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Protocol of randomized-controlled trial to examine the effectiveness of three different interventions to reduce healthcare provider burnout

Catalina Ruple[1], John Brodhead[2], Lila Rabinovich[1], Doerte U. Junghaenel[1,3], Tiffany Nakamura[4], Jonathan Wong[4], Sophia De-Oliveira[5], Joan Brown[6], Phuong Nguyen[5], Jenny Horn[7], Renee Middleton[7], Michelle Brahe[7], Cheng Wen[1], Sujeet Rao[8], Caroline Nguyen[8], Gil Shlamovitz[7,9], Dara Marino[5], Felipe Osorno[5] and Steven Siegel[4,10*]

Abstract

Background Burnout is among the greatest challenges facing healthcare today. Healthcare providers have been found to experience burnout at significant rates, with COVID-19 exacerbating the challenge. Burnout in the healthcare setting has been associated with decreases in job satisfaction, productivity, professionalism, quality of care, and patient satisfaction, as well as increases in career choice regret, intent to leave, and patient safety incidents. In this context, there is a growing need to reduce provider burnout through targeted interventions, yet little is known about what types of interventions may be most effective. The present study aims to contribute to and extend prior literature by using rigorous randomized controlled trial (RCT) methodology with a parallel group design to examine the effectiveness of different interventions in decreasing mental distress, increasing self-efficacy and attenuating inefficiencies and dissatisfiers in the work environment to achieve sustainable improvement.'

Methods The present study is an ongoing randomized controlled trial (RCT) that examines the effectiveness of three different types of interventions to reduce provider burnout: an intervention targeting emotional wellbeing and resilience, Electronic Health Record (EHR) skills training, and performance improvement training, relative to a no-treatment control group. This study aims to enroll a total of 400 healthcare providers in a large urban hospital system. Outcomes will be assessed at post-treatment and 6-month follow-up. Key outcomes include burnout, emotional health, intent to leave, EHR mastery, and confidence in performance improvement. Changes in outcome measurements from baseline to post-intervention across the intervention and control groups will be conducted using linear mixed-effects models (LMM).

Discussion This study is novel in that it compares several interventions addressing both personal as well as system-level drivers of provider burnout that have been theorized to operate among healthcare providers. In addition, post-treatment and longer-term follow-up assessments will provide insight into the maintenance of effects. Another

*Correspondence:
Steven Siegel
steven.siegel@med.usc.edu
Full list of author information is available at the end of the article

innovation is the inclusion of different types of patient-facing providers in the study population (doctors, nurses, and therapists).

Trial registration This study was registered at ClinicalTrials.gov (NCT05780892) on March 10th, 2023.

Keywords Burnout, Healthcare, Interventions, Randomized Controlled Trial, Emotional resilience, Electronic health records, Performance improvement

Background

Clinician burnout is among the greatest challenges facing healthcare today. Burnout syndrome is a psychological response to work-related stressors. It is characterized by emotional exhaustion, depersonalization or negative attitudes to self and others (patients, in the case of healthcare workers), and detachment from one's job (WHO 2019 [1–3]). Burnout is linked to reductions in work productivity, poor personal outcomes such as increased anxiety and depression, poor sleep, and impaired executive function [4–6].

Healthcare workers have been found to experience burnout at significant rates, with variations among subdisciplines [7–9]. Although burnout among this population has been a longstanding issue, COVID-19 has made the challenge more salient and led to a staggering increase in burnout rates: according to a CDC survey, 46% of healthcare workers reported feeling burnout in 2022, up from 32% four years prior [10].

The effects of burnout in the healthcare setting are vast and pose significant risks for providers as well as their patients. Burnout has been associated with decreases in job satisfaction, productivity, professionalism, quality of care, and patient satisfaction, as well as, increases in career choice regret, intent to leave, and patient safety incidents [11].

The causes of burnout in the healthcare sector are myriad and complex. Two conceptual and theoretical models provide a useful framework for understanding burnout: the job demands resources (JD-R) model [12] and self-determination theory [13]. According to JD-R, workplaces contain both job demands and resources [14]. An imbalance between demands and available resources can be detrimental to the workforce and contribute to burnout [12, 15]. According to self-determination theory, individuals need to satisfy certain intrinsic needs to maintain their psychological health, such as autonomy and competence [16].

Both models apply to healthcare workers' experience in the workplace. Excessive workloads, increasing clerical burden on providers, inflexible working conditions, and particular management structures that limit provider input are all contributors to burnout [17]. The COVID-19 pandemic's added risk of infection for providers and their families, necessary isolation, heavier workloads, heightened exposure to patient deaths, and the pressure of having to make difficult decisions without adequate care protocols were additional contributors to burnout in healthcare providers [18–21].

There is increasing recognition of the need to reduce provider burnout by means of targeted interventions that address its root causes. To date, most interventions have focused on psychological and mindfulness approaches for providers. Previous randomized controlled trials (RCTs) have yielded mixed results on the effect of psychological interventions. Some have found significant improvement in burnout [22–28] while others did not find improvement [29–31].

For other types of intervention approaches, the evidence is much more limited. For instance, a small number of evaluations of the effects of electronic health records (EHR) training on provider burnout found mixed results [32, 33]. Training on performance improvement – a continuous analytical and collaborative process for improving the provision of care – is even less well-understood; we identified a single study, which finds it significantly improved burnout among healthcare workers [34, 35].

Additionally, much of the prior research on burnout among healthcare providers has examined the immediate effects of a particular intervention, but few studies have examined whether improvements are maintained over time. Overall, studies with a longer follow-up found that the benefits of the intervention were sustained for at least 6 months [29, 36, 37].

The present study aims to contribute to and extend prior literature by using rigorous randomized controlled trial (RCT) methodology with a parallel group design to examine the effectiveness of three different types of interventions that would decrease mental distress, increase self-efficacy and attenuate inefficiencies and dissatisfiers in the work environment to achieve sustainable improvement [38]. This approach is unique in that it addresses personal as well as system-level contributors to healthcare provider burnout.

We hypothesize that all three interventions are effective at reducing burnout through similar yet also distinct therapeutic mechanisms. Specifically, one intervention includes psychological training using techniques that have been shown to impact individual mental health [39]. These sessions are offered by licensed therapists and

target feelings of demoralization, depression and anxiety that can result from chronic stress. The second intervention includes individualized training regarding the optimization of the Electronic Health Record (EHR), helping clinicians from different fields and settings achieve reduced time and effort needed for documentation [40, 41]. This is done by members of the clinical informatics team with the explicit plan to study the impact of customized EHR training. The third intervention is offered by members of the systems engineering group with the goal to engage healthcare providers from a wide array of specialties and settings and to empower them to enact self-directed changes to the health system environment.

Methods/design

Objectives

The primary objective of this study is to investigate the effectiveness of three specific interventions to address burnout, enhance provider wellbeing, and improve provider performance in a healthcare setting, within a hospital system affiliated with the University of Southern California.

Study design

This study is a RCT to assess the effectiveness of three interventions (emotional wellbeing and resilience, EHR skills training, and performance improvement) in reducing healthcare provider burnout. Participants are randomly assigned to one of the three intervention groups or a control group. Those assigned to an intervention complete 6 sessions, one approximately every two weeks for a 12-week period. All participants are assessed at baseline, immediately post-intervention, and at a 6-month follow-up, through the same outcome assessment regardless of their group assignment. In order to promote participant retention and completion of post- and follow-up assessments, a sequence of seven reminder emails are sent every two business days. Participants are compensated for participation in their assigned intervention sessions (one $5 Amazon gift card per completed session plus $100 upon completion of the training and assessments). They are also entered into a raffle to win $1500 in professional educational and training credits once they complete the survey immediately post-intervention. A flow diagram for the study design is presented in Fig. 1.

Study setting

The study is being conducted in a large teaching hospital setting in an urban area in the United States.

Sample

This study aims to enroll a total of 400 healthcare providers, 100 in each of the four study arms. A prior review on the effectiveness of work- and person-directed interventions for preventing stress in healthcare workers found that most randomized controlled trials consisted of fewer than 120 participants [42]. Consistent with related sample size recommendations [43], 100 healthcare providers per study arm were deemed appropriate for the present research.

Eligibility criteria

To participate in this study participants must be credentialed providers (MD/PA/NP across all specialties or clinical Ph.D./MS) or direct care providers/clinicians (RN, LVN, LPN, PT, RT, OT, SLP)[1] within the Keck Medicine of USC System. Participants are excluded if they are non-clinical or non-faculty staff (e.g., residents, administrators). Perioperative nurses are excluded because they use a significantly different workflow which goes beyond the scope of the electronic health record (EHR) skills training module design (EHR arm of the study). Patient care technicians and Certified Nursing Assistants (CNAs) are also excluded because their jobs require only minimal use of the EHR.

Recruitment

Recruitment is conducted through multiple channels. All healthcare providers within the Keck Medical system that are potentially eligible receive email invitations to participate in the study. The list of potentially eligible healthcare providers is provided by credentialed staff at Keck Medicine who have routine access to healthcare provider contact information, and the invitation emails will be sent by the project manager. The email invitations contain a short study description and a link to the screening survey hosted by Qualtrics. Additionally, flyers with study information are displayed in common areas such as break rooms. The study is also introduced in-person or virtually during department meetings.

Individuals who complete the screening survey and are deemed eligible for participation are directed to an online consent form. Once they provide written consent

[1] MD: Medical Doctor.
PA: Physician Assistant.
NP: Nurse Practitioner.
Ph.D.: Doctor of Philosophy.
M.S.: Master of Science.
RN: Registered Nurse.
LVN: Licensed Vocational Nurse.
LPN: Liscenced Practical Nurse.
PT: Physical Therapist.
RT: Respiratory Therapist.
OT: Occupational Therapist.
SLP: Speech and Language Pathologist.

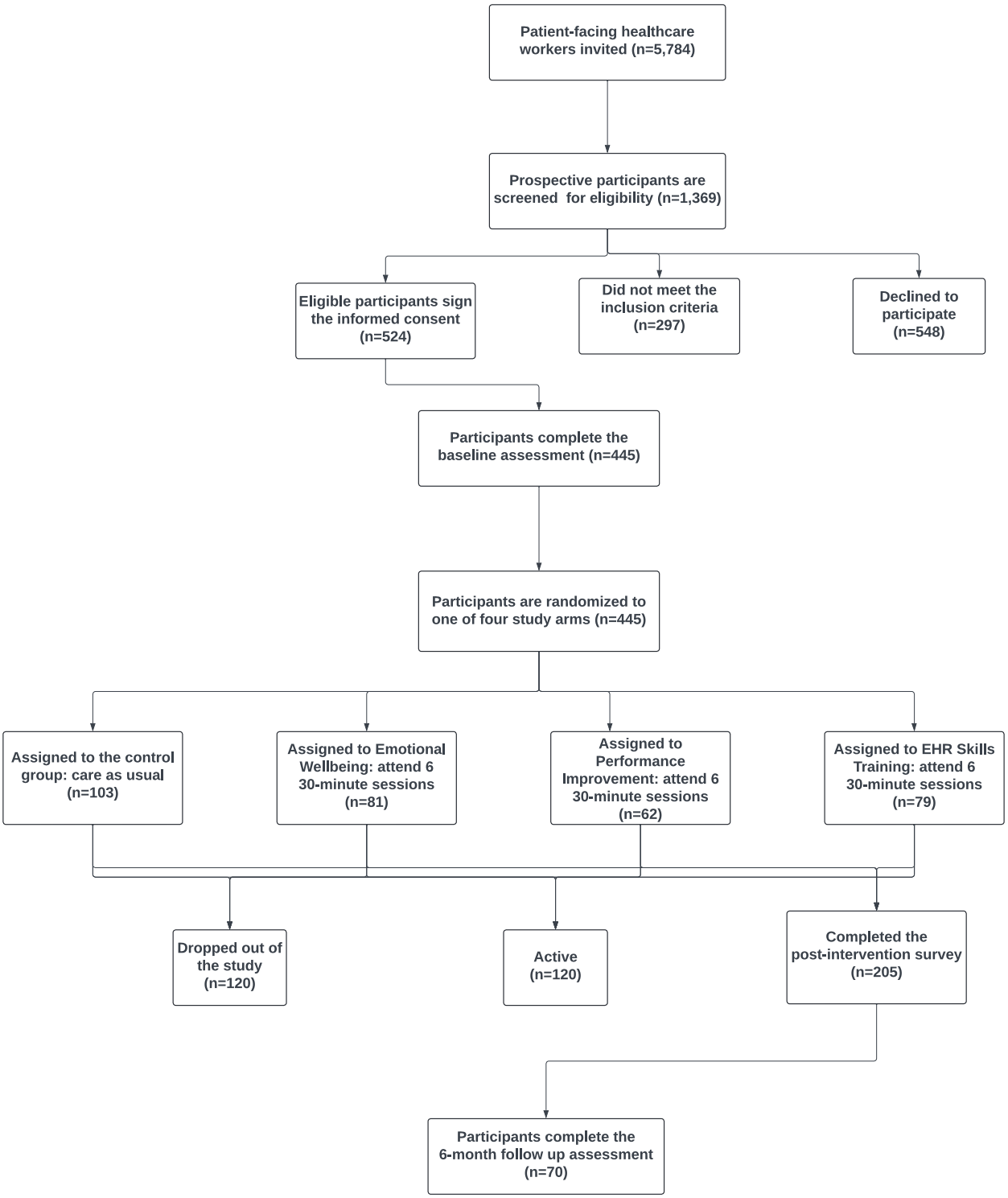

Fig. 1 Study flow diagram

to participate, participants complete the baseline assessment, after which they are randomized into one of the three intervention arms or the control group.

Randomization

Randomization is conducted through Excel to ensure equal cell sizes in the four study arms. Randomization is not stratified by provider demographic characteristics or clinical role. This study does not involve blinding or allocation concealment during data collection. The interventions will be made available to participants upon request after they complete the final study assessment.

Interventions

All interventions consist of individual (for the emotional wellbeing and EHR arms) or group (for the performance improvement arm) sessions. Each session lasts approximately 30 min. Participants receive email reminders of upcoming sessions; scheduling is flexible to improve adherence. When participants do not attend a session, a total of seven reminders (one every two business days) are sent before a participant is deemed a 'soft' drop-out. Participants are also able to discontinue participation upon request at any time.

Emotional wellbeing

This intervention focuses on improving healthcare providers' emotional wellbeing and mental health. Sessions utilize techniques shown to be effective in multiple clinical settings [22]. Specifically, the sessions incorporate Cognitive Behavioral Therapy (CBT), which utilizes problem-focused interventions geared towards helping the participant better understand how their thoughts, emotions, and behavior are linked and thus can be modified [44].

Additionally, the sessions incorporate Acceptance and Commitment Therapy (ACT) tools to increase cognitive flexibility and resilience. While CBT focuses on trying to control our thoughts and emotions, ACT focuses on helping participants change their perspective on distressful events, such as fostering acceptance about a stressful event, defusion from these events, and taking actions that are aligned with values [45]. The sessions can be either group or individual depending on participant preference and they can be done virtually, on site, or a combination of both. The sessions are led by a licensed therapist.

Electronic Health Record (EHR) Skills Training

The EHR skills training intervention focus on enhancing healthcare providers' experience with the Electronic Health Record, a critical tool for clinical staff in a healthcare setting. The sessions augment site and specialty-specific training to enhance utilization and personalization of current EHR capabilities. Session topics include, but were not limited to, understanding current EHR usage patterns and behaviors, chart review optimization for easier navigation, integration of specialty-focused workflows to improve EHR documentation, and personalized recommendations to improve efficiencies within the EHR. Between sessions, participants are encouraged to implement session learnings and to note EHR questions or challenges. A member of the clinical informatics team conducts each of the virtual, individual sessions.

Performance improvement

This intervention focuses on providing basic performance improvement knowledge and skills through didactic training, group discussions, and hands-on practice leading a performance improvement project.[2] The performance improvement concepts discussed in the sessions include Lean, systems thinking, change management, and sustainability. Following the learning portion of the session, participants choose a project area of focus that addresses an environmental issue they wish to improve as an individual. The project areas come from activities that do not add value to the organizations effectiveness of efficiency such as waiting/idle time, defects, injuries, overprocessing, inventory, transport, overproduction and human potential [46]. Once a project area of focus has been chosen, participants discuss challenges, successes, and feedback on the project of focus or activities accomplished since the previous session. Between sessions, participants have the option to follow through on tasks outlined in the learning session. The sessions are virtual group sessions and are completed virtually. The sessions are led by a member of the systems reengineering team at Keck.

Primary outcomes

The study examines various outcomes that, individually and together, may be indicative of burnout in our study population. Burnout is a multi-faceted phenomenon, affecting an individual's mental health, attachment to the job, and efficacy in the job among others. It is also theorized to be affected by system-level factors such as administrative burden and control over work processes. Our selected primary and secondary outcomes aim to give insights into burnout and its component elements.

Burnout

Burnout is assessed using the 7-item personal burnout subscale of the Safety, Culture, Operational Risk, Resilience/Burnout, and Engagement (SCORE) survey. The

[2] Performance Improvement shares some characteristics with "job crafting", an approach utilized in healthcare settings to facilitate self-initiated change and empowerment in the healthcare workforce [54].

Score survey is an outcomes-predictive and proprietary established scale designed to measure satisfaction in the workplace. It is routinely implemented in hospital settings for climate and workforce wellbeing evaluations. The rationale for selecting this instrument in the present study is to ensure comparability with other non-study related healthcare provider assessments in the hospital system.

Emotional health

Emotional health is measured through five specific constructs. *Emotional thriving and recovery* are assessed using two 4-item subscales embedded in the SCORE Survey. *Emotional wellbeing* is assessed using the Patient Health Questionnaire (PHQ-9), a 9-item validated scale designed to measure symptoms of depression [47] during the past two weeks, such as "feeling down, depressed, or hopeless" or "feeling tired or having little energy". This scale has demonstrated good internal consistency (0.90 in primary care study) [47] and has been successfully used to measure depression in clinician populations [48]. *Resilience* is assessed using the Brief Resilience Scale (BRS), a 6-item validated scale measuring an individual's perception of their ability to bounce back from stressful events [49]. The scale has demonstrated good internal consistency (>0.70 and <0.95) [49] and it has been successfully used to measure resilience in clinician populations [50]. *Overall well-being* is assessed using the 7-item Wellbeing Index. The wellbeing index identifies distress in a variety of dimensions such as anxiety and fatigue [51] and has been widely used in clinical populations [51].

EHR mastery

This is assessed through subjective evaluations and objective measures of EHR usage. *EHR self-reported skills* are assessed using a newly developed 7-item survey by the study team pertaining to an individual's skill and satisfaction with the EHR. *Objective EHR proficiency* is assessed through standard measures routinely collected by the EHR, such as percentage of clinical notes completed on time, reduction in the need to revise clinical records and reduction in time spent using the EHR.

Confidence in performance improvement

This is assessed using the Beliefs, Attitudes, Skills, and Confidence in Quality improvement (BASiC QI) scale. The BASiC QI scale is a 31 multidimensional self-assessment to assess knowledge, skills, and attitudes about performance improvement with 3 distinct subscales [52]. The scale has demonstrated high reliability (alpha = 0.90) and has been shown to successfully measure perceptions of quality improvement in clinical populations [52].

Intent to leave

This is assessed using the 3-item intent to leave subscale embedded in the SCORE survey.

Secondary outcomes

Secondary outcomes include workload using the 7-item workload subscale embedded in the SCORE survey; environmental satisfaction, which is assessed using the Safety, Culture, Operational Risk, Resilience/Burnout, and Engagement (SCORE) survey; and participation in decision-making, which is assessed using the 6-item participation in decision-making subscale embedded in the SCORE survey.

Participant safety monitoring

At all assessment time points, participants complete the PHQ-9 to measure depressive symptomatology and to screen for potential suicidal ideation. Any participant suspected of experiencing suicidal ideation based on their responses is immediately flagged by the online data collection system and a member of the research team will be notified. To ensure participant safety, one of our licensed clinical therapists on the team will reach out to the participant within 72 h of their assessment completion to conduct a follow-up assessment. In this follow-up, patient safety, potential need for care referral, and participant capacity to continue with study participation will be assessed. Mental health resources are made available, if appropriate and desired by the participants.

Data management

Study data will be collected electronically through Qualtrics, a secure web-based data collection system. Participant responses will be stored confidentially on the server and reviewed by a dedicated member of the research team. Participants are assigned a unique study ID number and potentially identifying information will be stored separately in a secure and password-protected location.

Data analysis

In the paper reporting on study results once data collection is complete, descriptive and exploratory analyses will be performed for all variables, including participants' characteristics and outcome variables. Each outcome measure will be completed by all participants at the three study assessments regardless of their group assignment. Preliminary analyses of pre-randomization values of outcomes and participant characteristics will be compared across arms to assure that randomization was successful across intervention arms. Variables

that are unequal at baseline will be included as covariates (for example, baseline workload, [53]. The primary focus of assessing changes in primary outcome measurements from baseline to post-intervention across the intervention and control groups will be conducted using linear mixed-effects models (LMM) to account for repeated measures and individual-level variability through random intercepts, while including fixed effects for group, time, and their interaction. Missing data will be addressed using full information maximum likelihood (FIML), which estimates model parameters using all available data under the assumption of missing at random (MAR). Bonferroni corrections will be applied to adjust for multiple comparisons. All analyses will be performed using SAS.

Ethical considerations

The University of Southern California Institutional Review Board approved this study (UP-22–01081). This study was also registered at ClinicalTrials.gov (NCT05780892) on March 10th, 2023. Protocol modifications were discussed by the research team, submitted for review to IRB and, where necessary, updated in the Clinical Trials registration. This research is conducted in accordance with the Declaration of Helsinki. This study adheres to the CONSORT guidelines.

Dissemination policy

Study results will be disseminated to the Keck health system via its regular newsletter and via the study website. Results will also be published in a peer-review journal and presented at conferences.

Discussion

This study aims to investigate the effectiveness of interventions addressing burnout in a healthcare provider population. This study is timely given the urgency of the rising burnout crisis in the healthcare sector and it has the potential to provide an important roadmap for hospital systems across the country for implementing strategies to facilitate provider flourishing and to improve patient care.

There are several strengths to this study. First, our approach is novel in that it compares interventions addressing both personal as well as system-level drivers of provider burnout that have been theorized to operate among healthcare providers: emotional challenges related to the provision of medical care in a hospital setting (potentially heightened during the COVID-19 pandemic), administrative burden, and impediments to effective clinical decision-making and workflow among hospital teams. Second, our use of a rigorous RCT design to test these interventions should bolster confidence in the observed effects. Third, our immediate post-treatment and longer-term follow-up assessments will provide insight into whether potential benefits of these intervention approaches can be maintained and at which magnitude. Another innovation is the inclusion of different types of patient-facing providers in the study population (doctors, nurses, and therapists). Finally, the study extends prior literature in that it adds to a limited evidence base on interventions targeting drivers other than psychological wellbeing at the individual provider level. A potential avenue for future research might be eliciting and integrating in-depth input by the healthcare workforce to further inform and optimize the interventions. This could include identifying "bright spots" in the healthcare system to determine which departments are most in need and to learn from existing strategies within specific departments that might alleviate provider burnout.

The study is not without limitations. First, the RCT is being conducted at a large urban, academic teaching hospital system. The results may not generalize to other healthcare systems, such as those in rural and underserved areas. Second, the study focuses on providers delivering care to patients and the intervention approaches may need to be adapted for non-patient facing healthcare workers. Finally, completion rates are impacted by evolving demands on clinicians over the 2 year period of active recruitment, potentially attenuating the impact of interventions.

Overall, this study is timely and has the potential to provide valuable lessons for healthcare systems grappling with how to address burnout and improve wellbeing among healthcare providers. If the proposed interventions demonstrate efficacy, they can provide a roadmap for facilitating healthcare provider flourishing through tangible strategies that can be adapted and implemented in other healthcare settings across the nation.

Abbreviations

USC	University of Southern California
NP	Nurse Practitioner
PA	Physician Assistant
MD	Doctor of Medicine
RN	Registered nurse
LVN	Licensed vocational nurse
LPN	Licensed practical nurse
MA	Medical assistant
PT	Physical therapists
OT	Occupational therapist
RT	Respiratory therapist
SLP	Speech and language pathologist
EHR	Electronic Health Record
Ph.D	Doctor of Philosophy

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Authors' contributions
D.J, L.R, and C.R prepared and finalized the main manuscript; S.S and J.B are the principal investigators. C.W. prepared the analysis section. All authors contributed to, reviewed, and approved the manuscript for publication.

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Data availability
The data sets used and/or analyzed during the current study are available from the corresponding author upon request.

Declarations

Ethics approval and consent to participate
The University of Southern California Institutional Review Board approved this study (registered under UP-22–01081). This study is also registered at clinicaltrials.gov (NCT05780892). Informed consent to participate was obtained from all participants enrolled in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Center for Economic and Social Research, University of Southern California, Los Angeles, USA. [2]Department of Internal Medicine, University of Southern California, Los Angeles, United States. [3]Department of Psychology, University of Southern California, Los Angeles, USA. [4]Department of Psychiatry and the Behavioral Sciences, University of Southern California, Los Angeles, United States. [5]Keck Medicine of USC, University of Southern California, Los Angeles, USA. [6]Department of Surgery, University of Southern California, Los Angeles, United States. [7]Keck School of Medicine, University of Southern California, Los Angeles, USA. [8]USC Dornsife Public Exchange, University of Southern California, Los Angeles, USA. [9]Department of Emergency Medicine, University of Southern California, Los Angeles, United States. [10]Department of Biomedical Engineering, University of Southern California, Los Angeles, United States.

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