



SHORT COMMUNICATION



Development of RESTORE: an online intervention to improve mental health symptoms associated with COVID-19-related traumatic and extreme stressors

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ABSTRACT

Background: Frontline healthcare workers, recovered COVID+ patients who had severe illness, and close others of COVID+ patients who have recovered or died are at risk for clinical levels of mental health symptoms in the context of the COVID-19 pandemic. RESTORE (Recovering from Extreme Stressors Through Online Resources and E-health) was specifically designed for this context. RESTORE is a transdiagnostic guided online intervention adapted from evidence-based cognitive-behavioural therapies.

Objectives: RESTORE was designed to address depression, anxiety, and posttraumatic stress disorder symptoms associated with exposure to COVID-19-related traumatic and extreme stressors, and to overcome multiple barriers to accessing psychotherapies.

Method: This paper describes the intervention components and platform, as well as the principles used to develop RESTORE. Current research and future directions in developing and testing RESTORE are outlined.

Results: Preliminary data from an initial uncontrolled trial evaluating RESTORE in frontline healthcare workers is highly promising.

Conclusion: We believe RESTORE has great potential to provide accessible, evidence-based psychological intervention to those in great need.

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PALABRAS CLAVE

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关键词

心理健康; COVID-19; 在线的; 干预; 跨诊断; RESTORE

HIGHLIGHTS

- RESTORE is a transdiagnostic online intervention adapted from evidence-based cognitive-behavioural therapies designed to address mental health symptoms related to exposure to COVID-19-related traumatic and extreme stressors, and to overcome barriers to accessing psychotherapy.

Desarrollo de RESTORE (restaurar): una intervención en línea para mejorar los síntomas de salud mental asociados a los estresores traumáticos y extremos relacionados con COVID-19

Antecedentes: Los trabajadores de salud de primera línea, los pacientes de COVID positivo recuperados que tenían una enfermedad grave y las personas cercanas a los pacientes de COVID positivo que se han recuperado o fallecido están en riesgo de presentar niveles clínicos de síntomas de salud mental en el contexto de la pandemia de COVID-19. RESTORE (por sus siglas en inglés: Recovering from Extreme Stressors Through Online Resources and E-health: Recuperación de estresores extremos a través de recursos en línea y salud electrónica) fue diseñada específicamente para este contexto. RESTORE es una intervención en línea guiada transdiagnóstica adaptada de terapias cognitivo-conductuales basadas en la evidencia.

Objetivos: RESTORE fue diseñado para abordar la depresión, la ansiedad y los síntomas del trastorno de estrés postraumático asociados con la exposición a factores estresantes traumáticos y extremos relacionados con COVID-19, y para superar múltiples barreras para acceder a psicoterapias.

Método: Este artículo describe los componentes y la plataforma de la intervención, así como los principios utilizados para desarrollar RESTORE. Se describen las investigaciones actuales y las direcciones futuras para desarrollar y testear RESTORE.

Resultados: Los datos preliminares de un ensayo inicial no controlado que evalúa RESTORE en trabajadores de salud de primera línea son muy prometedores.

Conclusión: Creemos que RESTORE tiene un gran potencial para brindar una intervención psicológica accesible y basada en la evidencia a quienes más lo necesitan.

RESTORE 的开发:一项改善 COVID-19 相关创伤性和极端应激源相关的心理健康症状的在线干预

背景: 在 COVID-19 疫情背景下, 一线医护人员, 重症 COVID+ 康复患者以及已康复或死亡的 COVID+ 患者的其他亲友都有出现临床心理健康症状的风险。RESTORE (通过在线资源和电子健康从极端应激源中恢复) 专为这种情况而设计。RESTORE 是一种改编自循证认知行为疗法的跨诊断指导的在线干预。

目的: RESTORE 旨在致力于 COVID-19 相关创伤性和极端应激源暴露相关的抑郁, 焦虑和创伤后应激障碍症状, 并克服心理治疗可得性的多种障碍。

方法: 本文介绍了干预组成和平台, 以及用于开发 RESTORE 的原则。概述了开发和测试 RESTORE 的当前研究和未来方向。

结果: 来自评估一线医护人员 RESTORE 的初始非对照试验的初步数据大有前景。

结论: 我们相信 RESTORE 有很大的潜力为急需帮助者提供易得, 询证的心理干预。

The negative mental health effects of the COVID-19 pandemic appear to be particularly pronounced among frontline healthcare workers (HCW) who have been exposed to traumatic or other extremely stressful situations in the course of their work. Accumulating evidence indicates that a substantial proportion of HCW have clinical levels of depression, anxiety, and posttraumatic stress disorder (PTSD) symptoms in the context of the pandemic (e.g. De Kock et al., 2021; Greenberg et al., 2021). Patients who have recovered from severe illness related to COVID-19 are also at risk for these symptoms (Bo et al., 2021; Janiri et al., 2021), and similar negative mental health outcomes are anticipated in close others of COVID+ patients (Simon, Saxe, & Marmar, 2020; Tanoue et al., 2020).

Although some individuals will recover from these negative mental health effects on their own, many will continue to experience symptoms at clinical levels for months and years after the pandemic (e.g. Hong et al., 2009; McAlonan et al., 2007). These mental health symptoms can be severe and debilitating, and are associated with significant individual and societal costs (e.g. Kessler, 2000; Lecrubier, 2001; Rehm & Shield, 2019). Thus, there is an urgent need for evidence-based psychological interventions for these individuals (Marques, Bartuska, Cohen, & Youn, 2020; Yang et al., 2020). It is imperative that any such interventions be designed to address the range of mental health symptoms that can result from traumatic or extreme stressor exposure, be easily accessible, and have potential for broad dissemination. E-health solutions are one avenue by which to increase accessibility to mental health interventions in a scalable way, and have been recommended as part of a plan to address mental health concerns in the wake of the COVID-19 pandemic (Rauschenberg et al., 2021; Torous, Myrick, Rauseo-Ricupero, & Firth, 2020). With these principles in mind, we developed RESTORE (Recovering from Extreme Stressors Through Online Resources and E-health; www.restoreonline.ca), an online, guided self-directed intervention to improve symptoms of depression, anxiety, and PTSD in individuals who have been exposed to traumatic or extremely stressful experiences in the context of the COVID-19 pandemic. This paper describes the intervention components and platform, as well as the principles used to develop RESTORE 1.0. Current research and future

directions in testing and further developing RESTORE are outlined.

1. Method

1.1. Target populations

We designed RESTORE for adults (18 years of age and older) experiencing depression, anxiety, and/or PTSD symptoms related to exposure to COVID-19-related traumatic or extreme stressors – this includes HCW, other essential service workers, as well as individuals who were seriously ill with COVID-19 and recovered, and close others of those who were seriously ill with COVID-19 (Inchausti, MacBeth, Hasson-Ohayon, & Dimaggio, 2020). RESTORE applies to a wide range of COVID-19-related extreme stressors including: death of a colleague or loved one; having to restrict loved ones from visiting someone at end of life; being unable to visit a close other who was seriously ill; believing that oneself or close other would die; believing that one caused the serious illness or death of another person; having been intubated; having to work in a high-risk for infection environment; witnessing many deaths; having to perform work duties outside of one's professional training; and being unable to carry out what one believes is the ethnically correct action (i.e. moral distress; Lamiani, Borghi, & Argentero, 2017). Throughout RESTORE, each concept is illustrated with several examples from the perspectives of frontline workers, individuals who were seriously ill with COVID-19, and close others of those who were seriously ill with COVID-19.

Inclusion criteria in current pilot testing are: exposure to a COVID-19-related traumatic or extreme stressor, a score above clinical threshold on either the Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001), Generalized Anxiety Disorder Scale-7 (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006), or PTSD Checklist Scale-5 (PCL-5; Weathers et al., 2013), fluent in English, and access to high-speed internet and a computer or tablet. Participants are asked to refrain from psychotherapy focused on stress responses related to the pandemic while they are doing the programme. A suicide attempt in the past year or more than fleeting thoughts of suicide are exclusions for participation.

1.2. Intervention development

1.2.1. Method of delivery

We chose an online self-directed intervention with guidance because: (1) Such interventions have been found in meta-analyses to be safe and highly efficacious for PTSD and other mental health symptoms following traumatic experiences (Sijbrandij, Kunovski, & Cuijpers, 2016); (2) Online delivery was essential given ongoing pandemic-related restrictions to in-person services; (3) Self-directed online interventions maximize the potential for broad dissemination and increase the likelihood of engaging individuals who are reluctant to seek out psychotherapy due to anticipated stigma, their own negative thoughts and expectations about mental health treatment, and financial and logistical barriers (Clement et al., 2015). For these reasons, RESTORE was purposefully designed to **not** be psychotherapy.

1.2.2. Intervention structure

The current version of RESTORE (RESTORE 1.0) includes eight modules 30 to 40 minutes each in length, intended to be completed over 4 to 8 weeks. Participants are encouraged to complete the modules at a pace of 2 per week, consistent with research showing that more frequent sessions are associated with better outcomes from cognitive-behavioural-therapy (CBT) (Gutner, Suvak, Sloan, & Resick, 2016). If a participant attempts to move from one module to the next within fewer than 24 hours, a message appears recommending they spend at least 24 hours on the practice assignments. However, they are not blocked from progressing. After 8 weeks, participants are prevented from further progressing through the intervention. This time limit was implemented to encourage completion, and at a pace likely to be effective. Participants are able to access completed modules for an additional 6 months.

1.2.3. Intervention content

The first three authors met to decide on intervention content. Our aim was to target mechanisms we hypothesized would maintain mental health symptoms in individuals exposed to COVID-19-related traumatic or extreme stressors, using evidence-based psychological interventions. This is in contrast to interventions that aim to enhance coping with stressors and symptoms. We decided to focus on addressing three main potential mechanisms: (1) social isolation and withdrawal from other positive activities; (2) avoidance of thoughts, feelings, and situations related to extremely stressful situations, and (3) negative cognitions about the cause, meaning, and implications of traumatic or extremely stressful events. Our decisions were based on existing theory and research

on maintaining mechanisms of depression, anxiety, and PTSD, the known importance of social support and the context of social isolation in the pandemic, and accounts by HCW, individuals who were severely ill with COVID-19, and close others of individuals who were severely ill with COVID-19 that highlighted the potential role of negative cognitions in mental health symptoms.

We adapted Cognitive Processing Therapy (CPT), an evidence-based CBT for PTSD (Resick, Monson, & Chard, Resick, et al., 2017), to facilitate acceptance of the COVID-19-related extremely stressful events, to resolve misplaced blame, and to shift negative beliefs about the implications of extremely stressful events. We also included graded exposure (Brown, Zandberg, & Foa, 2019) to address avoidance of difficult thoughts, feelings and situations, and positive activity scheduling (Cuijpers, van Straten, & Warmerdam, 2007) to combat behavioural inactivity.

Like CPT, RESTORE's approach to trauma and extreme stressor processing involves writing about the impact of the event(s), identifying 'Stuck Thoughts' preventing recovery, and learning to identify more helpful perspectives on the event(s) and its implications. Our approach to shifting 'Stuck Thoughts' in RESTORE is simplified to involve: brainstorming other perspectives; evaluating the evidence for, and helpfulness of, 'Stuck Thoughts' and potential alternative ways of thinking; choosing the best alternative(s); reflecting on how this affects feelings and behaviours; and trying out the new ways of thinking. RESTORE also addresses the importance of: expressing emotions that are natural to traumatic and extremely stressful events (e.g. sadness in the face of loss), working through, rather than avoiding, thoughts, feelings and grief, 'living a life of approach' (doing smaller day-to-day activities that reflect a lifestyle of approaching versus avoiding distress; Monson et al., 2021), and improving social connection. See Table 1 for an overview of each module's content.

1.2.4. Guidance methods

Given the known benefits (Sijbrandij et al., 2016), RESTORE includes guidance to promote engagement and troubleshoot any issues with participants' adherence to the intervention. All guides have a bachelor's degree and some background in mental health, but do not necessarily have clinical training. Participants can message their guide through the platform as needed, and pre-scheduled 15-minute check-ins occur after modules 1, 2, 4, 6 and 8. Participants can choose to have check-ins by phone or direct messaging. The guides monitor changes in symptom scores and encourage engagement and completion of the modules, including practice assignments. Guides may clarify content, answer questions about use of the

Table 1. Overview of RESTORE.

Module	Content	Practice assignments
1: Introduction to RESTORE	-Psychoeducation about extreme stressors and recovery	-Writing about the impact of the stressors -Daily increasing of positive activities
2: Understanding the Connection Between Thoughts, Feelings, and Beliefs	-Explanation of the connection between thoughts, feelings and beliefs -Psychoeducation about feelings including natural vs. created feelings -Psychoeducation about avoidance -Psychoeducation about social support and connection	-Daily increasing of positive activities -Daily increasing of positive activities -The ABCs
3: Living a Life of Approach	-Psychoeducation about approaching -LEARN to approach strategy	-Daily increasing of positive activities -3 approach practices
4: Accepting the Events of the Pandemic	-Thinking traps: undoing, situational neglect, hindsight bias -Identifying Stuck Thoughts about acceptance -BEND Your Thinking to shift Stuck Thoughts	-Daily increasing of positive activities -3 approach practices -BEND Your Thinking Worksheets
5: Rethinking Blame	-Psychoeducation about blame, responsibility, and the unforeseeable -Thinking traps: just world thinking -Identify Stuck Thoughts about blame	-Daily increasing of positive activities -3 approach practices -BEND Your Thinking Worksheets
6: Examining Your Big Picture Beliefs	-Psychoeducation about how beliefs about the self, world, and others can be affected by extremely stressful experiences -Identifying Stuck Thoughts about safety, trust and control	-Daily increasing of positive activities -3 approach practices -BEND Your Thinking Worksheets
7: Examining Your Big Picture Beliefs Part 2	-Identifying Stuck Thoughts about regard for self and others, and coping	-Daily increasing of positive activities -3 approach practices -BEND Your Thinking Worksheets
8: Moving Forward	-Review of previous modules -Reflecting on progress and work still to be done	-Encourage continued practice

platform, encourage and reinforce participants in practicing the skills to maximize potential benefit, and offer support.

Guides complete a 4-hour standardized RESTORE training focused on the guidance manual, in addition to 4 hours reviewing and interacting with the RESTORE platform and content, with an emphasis on understanding the principles of recovery from trauma and other extreme stressors (e.g. expressing natural emotions related to the events of the pandemic; approaching avoided people, places and situations; identifying more helpful perspectives about the trauma or extreme stressors) and the specific elements of RESTORE. Guides then participate in weekly 1-hour consultation meetings, including review of guidance check-ins, and logistical problem solving, to maintain fidelity to the guidance model. Iterative feedback is provided to ensure fidelity and to adapt to the functionality of the platform (e.g. frequency of reminder messages), which will inform future training.

With respect to safety, the guides review participant entries in the platform on a weekly basis for active suicidal ideation and other safety concerns. If a concern is identified within the module entries or during a check-in, the guides follow a protocol to assess risk and make a safety plan in consultation with a team psychologist. Also, if a participant endorses anything other than ‘not at all’ on the PHQ-9 item assessing thoughts about hurting oneself, a message is displayed with crisis support information.

The individual is encouraged to utilize crisis support if their concerns about hurting themselves are urgent, and they are instructed to contact emergency services if they are in immediate danger.

1.2.5. Intervention delivery methods

RESTORE is delivered via a website hosted on a secure server. Individuals sign up via the homepage and are then emailed a link to the screening measures. Potential participants consent to the screening process, and if eligible, complete a separate consent for participating in the intervention and research.

RESTORE is presented through a combination of written information, brief videos, interactive exercises, and practice assignments delivered through the online platform. Videos and interactive exercises were included to enhance user engagement. The RESTORE videos feature graphics and a professional actor who presents key information, and each module ends with a brief video wherein the first author describes the practice assignments for that module in order to lend credibility to the intervention. Care was taken to use non-pathologizing language (e.g. stressor responses vs. mental health symptoms) throughout the intervention in order to promote uptake and engagement in individuals who may be reluctant to be perceived as having a mental health problem.

Other features utilized to enhance user engagement include: completion of the PHQ-9, GAD-7 and PCL-5 at the beginning of each module and feedback via

a graph depicting progress over the course of the intervention; a progress bar depicting progression through each module; a requirement to complete one module before moving on to the next; and interactive point and click exercises to consolidate learning of key concepts.

1.3. Intervention evaluation

An initial uncontrolled trial evaluating RESTORE in frontline HCWs is underway and a second in individuals who had COVID-19 and their close others is about to begin. In addition to the within module assessments, participants complete the PHQ-9, GAD-7 and PCL-5, as well as other self-report measures at baseline, mid-intervention, end-of-intervention, and at 1-month follow-up. A qualitative interview is administered after the intervention period. Changes in mental health symptoms will be examined to evaluate preliminary efficacy. Feasibility will be assessed through recruitment, retention (intervention and assessment schedule), and adherence rates, as well as additional analytics and participant feedback.

To date, of the 18 participants who started RESTORE, 22% dropped out, 44% completed, and 34% are actively working through the program. All participants have taken at least 4 weeks to complete with no one having run out of time. Participant feedback has been very positive with all completers indicating that they plan to continue to practice specific RESTORE skills. Based on the within module data, 100% of the 8 individuals who have completed the intervention to date have experienced a reliable improvement on at least 1 of the 3 measures.

Quantitative and qualitative data from these studies will also be used to refine RESTORE before testing in larger-scale and randomized studies. Future studies will examine methods of implementation and their effectiveness including the optimal level and nature of guidance (e.g. automated versus personalized messages, text versus phone guidance) to identify the best path to keep users engaged with, and adherent to, the intervention while maintaining the intervention's reach and sustainability.

2. Discussion

There is some controversy in the field regarding what aspects, if any, of the COVID-19 pandemic should be categorized as Diagnostic and Statistical Manual of Mental Disorders, 5th edition (American Psychiatric Association, 2013) Criterion A stressors that could lead to PTSD, and thus be appropriate for trauma-focused interventions (Horesh & Brown, 2020; Karatzias et al., 2020). In our research, we will examine the types of

extreme stressors individuals report, how those stressors relate to symptoms of PTSD, anxiety, and depression, and whether those exposed to traditional Criterion A events, as opposed to more broadly defined stressors, have differential intervention responses.

In sum, in future research, we hope to not only demonstrate the intervention's efficacy and effectiveness, but also to identify how best to reach and engage those in need. We believe RESTORE has great potential to answer calls for an accessible, easy to disseminate and evidence-based intervention for this important context. Moreover, should RESTORE prove effective, it will add to our options for addressing other mass traumatic events that far outstrip our ability to provide services using traditional modes of delivery.

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Disclosure statement

Dr. Monson receives royalties related to the publishing of a treatment manual from which RESTORE was adapted. The authors have no other competing interests to declare. Dr. Kaysen's contribution to this publication was part of her work as a paid consultant and was not part of her Stanford University duties or responsibilities.

Data availability

There is no data related to this manuscript.

Ethics statement

Current research evaluating RESTORE has been approved by the first author's institutional review board. All participants provide their informed consent to participation.

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