group, $d = 0.37$, waiting control group $d = 0.33$). Therefore, it is questionable whether an early intervention to reduce psychological distress is necessary at all or if it is advisable to first observe if recovery occurs. However, since other studies have found that internet-based self-help interventions are effective in reducing COVID-19 related depressive symptoms (Al-Alawi et al., 2021; Aminoff et al., 2021; Wahlund et al., 2021), more research is needed to identify under which circumstances internet-based self-help interventions are effective in reducing COVID-19 related depressive symptoms and for whom. Nonetheless, the ROCO intervention led to an increase in emotion regulation (between-group effect of $d = 0.35$) and resilience (between-group effect of $d = 0.38$) as early as 3 weeks after treatment initiation. The effects remained stable in the 6-week follow-up. Given the content of the ROCO intervention, the improvement in emotion regulation and resilience is plausible. ROCO includes both a module that addresses emotions and emotion regulation and a module that focuses on strengthening resilience. Accordingly, the results could be explained by the content of the ROCO intervention. Taking into account that increasing resilience was mentioned as a consideration for dealing with the COVID-19 pandemic, these are encouraging results (Habersaat et al., 2020). Moreover, it has been shown that deficits in emotion regulation skills are associated with psychopathology such as depressive symptoms (Silk et al., 2003; Williams et al., 2004), while successful emotion regulation facilitates emotional adjustment (Berking et al., 2008). In the case of ROCO, these findings could indicate that the intervention only proves effective in the long-term, in particular when a new stressor occurs. Accordingly, the intervention could be particularly useful as first-step measure for preventive treatment.

Negative effect sizes for depressive, anxiety, and stress symptoms as measured by the DASS-21 were found for participants who were concurrently receiving psychological treatment

($d = -0.73$) or taking medication ($d = -0.85$). Even though the sample size for the three-way-interaction between time, group, and concurrent psychological treatment was small, these results might suggest that ROCO could be particularly beneficial for people who do not seek concurrent treatment. Lastly, the intervention group showed similar rates of deterioration with respect to depressive symptoms as the waiting control group. This result contradicts meta-analyses that showed that deterioration rates are lower in internet-based self-help interventions compared to control groups (Ebert et al., 2016; Karyotaki et al., 2018). One possible explanation for the similar deteriorations in the two groups is that the COVID-19 pandemic is an ongoing stressor (Kira et al., 2021) and, that the ROCO intervention was not successful in halting the deterioration in depressive symptoms due to the COVID-19 pandemic.

Limitations

Several limitations of our study have to be considered. Participants in the waiting control group received access to the ROCO intervention after completing the post-assessment at the end of the three-week waiting period. For this reason, between-group comparisons are not possible for follow-up measurements, which is why we could only examine the stability of the effects for the intervention group and, moreover, cannot determine, whether the decrease of DASS-21 values from the post to the follow-up measurement was due to the intervention, recovery, or other reasons. Another limitation concerns randomization. The randomization was not ideal, since the analysis of the demographic data revealed a significant group difference regarding educational status. Moreover, although we assessed whether participants used other treatments or took medications in addition to the ROCO intervention at each measurement time point, we do not have information regarding the quantity and quality of those other treatments. Other treatments or medication might also influence the results and limit the generalizability of the

study results. In this regard, the self-selection of the participants must be mentioned as another limitation. Due to self-selection, the participants may differ from the general population and the study results may be limited. Furthermore, we did not conduct a diagnostic interview, but used self-assessment questionnaires exclusively. Thus, we were not able to make diagnoses and the results may be affected by the subjective responses. Finally, drop-out rates at follow-up have to be mentioned as a limitation, even though drop-out rates at post-assessment were low.

Conclusions

Despite these limitations, the current trial provides further information on the use of internet-based self-help interventions during the COVID-19 pandemic. The investigated internet-based self-help intervention, ROCO, was not able to reduce primary depressive symptoms and is accordingly not suitable for the treatment of depressive symptoms. However, the present study showed evidence that the intervention has beneficial effects on emotion-regulation and resilience. These results suggest that the intervention may be useful for preventive purposes, such as dealing with potential future stressors. Future research is needed to examine for whom and how such an intervention is effective.

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Conflicts of interest

No conflicts of interest to disclose.

Declarations

Ethical approval has been obtained by the Cantonal Ethics committee Bern (BASEC2020-00990). Informed consent was obtained from all participants in the study.

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2.3 Manuscript of Article 3

Brog, N. A., Hegy, J. K., Berger, T., & Znoj, H. (under review). Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress. Submitted to *Frontiers in public health*.

Age, motivation, and emotion-regulation skills predict treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress

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Abstract

Introduction: First evidence suggests that internet-based self-help interventions effectively reduce COVID-19 related psychological distress. However, it is yet unclear which participant characteristics are associated with better treatment outcomes. Therefore, we conducted secondary analyses on data from a randomized controlled trial investigating the efficacy of a 3-week internet-based self-help intervention for COVID-19 related psychological distress. We explored several predictors (sociodemographic variables, psychopathological variables, resource-related variables, and treatment-related variables) of treatment outcomes, which were defined as post-treatment depressive symptoms and post-treatment resilience.

Methods: In a total of 107 participants with at least mild depressive symptoms, possible predictor variables and treatment outcomes were assessed using self-report measures. In a first step, we performed a separate linear regression analysis for each potential predictor. In a second step, predictors meeting a significant threshold of $p < 0.05$ were entered in linear multiple regression models. **Results:** The mean age of the participants was 40.36 years (SD = 14.59, range = 18-81 years) with the majority being female ($n = 87$, 81.3%). Younger age predicted lower post-treatment depressive symptoms. Additionally, higher motivation to use the intervention and better pre-treatment emotion regulation skills predicted higher post-treatment resilience.

Conclusion: The current study provides preliminary evidence regarding the relationship between participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related distress. Our results suggest that under the circumstances surrounding COVID-19 such interventions might be particularly beneficial for young adults. Moreover, focusing on participants' existing strengths might be a promising approach to promote resilience

through internet-based self-help interventions. **Trial registration:** ClinicalTrials.gov

NCT04380909. Retrospectively registered on 8 May 2020.

Keywords: COVID-19, Internet-based self-help, Depressive symptoms, Psychological distress, Resilience

Introduction

In March 2020, the World Health Organization (WHO) declared the COVID-19 (acute respiratory syndrome coronavirus 2; SARS-CoV-2) outbreak a pandemic (1). At the onset and during the COVID-19 pandemic, studies indicated a deterioration of mental health in the general population (2-6). In particular, evidence for an increase in depression and anxiety symptoms was found (7). For example, in a study in the USA, a tripling of the prevalence of depression symptoms in the general population during the COVID-19 pandemic was reported (8). Accordingly, mental health interventions mitigating a possible increase in psychological distress are needed. A promising approach is the use of internet-based self-help interventions since they do not require direct on-site contact and are easily scalable (9-11). Studies indicate that internet-based self-help interventions are an effective treatment option for various psychological problems, including depressive symptoms (12, 13). So far, few studies have investigated the efficacy of internet-based self-help interventions for COVID-19 related psychological distress in the general population. However, first results suggest that internet-based self-help interventions are efficacious in reducing COVID-19 related worry and associated symptoms (14), symptoms of depression, anxiety, and stress (15, 16), as well as in promoting resilience and emotion-regulation skills (17). Nonetheless, in one study, there was no significant reduction of depressive symptoms (17). Since there is still comparatively little research available, and it shows mixed results, it is important to find out who benefits from internet-based self-help for COVID-19 related psychological distress and who does not.

In the context of the COVID-19 pandemic, understanding the relationship between participant characteristics and treatment outcome is of particular interest since some studies point towards the need for tailoring interventions for specific risk populations (5, 7). Identifying

predictors of treatment outcomes in internet-based self-help for COVID-19 related psychological distress would allow interventions to be tailored to specific needs and thus improve intervention efficacy. Accordingly, knowledge of the predictors of treatment outcomes would inform how interventions could be improved for specific use in target populations or adapted for other target populations. For example, if age predicts treatment outcomes, interventions could be tailored and improved for specific age groups or adapted for those not yet reached. So far, potential risk factors for heightened psychological distress due to the COVID-19 pandemic include for example: pre-existing mental health problems (18-20), pre-existing physical health problems (19), younger age (21-24), identifying as non-binary (19), female gender (19-22), and difficulties in emotion regulation (25, 26).

However, to the best of our knowledge, no study to date has investigated predictors of treatment outcome in internet-based self-help interventions for COVID-19 related psychological distress. Therefore, to improve the understanding of the relationship between participant characteristics and treatment outcome in internet-based self-help for COVID-19 related psychological distress, we explored predictors of treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress called ROCO (17, 27). The efficacy of the ROCO intervention was evaluated in a randomized controlled trial, from which the data used in this study are drawn (17). The primary target of the ROCO intervention was a reduction of depressive symptoms. However, a considerable part of the intervention was also aimed at promoting resilience (27). Therefore, in the present study, we defined treatment outcomes as post-treatment depressive symptoms and post-treatment resilience. Based on the above mentioned previous research on possible risk factors for COVID-19 related psychological distress, we decided to explore sociodemographic variables (age, gender, and level of education),

psychopathological variables (ever having received a psychiatric diagnosis, previous or current psychotherapy, current medication, anxiety, stress, embitterment, loneliness, and mental and physical health quality), and resource-related variables (emotion regulation skills, optimism, and self-efficacy) as possible predictors. Moreover, we explored if treatment-related variables (motivation to use the self-help intervention, number of completed modules) predict treatment outcome.

Materials and Methods

Study Design

The data used in the current study were obtained in a parallel-group randomized controlled trial (RCT) investigating the efficacy of a short internet-based self-help intervention for COVID-19 related psychological distress called ROCO. In the RCT, an immediate treatment group was compared to a waiting control group, with both groups receiving care as usual (CAU; 17, 27). The protocol of the study was approved by the Ethics Committee of the Canton of Bern, and the trial was registered on ClinicalTrials.gov (NCT04380909).

For the present secondary analysis, data from both groups were combined, using the data of the respective treatment phase (immediate or delayed). The investigated predictors of post-treatment outcomes (depressive symptoms and resilience, respectively) were assessed before the respective treatment phase (i.e., for the immediate treatment group at baseline and for the waiting control group after the waiting period). Sociodemographic variables as well as information on previous or current psychological treatments (ever received a psychiatric diagnosis, prior experience with psychotherapy, current psychotherapy or medication intake) were collected for both groups at baseline.

Participants

We recruited German-speaking participants between April 2020 and February 2021, primarily through newspaper articles, internet forums on mental health, and advertisements on the internet. Interested participants registered on our study homepage and subsequently received the detailed study information. After providing informed consent, participants completed the online baseline assessment, consisting of questions concerning socio-demographic variables, previous or current psychological treatment, and various self-report questionnaires. The following inclusion and exclusion criteria were evaluated based on this baseline assessment: participants had to be at least 18 years of age, have access to the internet, show sufficient knowledge of the German language, provide an emergency address for the case of an acute crisis, and reach a minimum of 4 points on the Patient Health Questionnaire (PHQ; 28), which is interpreted as the presence of mild depressive symptoms. Participants were excluded if they reached a cut-off value of 8 points on the Suicide Behavior Questionnaire (SBQ-R; 29), which would indicate the presence of suicidal tendencies. Furthermore, participants reporting a known psychotic or bipolar disorder diagnosis were also excluded. A total of 107 participants met all the inclusion criteria and none of the exclusion criteria, thus constituting the current study sample. These participants were randomized in a 1:1 ratio to either the immediate treatment group or the waiting control group. Participants in the immediate treatment group received direct access to the 3-week internet-based ROCO intervention, whereas participants in the waiting control group had a waiting period of three weeks and then received access to the ROCO intervention (i.e., delayed treatment). Three weeks after randomization, all participants had to fill out a second assessment (post-treatment for the immediate treatment group; pre-treatment for the waiting control group).

All participants had to complete a third assessment six weeks after the randomization (follow-up for the immediate treatment group; post-treatment for the waiting control group).

Measures

All assessments were administered online and consisted of self-report questionnaires. We used the German versions of the self-report questionnaires.

Outcome measures

Depressive symptoms, the primary treatment target of the internet-based intervention, were measured with the PHQ-9 (28). The PHQ-9 is used to assess the severity of depressive symptoms. For this purpose, nine items are scored on a scale from 0 = not at all to 5 = nearly every day. The nine items correspond to the nine DSM-IV criteria for depression. From the nine items, a score is built: a score of 5 corresponds to mild depression, a score of 10 to moderate depression, a score of 15 to moderately severe depression, and a score of 20 to severe depression (30). In the present sample, the PHQ-9 had a satisfactory internal consistency (Cronbach's $\alpha = 0.72$ at pre-treatment and Cronbach's $\alpha = 0.74$ at post-treatment).

A secondary treatment target of the internet-based intervention was to promote resilience. Resilience was measured with the Connor-Davidson Resilience Scale (CD-RISC; 31). In the present study, the 10-item version of the CD-RISC was used. The ten items are answered on a scale from 0 = not true at all to 4 = true nearly all of the time. Higher scores correspond to more resilience. In the present sample, the CD-RISC showed good internal consistency (Cronbach's $\alpha = 0.88$ at pre-treatment and Cronbach's $\alpha = 0.90$ at post-treatment).

Predictors

We grouped possible predictor variables into four groups. The first group included sociodemographic variables, namely *age*, *gender*, and *level of education*.

The second group were psychopathological variables. At baseline, we assessed whether participants had *ever received a psychiatric diagnosis*, had *previously been in psychotherapy*, were *currently in psychotherapy*, and were *currently taking medication for mental health problems*. These variables were chosen as measures of pre-existing mental health problems and current psychological treatment needs, indicative of psychological burden (18, 32). At pre-treatment, we assessed several variables using self-report questionnaires. *Anxiety* and *stress* were measured by the corresponding subscales of the DASS-21 (33). Each subscale consists of seven items, which are answered on a scale from 0 = did not apply to me at all to 3 = applied to me very much or most of the time. On the anxiety subscale, a score of 4 represents mild anxiety, a score of 6 moderate anxiety, a score of 8 severe anxiety, and a score of 10 extremely severe anxiety. On the stress subscale, a score of 8 represents mild stress, a score of 10 moderate stress, a score of 13 severe stress, and a score of 17 extremely severe (34). In the present sample, the internal consistency at pre-treatment was close to satisfactory for the anxiety subscale (Cronbach's $\alpha = 0.68$) and good for the stress subscale (Cronbach's $\alpha = 0.81$). *Mental health quality* and *physical health quality* were assessed as measures of general health-related quality of life with the respective scales of the 12-Item Short-Form Health Survey (19, 35). Higher scores on the respective subscale indicate better mental health quality, respectively physical health quality. The SF-12 has a good test-retest reliability (36). *Embitterment* was measured with the 6-item version of the Bern Embitterment Inventory (37). Embitterment can be defined as the feeling of being disadvantaged by others and fate and might be a mental health reaction to the COVID-19 pandemic (38-40). Items are scored on a scale from 0 = I do not agree to 4 = I agree, with higher scores representing more embitterment (41). In the present sample, the internal consistency of the BEI at pre-treatment was good (Cronbach's $\alpha = 0.80$). *Loneliness* was

assessed using the 9-item version of the UCLA Loneliness Scale (ULS; 42) since several studies postulated a link between loneliness and mental health problems and the COVID-19 pandemic has been reported to increase loneliness (43, 44). The items are answered on a scale from 1 = never to 4 = often, with higher scores indicating more loneliness. In the present sample, the internal consistency of the ULS at pre-treatment was good (Cronbach's $\alpha = 0.85$).

The third group of predictor variables, which we subsumed under the umbrella term *resources*, were assessed at pre-treatment. *Self-efficacy* was assessed using the General Self-Efficacy Scale (GSE; 45). The 10 items are scored on a scale from 1 = not at all true to 4 = exactly true, with higher scores indicating more self-efficacy (45). In the present sample, the internal consistency of the GSE at pre-treatment was good (Cronbach's $\alpha = 0.89$). *Optimism* was assessed with the Life Orientation Test Revised (LOT-R; 46). The total score of the 10-item LOT-R is built from six items, since four items are filler items. A higher score indicates more optimism. The items are answered on a scale from 0 = strongly disagree to 4 = strongly agree (46). In the present sample, the internal consistency of the LOT-R at pre-treatment was good (Cronbach's $\alpha = 0.84$). *Emotion-regulation skills* were assessed with the Self-report measure for the assessment of emotion regulation skills (SEK-27; 47). The 27 items of the SEK-27 are answered on a scale from 0 = never to 4 = (almost) always, with higher scores corresponding to better emotion-regulation skills (47). In the present sample, the internal consistency for the SEK-27 at pre-treatment was excellent (Cronbach's $\alpha = 0.93$).

Finally, the fourth group of predictor variables were *treatment-related variables*. *Motivation* to use the internet-based intervention was assessed at baseline with one item (Please indicate your motivation to use the ROCO program in general). Participants could rate their motivation with a regulator from 0 = no motivation at all to 100 = greatest possible motivation.

The *number of completed modules* was measured after the treatment. It could range from 0 (no module completed) to 6 (all modules completed).

Description of intervention

The internet-based self-help intervention ROCO was aimed at persons experiencing COVID-19 related psychological distress. The acronym ROCO stands for resilience and optimism during COVID-19. The 3-week intervention consisted of six thematic modules, an introduction, and a conclusion. Additionally, the intervention comprised a page with information on what to do in an acute crisis, including a list of emergency contacts, a page with an overview of the weekly exercises, and a page with a symptom-tracking questionnaire, allowing participants to track their self-reported symptoms. The six thematic modules were based on cognitive-behavioral therapy and included texts, videos, graphics, and exercises. Each thematic module had a specific focus: in module 1, psychoeducation about COVID-19 related psychological distress was given. In module 2, participants learned about emotions and emotion regulation. In module 3, the identification and restructuring of thought patterns were addressed. In module 4, participants acquired knowledge about several possibilities to promote resilience. In module 5, relaxation techniques and sleep hygiene were discussed. Finally, in module 6, the topics of self-care and personal growth were approached. For a more detailed description of the intervention, see the study protocol of the ROCO RCT (27). Participants were advised to work through two modules per week. However, the participants could decide for themselves which modules they wanted to work on and in which order. A module took about 40 to 80 minutes to complete. Since the internet-based self-help program offered guidance on demand, the participants had the possibility to contact a psychologist via a chat function. The psychologist answered within three working days. Otherwise, there was no scheduled contact.

Statistical Analysis

All analyses were conducted using IBM SPSS Statistics (version 25). Independent samples *t*-tests and χ^2 -tests (for nominal data) were performed to examine group differences at baseline and pre-treatment. In a first step, potential predictors were identified using simple linear regression analyses. For each potential predictor a separate linear regression analysis was performed as follows: the potential predictor (e.g., age) was entered as predictor, the post-treatment score of the outcome (depressive symptoms or resilience) was entered as dependent variable, and the pre-treatment score of the respective outcome (e.g. depressive symptoms) was defined as covariate. We predetermined that predictors had to reach a *p*-value below 0.05 to be included in the subsequent multiple regression analyses. In a second step, a multiple regression analysis was performed for each outcome with the predictors identified in step 1 entered as predictors and the pre-treatment score of the respective outcome entered as covariate. To account for possible group effects, we additionally tested whether group (immediate vs. delayed treatment) was a significant predictor for the outcome while using the pre-treatment values of the respective outcome as covariate. If the group was a significant predictor ($p < 0.050$), it was added as covariate in the multiple regression analysis of the respective outcome. We did not replace missing data in the predictor variables. Hence only participants with complete data sets were considered for the respective outcomes.

Results

Sample characteristics

The total sample consisted of 107 German-speaking participants. On average, they were 40.36 years old ($SD = 14.59$, range = 18-81 years) and the majority were female ($n = 87$, 81.3%), had a university degree ($n = 64$, 59.8%) and previous experience with psychological

treatment ($n = 68, 63.6\%$). Overall, 28 participants (26.2%) were in concurrent psychological treatment and 24 participants (22.4%) were taking medication for psychological problems at baseline. The participants showed, on average, moderate depressive symptoms ($M = 10.37, SD = 4.18$) and mild anxiety and stress symptoms ($M = 4.33, SD = 3.26; M = 8.80, SD = 4.10$) at pre-treatment. Approximately one third of the participants ($n = 36, 33.6\%$) reported having received a psychiatric diagnosis at some point in their lives. Baseline or pre-treatment scores of the predictor variables and outcome measures are displayed in Table 1. There was a significant group difference in terms of education ($\chi^2_{(1)} = 5.055, p = 0.025$), indicating that participants in the immediate treatment group had a lower average level of education. Moreover, participants in the delayed treatment group completed significantly fewer modules of the intervention than participants in the immediate intervention group ($t_{(104.1)} = 2.719, p = 0.009$). Additionally, the delayed treatment group showed markedly lower pre-treatment depression scores compared to the immediate treatment group (immediate treatment group $M (SD) = 11.13 (4.36)$ vs. delayed treatment group $M (SD) = 9.60 (3.89)$). However, the group difference was not significant ($t_{(102.1)} = 1.908, p = 0.055$).

Identifying predictors of post-treatment depressive symptoms and resilience

In a first step, variables predicting post-treatment depressive symptoms and resilience were identified using simple linear regressions. We controlled for pre-treatment scores of the corresponding outcome measures (depressive symptoms or resilience). The results of the single predictor analysis are displayed in Table 2. In a second step, the variables that met the previously defined threshold of a p-value below 0.05 were included in a multiple regression model (see Tables 3 and 4). All models used centered predictor variables (grand mean-centered) to anticipate possible multicollinearity.

Table 1*Predictors and outcome measures at baseline or pre-treatment, overall and divided by group*

	Total <i>N</i> = 107	Immediate treatment group <i>n</i> = 53	Delayed treatment group <i>n</i> = 54	Statistic
Socio-demographic variables				
Age, <i>M</i> (<i>SD</i>)	40.36 (14.59)	40.68 (15.55)	40.04 (13.73)	$t_{(105)} = 0.227, p = 0.819^b$
Female, <i>n</i> (%)	87 (81.3)	46 (86.8)	41 (75.9)	$\chi^2_{(1)} = 2.078, p = 0.149$
University, <i>n</i> (%)	64 (59.8)	26 (49.1)	38 (70.4)	$\chi^2_{(1)} = 5.055, p = 0.025$
Psychopathological variables				
Psychiatric diagnosis, <i>n</i> (%)	36 (33.6)	21 (39.6)	15 (27.8)	$\chi^2_{(1)} = 1.681, p = 0.195$
Psychological treatment				
Previous, <i>n</i> (%)	68 (63.6)	38 (71.7)	30 (55.6)	$\chi^2_{(1)} = 3.009, p = 0.083$
Current, <i>n</i> (%)	28 (26.2)	14 (26.4)	14 (25.9)	$\chi^2_{(1)} = 0.003, p = 0.954$
Current medication, <i>n</i> (%)	24 (22.4) <i>n</i> ^a = 105	14 (26.4) <i>n</i> = 52	10 (18.5) <i>n</i> = 53	$\chi^2_{(1)} = 0.966, p = 0.326$
Anxiety (DASS-21), <i>M</i> (<i>SD</i>)	4.33 (3.26) <i>n</i> = 105	4.43 (3.51)	4.23 (3.01) <i>n</i> = 52	$t_{(101.3)} = 0.319, p = 0.741^b$
Stress (DASS-21), <i>M</i> (<i>SD</i>)	8.80 (4.10) <i>n</i> = 105	9.42 (4.03)	8.17 (4.12) <i>n</i> = 52	$t_{(103)} = 1.562, p = 0.119^b$
Embitterment (BEI), <i>M</i> (<i>SD</i>)	9.12 (5.04) <i>n</i> = 103	8.75 (4.88)	9.50 (5.22) <i>n</i> = 50	$t_{(101)} = -0.749, p = 0.440^b$
Loneliness (ULS), <i>M</i> (<i>SD</i>)	20.77 (4.46) <i>n</i> = 105	21.26 (4.82)	20.27 (4.04) <i>n</i> = 52	$t_{(100.6)} = 1.147, p = 0.261^b$
Mental health quality (SF-12), <i>M</i> , (<i>SD</i>)	31.66 (9.12) <i>n</i> = 105	31.10 (9.10)	32.23 (9.20) <i>n</i> = 52	$t_{(103)} = -0.636, p = 0.528^b$
Physical health quality (SF-12), <i>M</i> (<i>SD</i>)	53.65 (7.68) <i>n</i> = 105	53.43 (8.79)	53.87 (6.43) <i>n</i> = 52	$t_{(95.3)} = -0.292, p = 0.779^b$
Resources				
Optimism (LOT-R), <i>M</i> (<i>SD</i>)	14.33 (4.89) <i>n</i> = 103	14.43 (5.04)	14.22 (4.73) <i>n</i> = 50	$t_{(101)} = 0.222, p = 0.820^b$
Self-efficacy (GSE), <i>M</i> (<i>SD</i>)	26.29 (4.47) <i>n</i> = 104	25.91 (4.47)	26.69 (4.47) <i>n</i> = 51	$t_{(102)} = -0.890, p = 0.369^b$
Emotion regulation skills (SEK-27), <i>M</i> (<i>SD</i>)	62.70 (15.97) <i>n</i> = 103	62.64 (15.45)	62.76 (16.65) <i>n</i> = 50	$t_{(101)} = -0.037, p = 0.976^b$
Treatment-related variables				
Number of completed modules, <i>M</i> (<i>SD</i>)	3.51 (2.47)	4.15 (2.27)	2.89 (2.53)	$t_{(104.1)} = 2.719, p = 0.009^b$
Motivation, <i>M</i> (<i>SD</i>)	84.26 (14.14)	83.09 (17.20)	85.41 (10.35)	$t_{(85.0)} = -0.841, p = 0.417^b$

Outcome measures				
Depressive symptoms (PHQ-9), <i>M</i> (<i>SD</i>)	10.37 (4.18) <i>n</i> = 105	11.13 (4.36)	9.60 (3.89) <i>n</i> = 52	$t_{(102.1)} = 1.908, p = 0.055^b$
Resilience (CD-RISC), <i>M</i> (<i>SD</i>)	22.47 (6.68) <i>n</i> = 103	21.87 (6.62)	23.10 (6.75) <i>n</i> = 50	$t_{(101)} = -0.935, p = 0.359^b$

Note. *M*, Mean; *SD*, standard deviation; DASS-21, Depression Anxiety Stress Scale; BEI, Bern Embitterment Inventory; ULS, UCLA Loneliness Scale; SF-12, Short-Form Health Survey; LOT-R O, Life Orientation Test Revised; GSE, General Self-Efficacy Scale; SEK-27, Self-report Measure to measure emotion regulation skills; PHQ-9, Patient Health Questionnaire; CD-RISC, Connor-Davidson Resilience Scale. ^a *N*'s range from 103 to 107 due to occasional missing data. If *n* is not reported, it equals the number in the column header. ^b Bootstrap 1000 samples.

Since the variable group (immediate vs. delayed treatment) was a significant covariate for resilience ($\Delta R^2 = 0.034, \beta = -0.184, p = 0.013$), it was entered in the respective multiple regression.

Predictors of post-treatment depressive symptoms in multiple regression

Within the first multiple linear regression, we examined predictors for post-treatment depressive symptoms (see Table 3). The age of the participants at baseline was a significant predictor of post-treatment depressive symptoms (b (SE) = 0.043 (0.020), $p = 0.032$). The older the participants were, the higher their depressive symptoms were post-treatment.

Predictors of post-treatment resilience in multiple regression

Table 4 displays the results of the second multiple linear regression, in which post-treatment resilience was the outcome. Both motivation at baseline (b (SE) = 0.092 (0.032), $p = 0.006$) and pre-treatment emotion-regulation skills (b (SE) = 0.072 (0.036), $p = 0.047$) predicted post-treatment resilience. The higher the motivation of the participants to use the intervention was, the higher their resilience was post-treatment. Likewise, the better the emotion regulation skills of the participants were pre-treatment, the higher their resilience was post-treatment.

Table 2

Single-predictor linear regression analysis with post-treatment depressive symptoms respectively post-treatment resilience as dependent variable controlling for pre-treatment depressive symptoms, respectively pre-treatment resilience

Predictors	Depressive symptoms (PHQ-9)			Resilience (CD-RSIC)		
	ΔR^2	β	p	ΔR^2	β	p
Socio-demographic variables						
Age	0.066	0.259	0.006	0.004	0.066	0.382
Female Gender	0.019	-0.138	0.145	0.009	0.096	0.207
University	0.022	0.148	0.119	0.002	0.043	0.571
Psychopathological variables						
Anxiety (DASS-21)	0.044	0.246	0.026	0.000	0.005	0.950
Stress (DASS-21)	0.036	0.238	0.044	0.000	0.018	0.821
Embitterment (BEI)	0.001	0.030	0.767	0.011	0.113	0.158
Loneliness (ULS)	0.006	0.083	0.422	0.009	0.102	0.200
Mental health quality (SF-12)	0.000	0.012	0.925	0.000	0.021	0.794
Physical health quality (SF-12)	0.031	-0.178	0.063	0.001	-0.026	0.737
Psychiatric diagnosis	0.056	-0.237	0.011	0.000	0.002	0.982
Previous psychotherapy	0.069	-0.263	0.005	0.005	0.070	0.353
Current psychotherapy	0.063	-0.251	0.007	0.007	0.086	0.254
Current medication	0.005	-0.070	0.475	0.002	-0.045	0.573
Resources						
Self-efficacy (GSE)	0.011	-0.114	0.276	0.007	0.139	0.267
Optimism (LOT_R)	0.010	-0.103	0.302	0.000	0.008	0.934
Emotion regulation skills (SEK-27)	0.008	-0.103	0.349	0.024	0.189	0.037
Treatment-related variables						
Number of completed modules	0.026	-0.162	0.086	0.003	0.054	0.475
Motivation	0.020	0.141	0.135	0.027	0.163	0.030

Note. Block one: pre-treatment depressive symptoms ($R^2 = 0.297$, $\beta = 0.545$, $p < 0.001$), respectively pre-treatment resilience ($R^2 = 0.580$, $\beta = 0.762$, $p < 0.001$). Block two: predictor variables. PHQ-9, Patient Health Questionnaire; CD-RISC, Connor-Davidson Resilience Scale; DASS-21, Depression Anxiety Stress Scale; BEI, Bern Embitterment Inventory; ULS, UCLA Loneliness Scale; SF-12, Short-Form Health Survey; GSE, General Self-Efficacy Scale; LOT-R O, Life Orientation Test Revised; SEK-27, Self-report Measure to measure emotion regulation skills.

Table 3*Predictors of the post-treatment depressive symptoms (multiple regression)*

Predictors	Depressive symptoms		
	<i>b</i> (<i>SE</i>)	<i>t</i>	<i>p</i>
Pre-treatment depressive symptoms	0.299 (0.094)	3.193	0.002
Age	0.043 (0.020)	2.184	0.032
Anxiety (DASS-21)	0.179 (0.114)	1.565	0.122
Stress (DASS-21)	0.188 (0.096)	1.971	0.053
Psychiatric diagnosis	-0.763 (0.704)	-1.084	0.282
Previous psychotherapy	-1.313 (0.726)	-1.808	0.075
Current psychotherapy	-0.864 (0.768)	-1.125	0.264

Note. The model was significant ($F(7,73) = 10.715$, $p < 0.001$), adjusted $R^2 = 0.459$; the model includes an intercept ($b = 10.304$, $SE = 0.62$, $t = 16.650$, $p < 0.001$); predictors were selected based on single-predictor regressions (Table 2); predictors were grand-mean centered to avoid multicollinearity.

Table 4*Predictors of the post-treatment resilience (multiple regression)*

Predictors	Resilience		
	<i>b</i> (<i>SE</i>)	<i>t</i>	<i>p</i>
Pre-treatment resilience	0.691 (0.086)	8.007	< 0.001
Group (immediate vs. delayed treatment)	-2.465 (0.917)	-2.687	0.009
Emotion regulation skills (SEK-27)	0.072 (0.036)	2.023	0.047
Motivation	0.092 (0.032)	2.851	0.006

Note. The model was significant ($F(4,71) = 35.858$, $p < 0.001$), adjusted $R^2 = 0.650$; the model includes an intercept ($b = 23.790$, $SE = 0.61$, $t = 38.857$, $p < 0.001$); predictors were selected based on single-predictor regressions (Table 2); predictors were grand-mean centered to avoid multicollinearity.

Discussion

In the present study, we aimed to identify predictors of treatment outcome in users of an internet-based self-help intervention for COVID-19-related psychological distress. With regard to depressive symptoms, being younger predicted lower depressive symptoms after the 3-week intervention. With regard to resilience, higher motivation to use the intervention and better emotion regulation skills pre-treatment predicted higher resilience after the 3-week intervention.

We found that higher age was associated with worse treatment outcomes regarding depressive symptoms. This finding is inconsistent with previous research on predictors of internet-based self-help interventions for depression, in which age was not predictive of treatment outcome (48-52). The present finding is not straightforward to explain but could be related to the specific circumstances of the COVID-19 pandemic. A possible explanation could be a differential influence of various COVID-19-related stressors on psychological distress depending on age and that the intervention under study provided better support in dealing with certain stressors. For example, in a sample of 22-year-olds, secondary consequences of the COVID-19 pandemic, such as disruption of lifestyle or economic disruption were more strongly associated with psychological distress than COVID-19-related health risk exposures (53). Moreover, in one study, avoidant coping moderated the relationship between COVID-19 related psychological distress and depressive symptoms more strongly in younger adults compared to older adults (54). Therefore, younger adults might benefit more from an intervention fostering adaptive coping than older adults. Given that research increasingly suggests that young adults are particularly affected mentally by the COVID-19 pandemic, the present finding is promising, despite the difficult explanation (21-24).

Regarding resilience, we found that higher motivation to use the intervention and better emotion regulation skills pre-treatment predicted better treatment outcome. To the best of our knowledge, there have been no studies examining predictors of treatment outcome in interventions promoting resilience, let alone internet-based interventions. However, in an internet-based self-help intervention for stress, higher motivation seemed to predict better adherence (55). Accordingly, it could be assumed that the effect of higher motivation on treatment outcome regarding resilience is mediated by adherence in our study as well. Yet, this assumption is not supported by our data, as the number of completed modules did not predict the treatment outcome in terms of resilience (b (SE) = 0.162 (0.226), $p = 0.475$). However, these results could be attributed to the fact that we measured adherence only by the number of completed modules. Some studies point out that adherence involves much more than mere technological usage (56, 57). Therefore, it could be possible that highly motivated participants are otherwise more engaged with the internet-based intervention, for example, by addressing the content of the intervention in more depth or implementing it more thoroughly in their daily lives, which in turn could improve treatment outcome.

In addition to motivational conditions, pre-treatment emotion regulation skills also appear to predict how much participants benefit from an internet-based intervention for COVID-19 related psychological distress in terms of resilience. The better treatment outcome regarding resilience in participants with better pre-treatment emotion regulation skills could be caused by so-called capitalization. Capitalization describes the fact that pre-existing strengths of patients are reinforced and built on in therapy (58). In one study, tailoring treatment by focusing on patients' respective strengths rather than on their respective deficits led to better treatment outcomes in depressed patients (59). Since the intervention under study focuses, among other

aspects, on building emotion regulation skills, it could be argued that emotion regulation skills were capitalized in participants with better pre-treatment emotion regulation skills. Previous research found that emotion regulation skills are associated with higher resilience (60) and better emotional adjustment (61). Therefore, capitalizing emotion regulation skills might lead to benefits in resilience. In conclusion, it appears that in the present study, participants with higher pre-treatment resources (motivation or emotion-regulation skills) benefited more from the internet-based self-help intervention regarding resilience.

In the current study, multiple possible predictor variables did not predict post-treatment depressive symptoms and resilience. For example, female gender predicted neither treatment outcome. This finding is consistent with studies that found no effect of female gender on treatment outcome (48-50, 62). However, there are also some studies that have shown that female gender predicted better treatment outcome (63-65).

The current study comes with several limitations. First, our sample was relatively small for predictor analysis. The sample might have been underpowered since predictor effects in internet-based interventions tend to be small. Moreover, as only participants with complete data sets were included in the analysis, sample size was further reduced for some outcomes due to drop-out. Second, participants in the delayed treatment group completed significantly less modules than participants in the immediate treatment group ($t_{(104.1)} = 2.719, p = 0.009$). One possible reason for this result could be that the burden of the participants in the delayed treatment group has already decreased during the waiting period. Accordingly, there is a clear, albeit not significant, difference in the pre-treatment depression scores (immediate treatment group $M (SD) = 11.13 (4.36)$ vs. delayed treatment group $M (SD) = 9.60 (3.89)$). The current sample might have been already less burdened at pre-treatment, and therefore might not be representative of

people with COVID-19 related psychological distress actively seeking support. Third, we relied only on self-report outcome measures and did not conduct a clinical assessment. Accordingly, responses could be subjectively biased. This could particularly concern information on psychological burden.

Conclusion

Despite the limitations mentioned above, the current study gives preliminary evidence on the relationship between participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related distress. One promising finding is that young adults, who can be considered a psychologically vulnerable group in the COVID-19 pandemic, seem to benefit from such an intervention in terms of depressive symptoms. Moreover, participants with higher motivation and better pre-treatment emotion regulation skills seemed to be able to build on their strengths and showed better treatment outcome in terms of resilience. Therefore, it could be beneficial to tailor interventions to respective strengths of the participants in order to promote resilience. Also, further studies are needed to make informed decisions about the relationship of participant characteristics and treatment outcome in internet-based self-help interventions for COVID-19 related psychological distress.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

NAB drafted the manuscript and was responsible for its conceptualization, methodology, formal analysis, data curation, and writing. JKH was responsible for data curation and writing –

reviewing and editing. TB and HJ were responsible for project administration, resources and writing – reviewing and editing.

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Supplementary Material

Not applicable, no supplementary material is provided.

Data Availability Statement

Data are available from the first author upon reasonable request.

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3 General discussion

The ongoing COVID-19 pandemic is associated with various pandemic-related stressors and accordingly poses a burden on mental health (e.g., Taylor, 2021b). Based on the psychological impact of previous pandemics, negative effects on mental health were also expected due to the COVID-19 pandemic (e.g., Lau et al., 2005). Even though the general population generally proved resilient, the COVID-19 pandemic resulted in psychological distress for a substantial minority (e.g., Shevlin et al., 2021). Accordingly, psychological interventions are needed to mitigate the negative mental health impact of the COVID-19 pandemic. Internet-based self-help interventions have proven to be effective in the treatment of various psychological problems (e.g., Andersson & Cuijpers, 2009) and could also be promising in the treatment of COVID-19 related psychological distress (e.g., Wahlund et al., 2021).

Based on the three previously presented articles, this doctoral thesis aims to investigate whether an internet-based self-help intervention is an effective treatment option for COVID-19 related psychological distress and to identify who might benefit from it.

The first article describes the study protocol of the RCT evaluating the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress. In the second article, findings on the efficacy and in the third article, findings on predictors of treatment outcome in this internet-based self-help intervention for COVID-19 related psychological distress are reported. In the following, the findings of the second and third article will be summarized and discussed. Moreover, implications for coping with future pandemics are discussed.

3.1 Findings on efficacy

In the second article, the main results of the RCT are reported. 107 participants were randomized to either an intervention condition with direct access to the 3-week internet-based self-help intervention plus CAU or to a waiting control condition consisting of CAU only. Contrary to our expectation, the 3-week intervention was not effective in reducing depressive symptoms (between-group effect-size $d = 0.04$) and other outcomes such as anxiety and stress symptoms (between-group effect size: $d = -0.19$). However, the 3-week intervention resulted in a significant increase in emotion regulation skills (between-group effect-size $d = 0.35$) and resilience (between-group effect-size $d = 0.38$). These effects were stable in the 6-week follow-up. In addition, we analyzed negative effects of the intervention. The reliable change index showed that 20% of participants in the intervention condition and 19.23% of participants in the waiting control condition showed worsening of depressive symptoms. We also analyzed whether concurrent psychological treatment or medication use moderated pre-post effects. These analyses revealed negative effect sizes regarding general psychological distress (depressive, anxiety, and stress symptoms) for participants who were in concurrent psychological treatment (between-group effect size $d = -0.73$) or taking medication (between-group effect size $d = -0.85$).

Our findings on the efficacy of the internet-based self-help intervention regarding depressive, anxiety, and stress symptoms are inconsistent with the results of previous studies investigating internet-based self-help interventions for COVID-19 related psychological distress. In these studies, internet-based self-help interventions significantly reduced COVID-19 related worry (Wahlund et al., 2021) as well as depressive, anxiety, and stress symptoms (Al-Alawi et al., 2021; Aminoff et al., 2021). In the second article, several reasons such as severity of depressive symptoms at baseline, duration of the internet-based self-help intervention, and the

use of the Patient Health Questionnaire (Kroenke & Spitzer, 2002) as a measure of depression were provided for the results regarding the main outcome depressive symptoms. Against the background of the COVID-19 pandemic, one of the mentioned reasons should be addressed in more detail. In our RCT, participants in both groups showed improvements of depressive symptoms over time (intervention group within-group effect size $d = 0.37$ and waiting control group within-group effect size $d = 0.33$). In other words, regardless of the intervention, participants showed a decrease of depressive symptoms. This could indicate that participants on average showed *recovery*, since recovery is defined as initial psychological distress at the time of an adversity, followed by gradual improvement to previous levels of mental health (Infurna & Luthar, 2018). A similar trend was observed in the general population during the COVID-19 pandemic. As with other critical life events (Clark & Georgellis, 2013; Galatzer-Levy et al., 2018; Infurna & Luthar, 2018), a majority seemed to show recovery of psychological distress during the COVID-19 pandemic (Shevlin et al., 2021). Given the observation that COVID-19-related psychological distress seems to recover on average, the question arises whether interventions are needed at all. Considering that a substantial minority of the general population shows chronic or delayed onset of COVID-19 related psychological distress (Shevlin et al., 2021), interventions mitigating mental health effects are still needed. However, targeting individuals at risk for a chronic or delayed onset of psychological distress appears to be pivotal. Accordingly, research should seek to identify which individuals are at risk for such trajectories and how to target these individuals.

In conclusion, the intervention in our RCT not only did not significantly reduce depressive symptoms but also failed to halt deterioration of depressive symptoms related to the

ongoing COVID-19 pandemic. Therefore, the investigated internet-based self-help intervention cannot be recommended for the treatment of depressive symptoms.

However, the 3-week internet-based self-help intervention did significantly increase emotion regulation skills and resilience. These effects remained stable at the 6-week follow-up. Emotion regulation skills such as understanding and accepting emotions (Berking & Hondong, 2018) and ways to strengthen resilience such as active coping and optimism (Wu et al., 2013) were each addressed in a module of the intervention. Furthermore, other modules also contain content that impacts emotion regulation and resilience such as cognitive reappraisals (Troy & Mauss, 2011; Wu et al., 2013), progressive muscle relaxation (Berking & Hondong, 2018; Rees, 2011), and self-care (Riegel et al., 2021). Given the content of the internet-based self-help interventions, the improvements in emotion regulation skills and resilience are comprehensible.

The observed beneficial effects on emotion regulation and resilience are promising. In studies investigating the effects of emotion regulation on mental health during the COVID-19 pandemic, deficits in emotion regulation predicted deterioration of quality of life (Panayiotou et al., 2021) and greater acute stress (Tyra et al., 2021). These findings are consistent with previous research showing that deficits in emotion regulation are associated with psychopathology (Lukas et al., 2018) and might contribute to the development of depression (Berking et al., 2014). Moreover, successful emotion regulation has prospective effects on emotional adjustment (Berking et al., 2008) and contributes to resilience (Min et al., 2013; Troy & Mauss, 2011).

Resilience itself also shows association with COVID-19 related psychological distress: The higher the resilience, the lower the level of psychological distress (Kimhi et al., 2020). Likewise, resilience has been associated with lower psychological distress after traumatic events (Hoge et al., 2007; Southwick et al., 2005) and better coping abilities in the face of adversity

(Hjemdal et al., 2006). Against this background, interventions to improve emotion regulation skills and resilience seem crucial in coping with the COVID-19 pandemic.

In our RCT, we found small-to-medium effect sizes regarding emotion regulation skills and resilience. In meta-analyses on interventions targeting resilience, similar effect sizes were reported (Joyce et al., 2018; Liu et al., 2020). However, in these meta-analyses any interventions promoting resilience were included and evidence regarding the efficacy of internet-based self-help interventions for resilience is missing. Moreover, according to Chmitorz et al. (2018) previous interventions targeting resilience show problems in terms of concepts, methods, and design and therefore, the efficacy of these interventions cannot be properly evaluated. Nonetheless, our RCT provides first evidence, that an internet-based self-help intervention of three weeks significantly improves emotion regulation skills and resilience during an ongoing stressor like the COVID-19 pandemic.

Since resilience and emotion regulation are associated with prospective emotional adjustment and better coping abilities in the face of adversity, such an intervention might be useful for prevention. However, as Wahlund et al. (2021) stated, this raises the question if individuals can be “psychologically inoculated” by enhancing certain skills. Whether the internet-based self-help intervention can prevent psychological distress resulting from future stressful life events cannot be answered based on the available data. Nevertheless, the preventive use of internet-based self-help interventions could be promising.

In an additional analysis we found large negative effect sizes regarding general psychological distress for participants who were in concurrent psychological treatment or taking medication. Even though the sample size for this analysis was small, these results might suggest that the internet-based self-help intervention should be used as stand-alone intervention.

Overall, our findings on the efficacy of an internet-based self-help intervention for COVID-19 related psychological distress add heterogeneity to the findings on the efficacy of such interventions. In contrast to other interventions (Al-Alawi et al., 2021; Aminoff et al., 2021; Wahlund et al., 2021), our internet-based self-help intervention was not effective in reducing COVID-19 related psychological distress. However, the intervention significantly increased emotion regulation skills and resilience during the ongoing COVID-19 pandemic. These findings might suggest that this or similar internet-based self-help interventions could be used for the prevention of future psychological distress caused by adversity.

3.2 Findings on predictors of treatment outcome

In the third article, results from a secondary analysis ($N = 107$) on predictors of treatment outcomes of the internet-based self-help intervention are reported. In this secondary analysis, treatment outcomes were defined as depressive symptoms and resilience. Regarding depressive symptoms, we found that younger age at baseline predicted lower depressive symptoms after the 3-week intervention (b (SE) = 0.043 (0.020), $p = 0.032$). Regarding resilience, we found that higher motivation to use the intervention (i.e., Please indicate your motivation to use the ROCO program in general; b (SE) = 0.092 (0.032), $p = 0.006$) and better pre-treatment emotion regulation skills (b (SE) = 0.072 (0.036), $p = 0.047$) predicted higher resilience after the 3-week intervention.

Our finding, that younger age was associated with better treatment outcome regarding depressive symptoms is inconsistent with previous research on predictors in internet-based self-help interventions for depression. In these studies, age did not predict treatment outcome (Hobbs et al., 2018; Høifødt et al., 2015; Niles et al., 2021; Schneider et al., 2018; Warmerdam et al.,

2013). This contradictory finding cannot be easily explained. However, reasons might be related to the COVID-19 pandemic. First, the impact of pandemic-related stressors might vary depending on age. For young adults, economic consequences of the pandemic (e.g., impact on career) or changes in lifestyle due to preventive measures seem to be particularly associated with psychological distress (Ranta et al., 2020; Shanahan et al., 2020). The internet-based self-help intervention might be more useful for coping with these adversities than for example with health-related anxiety. Second, an intervention that has positive effects on coping (emotion regulation and resilience) might be more beneficial for younger adults than older adults. Indeed, one study reported that avoidant coping mediates the relationship between COVID-19 related psychological distress and depression more strongly in younger adults compared to older adults (Minahan et al., 2021). Regardless of the underlying reasons, the finding that in particular young adults might benefit from an internet-based self-help intervention during the COVID-19 pandemic is promising. Research findings suggest that young adults are at increased risk for developing COVID-19 related psychological distress (Birditt et al., 2021; Kimhi et al., 2020; Kowal et al., 2020; Li & Wang, 2020; Smith et al., 2020). These results are consistent with the finding that older adults show lower psychological distress after natural disasters than younger adults (Knight et al., 2000) and in general, perceive stressful events as less distressing (Neubauer et al., 2018).

Moreover, we found that higher motivation to use the intervention and better pre-treatment emotion regulation skills were associated with better treatment outcome regarding resilience. Given the lack of studies to date on predictors of treatment outcome in resilience enhancing interventions, let alone internet-based interventions, the results cannot be directly compared. Nonetheless, it appears that participants with higher pre-treatment resources

(motivation or emotion regulation skills) benefited more from the internet-based self-help intervention regarding resilience. The assumption discussed in the third article that motivation influences treatment outcome via adherence was not confirmed by our data. That said, we operationalized adherence only by the number of completed modules and adherence might involve more than mere technological usage (Ryan et al., 2018; Sieverink et al., 2017).

However, a reason for the reported results regarding resilience might be *capitalization*. Capitalization describes enhancing skills in therapy that represent a patient's relative strengths (Flückiger et al., 2009; Murphy et al., 2022). Luthar and Cicchetti (2000) proposed capitalization as one of ten guiding principles for interventions that aim to promote resilience. As previously mentioned, emotion regulation and resilience are closely linked (Min et al., 2013; Troy & Mauss, 2011). Given that emotion regulation skills were addressed by the internet-based self-help intervention, they may have been capitalized in participants with better pre-existing emotion regulation skills leading to better treatment outcomes regarding resilience. In addition to existing skills, such as emotion regulation skills, motivational readiness also represents a resource that can be capitalized (Flückiger et al., 2009).

Tailoring mental health interventions by targeting pre-existing strengths has shown promising results (Cheavens et al., 2012; Sauer-Zavala et al., 2019). For example, Cheavens et al. (2012) randomized depressed patients to either a treatment that focused on patients' respective strength or a treatment that focused on patients' respective deficits. Participants receiving the treatment focusing on strength showed better treatment outcomes. Likewise, Sauer-Zavala et al. (2019) reported that participants receiving treatment modules in the order of their strengths showed earlier improvements than participants receiving treatment modules in the order of their deficits. Moreover, one recently published study suggests that differences between

treatments focusing on strengths and treatments focusing on deficits is partly caused by framing of these treatments (Murphy et al., 2022). Murphy et al. (2022) conclude that participants might be more strongly encouraged by skills they believe already represent respective strengths. Therefore, when tailoring an intervention to strengths, patients should also be informed accordingly (Murphy et al., 2022). In conclusion, capitalization yields promising results and might explain our finding, that participants with higher pre-treatment resources showed better treatment outcomes regarding resilience.

Overall, the present results can only provide preliminary evidence on the relationship between participant characteristics and treatment outcome in internet-based interventions for COVID-19 related psychological distress. However, results suggest that an at-risk group, namely young adults, benefit more from such an intervention in terms of depressive symptoms. Moreover, results suggest that participants with higher motivation and better pre-treatment emotion regulation skills showed better treatment outcome in terms of resilience. As one reason might be capitalization, it could be beneficial to tailor interventions to relative strengths of participants in order to promote resilience. However, to make informed conclusions about who might benefit from an internet-based self-help intervention for COVID-19 related psychological distress, further studies need to be performed.

3.3 Limitations of the presented articles

The discussed findings on efficacy and predictors of treatment outcome must be considered in the light of several limitations. Against the background of methodological recommendations for studies of psychological interventions, main limitations of the presented articles will be addressed.

RCTs represent the gold standard for proving the efficacy of interventions. The choice of the control condition is an essential part of an RCT (Gold et al., 2017; Guidi et al., 2018). In our RCT, we compared an intervention condition receiving direct access to the internet-based self-help intervention to a waiting control condition. Participants in both conditions were allowed to use CAU. Therefore, our control condition was a combination of CAU and waiting control condition. When using waiting control conditions, groups can no longer be compared after the waiting control condition has received the intervention. For example, since participants in our waitlist control condition received access to the internet-based self-help intervention after three weeks, we were no longer able to make between-group comparisons at follow-up assessments. Further, when CAU is used, the lack of monitoring of CAU is criticized. For some participants, CAU could mean no treatment at all or a variety of treatments. Since CAU could be highly heterogeneous it may influence results (Gold et al., 2017; Guidi et al., 2018). For example, in our RCT, we assessed whether additional treatment was sought, but not its quantity or quality. This, in turn, might influence the generalizability of our results. However, the choice of the control condition should always be made in consideration of the interests of participants, researchers performing the trial and the purpose of a trial (Gold et al., 2017). Regarding the interests of participants, it should always be considered whether withholding potentially effective treatments is ethical (Gold et al., 2017).

In general, the main target of psychological interventions and focus of RCTs is symptom reduction (Cuijpers, 2019). Symptoms can be self-reported or evaluated by a clinician. The exclusive use of self-report questionnaires to assess symptoms, as we did in our RCT, could lead to subjective bias in the results from participants' responses. On the one hand, participants experience their symptoms and may be most able to evaluate them accordingly. A clinician's

assessment of symptoms, on the other hand, could provide a more objective assessment of intervention effects (Cuijpers, 2019). Moreover, when participants self-report their symptoms, the assessment seems to be more conservative than when symptoms are assessed by clinicians. In a meta-analysis, effect sizes of self-report measures were significantly smaller compared to effect sizes of clinician-rated measures (Cuijpers et al., 2010). Ultimately, RCTs might benefit from combining self-reports and assessments by a clinician.

Sampling might lead to further limitations in RCTs investigating mental health interventions (Danaher & Seeley, 2009; Ybarra & Eaton, 2005). Self-selection of participants, like in our RCT, restrict the representativeness of the sample. Self-selected samples may differ from the population of interest and therefore, reduce the external validity of results (Ybarra & Eaton, 2005).

3.4 Implications for future pandemics

The frequency of epidemics and pandemics has increased in recent decades (Lindahl & Grace, 2015). This trend is linked to the *Anthropocene*, an era of constant increase and intensification of human interactions with Earth systems (Chin et al., 2020; Priyadarsini et al., 2020). In accordance, the increase in frequency of epidemics and pandemics in the mid-20th century mirrors trends that reflect an accelerating human impact on Earth such as percentage of tropical forests loss, billions of urban populations, or increase in CO² emission (Chin et al., 2020). Recent emerging infectious diseases are dominated by *zoonotic infections* such as that approximately 75% of emerging diseases were of zoonotic origin (Lindahl & Grace, 2015; Priyadarsini et al., 2020). Examples are HIV, Ebola virus, Zika virus, avian and swine flu, SARS-COV, MERS and COVID-19 (Priyadarsini et al., 2020). Since contact between humans

and animals has intensified, the risk of infectious diseases spilling over from animal populations has increased (Chin et al., 2020). In addition, changes in global travel patterns are also accelerating the spread of infectious diseases (Priyadarsini et al., 2020). In accordance, the occurrence of further epidemics and pandemics such as the ongoing COVID-19 pandemic seems likely in the near future.

Similar to other critical/stressful life events, so far findings on psychological distress in the COVID-19 pandemic indicate resilience in the general population. Accordingly, for a majority, the initial increase in psychological distress appears to decrease over time. However, this observation of common resilience should not lead to withholding resources on part of the policymakers. First, a substantial minority shows chronic or delayed onset of psychological distress. Second, even individuals recovering from psychological distress nevertheless show psychological distress for a period of time, which can range from days to months (Infurna & Luthar, 2018). Thus, given the ongoing COVID-19 pandemic and the possibility of future pandemics, researchers should still seek ways to reduce pandemic-related psychological distress. In particular, in anticipation of future pandemics, researchers should also seek ways to promote resilience to pandemic-related psychological distress.

Despite limitations, some implications for possible future pandemics can be derived from the results discussed in this dissertation regarding the efficacy and predictors of treatment outcome in an internet-based self-help intervention for COVID-19 related psychological distress.

The body of evidence on the efficacy of internet-based self-help interventions targeting pandemic-related psychological distress is inconclusive. While other studies have demonstrated the effectiveness of such interventions (Al-Alawi et al., 2021; Aminoff et al., 2021; Wahlund et al., 2021), our intervention did not prove effective in reducing psychological distress (e.g.,

depressive symptoms). For this reason, it seems important to do further research on the efficacy of internet-based interventions for pandemic-related psychological distress. One possible approach could be to target interventions to at-risk groups for pandemic-related psychological distress. For instance, in our study, it was shown that especially young adults benefited from the internet-based self-help intervention regarding depressive symptoms. Young adults have been found to be an at-risk group for psychological distress due to the COVID-19 (e.g., Birditt et al., 2021), but also in general following stressful life events (e.g., Neubauer et al., 2018). The following implications could be drawn: First, targeting interventions to at-risk groups does seem promising for coping with pandemic-related psychological distress. Second, previous research on at-risk groups for psychological distress after both stressful life events and the COVID-19 pandemic needs to be consulted and advanced so that at-risk groups can be identified and targeted.

In addition to treating pandemic-related psychological distress, efforts should also be aimed at prevention. Our intervention significantly increased resilience and emotion regulation skills during the ongoing COVID-19 pandemic. This treatment gains sustained at a 6-week follow-up. This implies that an internet-based self-help intervention might be able to improve resilience in only three weeks. Resilience is associated with lower psychological distress both during the COVID-19 pandemic (Kimhi et al., 2020) and in general after stressful life events (e.g., Hoge et al., 2007). Therefore, in anticipation of future pandemics, the potential of internet-based self-help interventions to promote resilience should be further investigated. Moreover, it may be promising to investigate interventions that are tailored to participants' relative strengths. At least such capitalization could explain that in our study, participants with higher pre-existing emotion regulation skills benefited more from the intervention in terms of resilience. Thus, given

that the frequency of pandemics may increase, the question eventually arises whether individuals can be "vaccinated" not only against possible pathogens, but also against pandemic-related psychological distress.

3.5 Conclusion

To conclude, the interaction of humans with Earth systems may have resulted in an increased likelihood of pandemics. Therefore, despite the negative impact, the ongoing COVID-19 pandemic also presents an opportunity to improve the understanding of pandemic-related psychological distress and its treatment and prevention. Internet-based self-help interventions could be beneficial in both the treatment and prevention of pandemic-related psychological distress. However, further research is needed to provide more clarity regarding the efficacy and the relationship between patient characteristics and treatment outcomes in internet-based self-help interventions for pandemic-related psychological distress. Policymakers and researchers should not miss this ongoing opportunity to prepare for pandemics to come. As a result, research efforts might enable to not only warn about a “tsunami” of mental illness, but also support the population in coping with pandemics and their psychological impact.

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Erklärung zur Dissertation

Hiermit bestätige ich, dass ich die Dissertation (Titel):

Coping with a pandemic: Findings on efficacy and predictors of treatment outcome
in an internet-based self-help intervention for COVID-19 related psychological distress

im Fach

Psychologie

unter der Leitung von Prof. Dr. Hansjörg Znoj

ohne unerlaubte Hilfe ausgeführt und an keiner anderen Universität zur Erlangung eines
akademischen Grades eingereicht habe.

Datum 30.01.2022

Unterschrift

