RECHARGE – A Brief Psychological Intervention to Build Resilience in Health Care Workers During the COVID-19 Pandemic: Study Protocol for a Randomized Controlled Trial

Naser Morina (✉ naser.morina@usz.ch)

UniversitätsSpital Zürich: UniversitätsSpital Zurich <https://orcid.org/0000-0002-6470-4408>

Sonja Weilenmann

UniversitätsSpital Zürich, Universität Zürich

Katie S Dawson

University of New South Wales School of Psychology

Jutta Ernst

UniversitätsSpital Zürich: UniversitätsSpital Zurich

Zelim Zanitti

UniversitätsSpital Zürich: UniversitätsSpital Zurich

Roland von Känel

UniversitätsSpital Zürich: UniversitätsSpital Zurich

Matthis Schick

UniversitätsSpital Zürich: UniversitätsSpital Zurich

Tobias R Spiller

UniversitätsSpital Zürich: UniversitätsSpital Zurich

Richard A Bryant

University of New South Wales School of Psychology

Study protocol

Keywords: COVID-19, randomised controlled trial, protocol, health care workers, psychological treatment, distress, crisis intervention, pandemic, resilience

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**RECHARGE – a brief psychological intervention to build resilience in health care
workers during the COVID-19 pandemic:
study protocol for a randomized controlled trial**

Naser Morina^{1,2*}, Sonja Weilenmann^{1,2}, Katie S. Dawson³; Jutta Ernst⁴, Zelim Zanitti¹,
Roland von Känel^{1,2}, Matthias Schick^{1,2}, Tobias R. Spiller^{1,2}, Richard A. Bryant³

NM & SW contributed equally to this paper.

¹Department of Consultation-Liaison Psychiatry and Psychosomatic Medicine, University
Hospital Zurich, University of Zurich, Zurich, Switzerland

²Medical Faculty, University of Zurich, Zurich, Switzerland

³School of Psychology, University of New South Wales, Sydney, Australia

⁴Centre of Clinical Nursing Science, University Hospital Zurich, University of Zurich, Zurich,
Switzerland

*Corresponding author:

Naser Morina, PhD, Department of Consultation-Liaison Psychiatry and Psychosomatic
Medicine, University Hospital Zurich, University of Zurich, Culmannstrasse 8, CH-8091
Zurich, Switzerland, naser.morina@usz.ch, Tel +41 44 255 52 80

Abstract

Background: Health care workers (HCWs) typically face high work demands, which can be exacerbated during crises such as the COVID-19 pandemic. These demands may result in high psychological distress and reduced work performance. Although there are psychological interventions to reduce stress in HCWs under normal working circumstances, no intervention have been specifically developed to addresses stress in the context of public health crises such as the current COVID-19 pandemic. This study aims to evaluate the effectiveness of RECHARGE, a psychological intervention specifically developed for HCWs to reduce distress in HCWs. It is based on a brief crisis intervention of the World Health Organization that teaches basic stress management skills from cognitive behavioural therapy.

Methods: A randomized controlled trial (RCT) will be carried out among 160 physicians, nurses, and other HCWs working in hospitals in Switzerland during COVID-19, who are at least moderately distressed. HCWs will be randomised to RECHARGE (n=80) or active treatment as usual (ATAU) (n=80). Pre-intervention (week 1, T1), post-intervention (week 4, T2) and 2-month follow-up (week 12, T3) assessments include psychological distress as primary outcome, and indicators of mental ill-being (worries, anxiety, depression, burnout, traumatic stress, distress due to perceived ethical dilemma) and work performance as secondary outcomes. These outcomes will be compared between HCWs in the RECHARGE and ATAU groups.

Discussion: RECHARGE is an evidence-informed brief, flexible, easily scalable, fully online psychological program that allows delivery in pandemic conditions, including social isolation. Therefore, this program can serve as a much-needed template for an intervention to reduce stress and enhance work performance in HCWs during the COVID-19 pandemic. If proven effective, RECHARGE may not only be used to reduce elevated stress in HCWs in Switzerland, but also globally.

26 **Key words:** COVID-19, randomised controlled trial, protocol, health care workers;
27 psychological treatment; distress, crisis intervention; pandemic; resilience;
28
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30 <https://clinicaltrials.gov/ct2/show/record/NCT04531774>

Background

Working in healthcare is inherently demanding. Many physicians, nurses and other healthcare workers (HCWs) have to work long hours and night shifts, manage high administrative workloads, often experience a poor work-life balance, and face difficult situations with their patients [1]. As a result, HCWs may suffer from psychological distress such as burnout, anxiety, and depression, which are highly prevalent in HCWs, and may show a reduced work performance [1]. During pandemics such as the current SARS-CoV-2 outbreak, also referred to as COVID-19, HCW burden can be exacerbated. In addition to an even higher workload and increased ethical dilemmas in patient care, HCWs have to deal with insufficient resources for personal protective equipment, fear of infection and infecting family members, and with social isolation [2-4]. In a rapid review and meta-analysis on the psychological effects of emerging virus outbreaks on HCWs, Kisely and colleagues reported that working with infected patients is associated with higher levels of psychological distress [2]. Similarly, in a review on the psychological effects of the COVID-19 pandemic on HCWs, Pappa and colleagues found a high prevalence of anxiety, mood, and sleep disorders during the pandemic [3].

Organisational and individual support is key to alleviating stress among HCWs both in times of crises such as pandemics [2, 3, 5] and under normal working circumstances [6, 7]. Accordingly, several psychosocial interventions to reduce stress in HCWs under normal working circumstances have been tested. Results show that both organisational and individual-level interventions are effective in reducing common mental health symptoms and burnout among physicians [7, 8]. Among the individual-level interventions, cognitive-behavioural (focusing on stress management) and mindfulness-based programmes were shown to be the most effective ones [6-8]. However, there are hardly any evidence-based interventions that address stress during times of public health crises [9].

To meet this need, an individual-level intervention, RECHARGE, was developed specifically for HCWs to alleviate stress during pandemics and other public health crises. RECHARGE is an abbreviated and adapted version of *Problem Management Plus*, an evidence-based intervention from the *World Health Organization* that helps to cope with stress in the wake of adversity [10, 11]. As a brief psychological intervention for adults affected by adversity emerging from stress exposure, RECHARGE teaches people well-documented strategies to manage acute stress. Strategies are based on principles cognitive-behavioural therapy, including psychoeducation, a stress reduction technique, skills to managing worries and problem-solve, behavioural activation with a focus on meaningful activities, and relapse prevention [10]. Because pandemics can trigger problems for HCWs that may be different from normal circumstances (e.g., fear of infecting themselves and others, social or leisure time activities may be restricted), some of the strategies were amended to accommodate the current situation. As a result, RECHARGE is applicable to pandemics and other crises, as well as to normal working circumstances within health care.

RECHARGE may be particularly suitable to reduce psychological distress in HCWs in times of crisis because the strategies are easy to learn and implement, transdiagnostic, and address stress in otherwise healthy populations. RECHARGE was designed so that it can be delivered remotely (e.g., via video-conferencing platforms) and by a range of trained personnel, including those with no prior mental health qualifications (notably peers). This approach was undertaken to ensure the intervention is scalable and can also be implemented when time is sparse and personal contacts are restricted due to risk of contagion. To test the potential efficacy of the RECHARGE intervention, a randomized controlled trial (RCT) will be conducted to alleviate psychological distress in HCWs during the COVID-19 pandemic in Switzerland.

Methods

Aim and design

The primary aim of this study is to evaluate the effectiveness of RECHARGE to reduce distress in HCWs during the COVID-19 pandemic. As secondary aim, the study explores whether RECHARGE reduces symptoms of mental-health condition, and enhances work performance. We will conduct an RCT comparing RECHARGE to *active treatment as usual* (ATAU) in 160 study participants. Allocation to one of the two arms will be randomized with a parallel assignment on a 1:1 basis. See Figure 1 for an overview of the design.

Due to physical distancing rules and the possibility of home confinement during the COVID-19 pandemic, all procedures will be conducted online via Skype for Business. The advantage of remotely-delivered interventions is that they allow for flexibility with regards to when and where sessions can occur. This makes the interventions feasible in the context of quarantine or social isolation, and is also highly flexible in terms of timing of delivery. This is important for HCWs to easily integrate participation into their schedules, even under stressful circumstances such as the pandemic.

Hypotheses

The primary outcome of this RCT is psychological distress as measured by the *Kessler Psychological Distress Scale – K-10* [12, 13] at 2-month follow-up. We hypothesise that HCWs in the intervention condition (RECHARGE) demonstrate a lower level of psychological distress on the K-10 at 2-month follow-up than HCWs in ATAU.

The secondary outcomes of this RCT are mental health conditions and work performance. We hypothesise that HCWs in the intervention condition demonstrate lower levels of worry, anxiety, depression, burnout, posttraumatic stress, distress due to perceived ethical dilemmas,

and impaired work performance at 2-month follow-up than HCWs in ATAU. Furthermore, we will compare psychological distress, mental health conditions, and work performance not only at 2-month follow-up, but also immediately after the intervention and after 6 months.

Participants

We will enrol 160 HCWs, who for the purpose of the study will include those who define themselves as HCW (also in training) and work in a healthcare role (e.g. nurses, physicians, etc.). Patient contact is no requirement to participate in this study. Participants will be working in German-speaking cantons in Switzerland who meet the following eligibility criteria:

Inclusion criteria:

- ≥ 18 years of age;
- German-speaking;
- Access to a teleconferencing platform;
- At least a moderate level of distress as defined by a score of ≥ 16 on the Kessler Psychological Distress Scale [13].

Exclusion criteria:

- Enrolment in a similar intervention (e.g., coaching to reduce stress or enhance well-being);
- Currently in psychiatric or psychotherapeutic treatment;
- Currently on sick leave for more than two weeks

Sample size

We calculated our required sample size based on a previous trial with *Problem Management Plus* [14]. On the premise that this adapted version of *Problem Management Plus* will operate

similarly in the current context of COVID-19, we based our sample size calculations on the estimated effect size of Cohen's $d=0.4$. Calculations suggest a minimum total sample size of 130, with 65 participants per group (power $1-\beta = 0.8$, $\alpha = .05$, 2-sided). Taking into account an expected 20% attrition at 2-month follow-up, we aim to include a total number of 160 participants (80 in each condition).

Procedure

Participants will be consecutively recruited via (a) (online) advertisements on various platforms, (b) presentations at hospitals (c) local publications (e.g., meetings, newsletters, journals), (d) professional associations, and (e) word-of-mouth recommendations. Potential participants can enlist themselves via the study website, where they are directed to an online questionnaire. After reading our online study information and informed consent form, participants are asked to give informed consent by checking the consent box. Then, participants complete a series of questions screening demographic variables (gender, age, profession and area of work, professional experience, percentage of work) and eligibility criteria.

After the study coordinators have checked the eligibility criteria, participants receive a link to complete an online questionnaire assessing distress, worries, anxiety, depression, burnout, posttraumatic stress, distress due to perceived ethical dilemmas, work performance, and additional information (work hours, sleep hours, shift work, COVID-19 worries, the use and perceived utility of RECHARGE stress management strategies) at baseline (T1). They will then be randomized into one of the two arms and receive either RECHARGE (intervention) or information on stress management (ATAU). RECHARGE has a typical duration of two to four weeks but can take longer in case of difficulties in scheduling the intervention appointments. The maximal duration between the completion of the baseline measures (T1)

and the completion of RECHARGE is four weeks. An online questionnaire assessing the same variables as at T1 will again be completed four weeks (T2), 12 weeks (two-months follow up; T3), and 28 weeks (six-months follow-up; T4) after T1. Independence of assessments will be guaranteed by virtue of online testing. Each participant will receive an email from the trial coordinator that will contain a link to the assessment questionnaires.

Randomization

Randomization will be performed by entering the participants' ID in the order of their enrolment into a computerized list, which randomly assigns the participants to one of the two study arms. The list is generated off-site at the University of New South Wales (Australia), which is not involved in treatment delivery or data collection.

RECHARGE

The intervention consists of 4 sessions, each comprising 60 minutes, with a minimal time interval of 2 days between the sessions. The sessions will be delivered online via Skype for Business by coaches, who are trained peers (i.e., physicians, nurses, psychologists, and psychiatrists). While physician-coaches will only coach physicians and nurse-coaches only nurses, psychologist- and psychiatrist-coaches can deliver the intervention to all HCWs. Prior to the intervention, the coach will call the participant to introduce the program and schedule the sessions. The four sessions are structured as follows:

- **Session 1. Psychoeducation and managing stress:** Psychoeducation aims to inform participants about common emotional and physical reactions to distressing situations at work and/or during the pandemic. It thus helps the participants to understand, normalize and reduce their reactions to the current situation. In addition, a brief and

simple arousal reduction technique (slow breathing) will be taught to enhance relaxation in the face of acute stressors.

- **Session 2. Managing worries:** This strategy helps participants to categorise their worries into solvable and unsolvable problems. It is a new strategy that is not part of PM+ and it was thought to be important for this particular population facing pandemic-related adversity. Participants are taught to address solvable worries with problem solving techniques. Alternatively, for unsolvable worries, participants are taught a combination of mindfulness and cognitive techniques to postpone their worries. This strategy supports participants in managing their worries.
- **Session 3. Meaningful activities:** By using behavioral activation, this strategy is aimed at re-engaging participants gradually with meaningful activities that give them a sense of pleasure, achievement, and social connection. This strategy aims to improve participants' level of activity by incorporating attention training to enhance their mood and functioning.
- **Session 4. Staying well:** In this last session, the coaches provide education on how to maintain gains made and prevent a relapse. They help participants to identify foreseeable stressful situations and develop a plan to cope with them. Moreover, participants identify goals for the future and ways of achieving them. Finally, participants, consider how to extend their learning from the program in other areas of life.

In between the sessions, participants are asked to practise the previously taught strategies at home with the help of handouts. Their progress will be reviewed during the following session.

Coaches

204 Coaches that will deliver RECHARGE will meet the following criteria:

- 205 - ≥ 18 years of age
- 206 - German-speaking
- 207 - Working as HCW in Switzerland
- 208 - Having a completed education in medicine, nursing, psychology or any other
- 209 profession within health care.

210 Coaches in this study will receive two days training by WHO certified *Problem Management*
211 *Plus* master trainers who have adapted *Problem Management Plus* to RECHARGE. As a
212 further part of their training, coaches are required to deliver the intervention to two mock
213 participants and be a mock participant for the intervention themselves. Adherence to the
214 RECHARGE manual will be ensured by the master trainers, who will watch a video-taped
215 intervention (i.e., all four sessions) with one of the mock participants and, using a checklist to
216 ensure basic elements of the RECHARGE intervention have been followed as required.
217 Moreover, the coaches will receive one-hour weekly group supervision by the master
218 trainers, the frequency of which will be reduced gradually over the duration of the study,
219 depending on perceived competency of the coaches.

220

221 *Active Treatment-as-Usual (ATAU)*

222 In the ATAU condition, HCWs will be referred to two recommended webpages that outline
223 adaptive, well-validated coping strategies for managing distress; one is from the University
224 Hospital Zurich and the other from the Mental Health Network Switzerland (*Netzwerk*
225 *Psychische Gesundheit Schweiz*) operated by the Swiss government. Participants are asked to
226 consult these webpages and follow instructions accordingly whenever they feel distressed.

227

228 *Screening measures*

229 *Screeners and primary outcome*

230 Distress: The *Kessler Psychological Distress Scale – K-10* [12, 13], a brief screening
231 questionnaire assessing general psychological distress will be used. It consists of ten items
232 (e.g., “During the last 30 days, about how often did you feel tired out for no good reason?”)
233 rated on a 5-point Likert scale (1 = *none of the time*, 5 = *all of the time*). The questionnaire
234 will be adapted to refer to the past two weeks.

235

236 *Secondary outcomes*

237 Worries: The *Generalized Anxiety Disorder 7* [GAD-7; 15] is a 7-item self-report
238 questionnaire that measures how often during the past two weeks the participants have been
239 bothered by problems involving worry. Items are answered on a 4-point Likert scale (0 = *not*
240 *at all*, 3 = *nearly every day*), with a higher score indicating higher levels of worry.

241 Anxiety and depression: The *Hospital Anxiety and Depression Scale* [HADS; 16] is a well
242 validated and widely used 14-item scale measuring symptoms of anxiety and depression (e.g.,
243 “I feel tense or wound up”). A higher score indicates a higher symptom level of anxiety and
244 depression.

245 Burnout: The *Maslach Burnout Inventory - Health Services Survey* [MBI-HSS; 17] is
246 considered the gold standard in measuring burnout in HCWs. West and colleagues [18, 19]
247 have validated a two-item screening instrument in physicians including “I feel burned out
248 from my work” and “I have become more callous toward people since I took this job” (0 =
249 *never*, 6 = *daily*), which will be used in the present study. A higher score indicates a higher
250 level of burnout.

251 Posttraumatic stress: A 4-items short form of the *Posttraumatic Stress Disorder (PTSD)*
252 *Checklist* [PCL-5; 20] that measures PTSD symptoms corresponding to the DSM-5 criteria

will be used. Items (e.g., “Feeling distant or cut off from other people?”) are measured on a 5-point Likert scale (0 = *not at all*, 4 = *extremely*).

Distress due to perceived ethical dilemmas: The 4 items short form of the *Moral Injury Appraisals Scale* [MIAS; 21] will be included to assess distress as a consequence of acting or being witness to others acting against one’s own moral rules (e.g., “I am troubled because I acted against important moral rules”). Items are answered on a 4-point Likert scale (1 = *not at all*, 4 = *very much*), with a higher score indicating a higher level of distress.

Work performance: The *Work Ability Index* [WAI; 22, 23] assesses the self-perceived work ability and productivity with seven items (e.g., “Assume that your work ability at its best has a value of 10 points. How many points would you give your current work ability?” (0 = *completely unable to work*, 10 = *best work ability at present*)). Item 3 (disease catalogue) and item 7 (mental well-being) were not included in the study. Item 7 was deemed redundant because of other measurements that assess mental well-being, while the time frame used in item 3 is not applicable to this study and the item was already partially integrated into one exclusion criteria. A higher score indicates a higher work ability.

All questionnaires except for the PCL-5 (past month) will be adapted to refer to the past two weeks.

Other outcomes

We developed other single items in order to measure: *work hours* (“At the moment, how many hours per week do you work?”), *sleep hours* (“On average, how many hours per night did you sleep during the past two weeks?”), *shift work* (“Did you work shifts during the past two weeks?”), and *COVID-19 worries* (“At the moment, do you feel stressed by the COVID-19 pandemic?”, “I have worries regarding COVID-19. These items are answered on 5-point scales (0 = *not at all*, 4 = *very strongly*). We developed a 9-item scale - *Reducing Tension*

278 *Checklist* (RTC) - to measure the use and perceived utility of the various strategies that are
279 trained during the intervention.

280

281 *Analysis*

282 All analyses will be conducted using *R* and SPSS software. For the RCT, both intention-to-
283 treat (ITT) analysis and completers' (per protocol) analyses will be carried out. The primary
284 analysis will be the ITT analysis. Different trajectories of outcomes will be analyzed using
285 mixed linear modelling, defining treatment as fixed effects, baseline measurement of primary
286 endpoint as covariate, and subject as random effects. The benefit of this approach is that it
287 presumes intent-to-treat analyses as hierarchical linear modelling allows the number of
288 observations to vary between participants and effectively handles missing data. Time,
289 treatment condition, and their interaction will be included in the models. Baseline measures
290 (e.g. age, gender, levels of worries, depression, anxiety, etc.) will be used as covariates to
291 determine predictors of treatment response for each arm. Results will be presented as
292 differences in mean change on the K-10 (primary outcome) and on all other variables
293 (secondary outcomes) from baseline to T3 compared between RECHARGE and ATAU groups,
294 with 95% confidence intervals and p-values. In addition, differences in mean change on all
295 variables will also be calculated from baseline to T2 and T4.

296

297 *Adverse events reporting - Data and Safety Monitoring Committee*

298 Adverse events will be reported according to the Swiss Human Research Ordinance. In
299 addition, based on the principles set out by Ellenberg and colleagues [24], adverse events will
300 be reported to the Data and Safety Monitoring Board (DSMB), comprising an independent
301 clinical specialist, statistician, and trial methodologist. Stopping or modifying the trial for

safety will consider the balance of ensuring safety and how stopping will impact clinical practice.

Discussion

In times of crises such as the current COVID-19 pandemic, HCWs can face many additional stressors compared to normal circumstances. These include higher work demands, fear of contagion, and social isolation. Psychological interventions are needed to address complex stressors put on HCWs during times of crises and support them in their stress management. Importantly, such interventions have to deal with extraordinary circumstances due to the crisis, which, in the case of the COVID-19 pandemic, include home confinement, social distancing, and workloads potentially much higher than usual. This necessitates online delivery, high flexibility, and minimal time costs of the intervention. Moreover, as many HCWs are affected by adversities at the same time, such an intervention needs to be easily scalable. RECHARGE accommodates these demands as its strategies are simple and well validated in times of crises [11, 25], its delivery is brief, flexible in terms of time and personnel needed, and fully online accessible. Moreover, training of coaches is brief and does not require mental health specialists, which improves scalability of the intervention. Therefore, we believe that this program will deliver a much-needed template for an intervention to reduce stress and enhance coping in HCWs in times of crises. RECHARGE could help to ensure HCW well-being, and uphold the performance of the workforce that is vital to deal with the overload posed upon the health care system by virus outbreaks.

If proven effective, RECHARGE may not only be used in Switzerland to support the response of HCWs to the current pandemic, but also globally and for other crises. In addition, it may be helpful under non-pandemic circumstances within health care, or could be used as a program to enhance resilience to stress in preparation of pandemics. Finally, it may be

adapted so that a variety of populations with increased psychological distress (e.g., other hospital staff or individuals working in other areas) can benefit from the intervention. RECHARGE may even be tested in different formats (e.g., group version).

Trial Status

The study is currently recruiting and enrolling participants. Recruitment began on August 28, 2020, and the approximate date for completion of recruitment will be June 30, 2021.

Ethical consideration and informed consent

As confirmed and reviewed by the Cantonal Ethics Committee of Zurich (Switzerland), this study does not fall within the scope of the Human Research Act (BASEC-NR: 2020-00796). Therefore, an authorization from the ethics committee was not required. Nevertheless, this study was conducted according to the Swiss Human Research Ordinance (i.e., under strict confidentiality and privacy, with coding of health-related personal data) and the criteria set by the declaration of Helsinki. All participants receive written information on the nature, purpose and procedure of the project, their right to withhold or revoke their consent at any time, and their right to receive information. All participants give their informed consent by checking the consent box in our online study information and informed consent form prior to any study-related procedures.

Consent for publication

Not applicable.

Availability of data and material

This study follows open science practices and will use open access journals and repositories to publish results.

The data will be available from the author on reasonable request.

Clinical Trial Registration

This study has been preregistered in the Clinical Trials Registry of the U.S. National Library of Medicine on August 26, 2020 ([NCT04531774](https://clinicaltrials.gov/ct2/show/study/NCT04531774)).

Competing interests

The authors declare that they have no competing interests.

Author's contributions

All authors were involved in the concept and design of the study. KSD, NM, RB and SW developed the RECHARGE manual. NM and SW drafted the study protocol for ethics review and for the manuscript, and all authors commented and approved of the final versions.

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447

448

449

450 Figure 1: Flow diagram

STUDY PERIOD

Timepoint	Enrolment			Post Allocation			
	Registration T0a (Week 0)	Allocation		Baseline	Postmeasurement	2 month Follow Up	6 month Follow Up
		T0b (Week 0)	T0c (Week 0)	T1 (Week 1)	T2 (Week 5)	T3 (Week 13)	T4 (Week 29)
Enrolment:							
Personal Data	X						
Informed Consent	X						
Eligibility Screen		X					
Occupational Data		X					
Randomization			X				
Interventions:							
RECHARGE
ATAU
ASSESSMENTS:							
K-10		X		X	X	X	X
GAD-7				X	X	X	X
HADS				X	X	X	X
MBI-HSS				X	X	X	X
PCL-5				X	X	X	X
MIAS				X	X	X	X
WAI				X	X	X	X

Table 1: SPIRIT Overview

Figures

Figure 1

Flow diagram

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [RECHARGESPIRITCheckliste.pdf](#)