IIR 19-097: Mindful Hand Hygiene to Reduce Infections Among Veterans While Enhancing Provider Well-Being

Funding Agency: VA Health Services Research and Development

Principal Investigator: M. Todd Greene, PhD

Co-Principal Investigator: Sanjay Saint, MD, MPH

Multi-Site Project – Sites with Subject Participation

LTC Charles S. Kettles VA Medical Center, Ann Arbor, MI – (506)

Michael E. DeBakey VA Medical Center, Houston, TX -

Support Site Only - No Subject Participation

VA Palo Alto Healthcare System, Palo Alto, CA -

NCT05261282 Version: 05/31/2023

Abstract

Objectives: Hand hygiene is a key element of preventing healthcare-associated infection (HAI), yet maintaining healthcare provider adherence to this basic practice remains challenging. Mindfulness is an approach that can help clinicians shed preconceived biases through nonjudgmental awareness and more broadly facilitate improvements in patient safety. While targeted interventions and bundled approaches to improve hand hygiene adherence and reduce HAI have been implemented, interventions incorporating introspective techniques, such as mindfulness, are limited. The goal of this study is to utilize a mindfulness-based approach to optimize provider hand hygiene adherence, improve provider well-being and enhance the quality and safety of care delivered to Veterans.

Research Plan: We will conduct a randomized controlled mixed-methods trial at 2 diverse VHA hospitals. Physicians and nurses randomized to the intervention arm will receive mindfulness education and tools to prompt mindfulness during hand hygiene. Measures of hand hygiene (adherence, duration, and perceptions) and measures of provider mindfulness and well-being will be collected and compared between the intervention and control groups.

Methods: Participants in this study will include physicians and nurses at the LTC Charles S. Kettles Veterans Affairs (VA) Medical Center (Ann Arbor VAMC) and the Michael E. DeBakey VA Medical Center (MEDVAMC) in Houston, TX. Participants in the intervention groups will receive mindfulness education, participate in mindfulness guided discussions, will be encouraged to use a mindfulness mobile application as a practice reminder and additional resource, and be instructed to integrate moments of mindfulness with repeated moments of hand hygiene during the course of caring for patients. The control groups will receive no such education or intervention and will continue usual care. All participants will be asked to complete a survey aimed at measuring mindfulness, well-being, and hand hygiene perceptions at baseline, after completion of the intervention period, and at 6 months follow-up. To evaluate the impact the intervention has on hand hygiene, hand hygiene observations will be conducted on each participating unit and physician team. We will also conduct a qualitative evaluation (intervention participants only) to better understand the perception of the intervention and assess any barriers or facilitators encountered. For this evaluation, we will conduct individual or group interviews as well as audio record the guided discussions with participants.

Clinical Relevance: At the conclusion of the study, we will aim to have a hand hygiene-based mindfulness intervention package that we can subsequently work to deploy more broadly across VHA hospitals to improve the safety of Veterans and the well-being of those providing their healthcare.

List of Abbreviations

Ann Arbor VAMC	Lieutenant Colonel Charles S. Kettles Veterans Affairs Medical Center
App	Mobile application
CCMR	Center for Clinical Management Research
CMARRS	Center for Mobile Apps Research Services
FFMQ	Five Facet Mindfulness Questionnaire
HAI	Healthcare-associated infection
iOS	Apple Mobile Operating System
IPA	Intergovernmental Personnel Agreements
IQuEST	Center for Innovations in Quality, Effectiveness and Safety
IRB	Institutional review board
LTC	Lieutenant Colonel
MEDVAMC	Michael E. DeBakey Veterans Affairs Medical Center
MI	Michigan
PD/PI	Project Director/Principal investigator
PSHW	Perceptions Survey for Healthcare Workers
PTSD	Post-traumatic stress disorder
STREAM	Skills Training for Resilience, Effectiveness, and Mindfulness
TX	Texas
U of M	University of Michigan
VA	Veterans Affairs
VAAAHS	Veterans Affairs Ann Arbor Healthcare System
VHA	Veterans Health Administration
WBI	Well-Being Index

Contents

Protocol Title: Mindful Hand Hygiene to Reduce Infections Among Veterans While Enhancing Provider Well-Being

1.0 Study Personnel

LTC Charles S. Kettles VA Medical Center (Ann Arbor VAMC), Ann Arbor, MI

Personnel	Role on Project	Title – Affiliation	Email	Phone
M. Todd Greene, PhD, MPH	Principal Investigator	Research Health Science Specialist VA Center for Clinical Management Research (CCMR), Ann Arbor VAMC; Associate Research Scientist, Division of Hospital Medicine University of Michigan (U of M)	Michael.Greene2@va.gov; mtgreene@med.umich.edu	
Sanjay Saint, MD, MPH	Co-Principal Investigator	Chief of Medicine, VA Ann Arbor Healthcare System (VAAAHS); George Dock Professor of Internal Medicine, U of M	saint@med.umich.edu	
Molly Harrod, PhD	Co-Investigator	Director Qualitative Methods Core, VA CCMR	Molly.Harrod@va.gov	
Nathan Houchens, MD	Co-Investigator	Associate Chief of Medicine VAAAHS	nathanho@med.umich.edu	
Virginia Sheffield	Co-Investigator	Clinical Assistant Professor, VAAAHS	vmmorris@med.umich.edu	
Staff				
David Clive	Research Assistant	VA CCMR	David.Clive@va.gov	
Jason Engle, MPH	Research Assistant	WOC – U of M Hospital Medicine	Jason.Engle@va.gov	
Karen Fowler, MPH	Project Manager	VA CCMR	Karen.Fowler@va.gov	
Serene Jacob, MSN	Research Nurse	VAAAHS Department of Medicine	Serene.Jacob@va.gov	
Latoya Kuhn, MPH	Project Manager	VA CCMR	Latoya.Kuhn@va.gov	
Martha Quinn	Qualitative Analyst	WOC – U of M School of Public Health	marthaq@umich.edu	
David Ratz	Data Analyst	VA CCMR	David.Ratz@va.gov	
Erica Paulos	Data Analyst	VA CCMR	Erica.Paulos@va.gov	

Michael E. DeBakey VA Medical Center (MEDVAMC), Houston, TX

Personnel	Role on Project	Title – Affiliation	Email	Phone
Barbara Trautner, MD, PhD	Co-I; Site Principal Investigator	Research Investigator MEDVAMC Center for Innovations in Quality, Effectiveness and Safety (IQUEST) Professor of Infectious Diseases, Baylor College of Medicine	Barbara.Trautner@va.gov; trautner@bcm.edu	
Prathit Kulkarni, MD	Co-Investigator	Assistant Chief of Medicine MEDVAMC; Assistant Professor of Infectious Diseases, Baylor College of Medicine	pakulkar@bcm.edu	
Laura Dillon	Research Assistant	Health Service Specialist, MEDVAMC	Laura.Dillon2@va.gov	
Michelle Espiritu	Research Assistant	Research Coordinator, MEDVAMC	Michelle.Espiritu@va.gov	

VA Palo Alto Healthcare System, Palo Alto, CA

Personnel	Role on Project	Title – Affiliation	Email	Phone
Jason Owen, PhD	Co-Investigator	Co-Director VA Center for Mobile Apps Research Services (CMARRS)	Jason.Owen@va.gov	

2.0 Introduction

Appropriate hand hygiene is essential in infection prevention, yet hand hygiene adherence among healthcare providers remains a challenge. Hand hygiene is widely accepted as a crucial component of infection prevention in healthcare settings,[1-4] and guidelines providing specific recommendations to promote proper hand hygiene and reduce transmission of pathogenic microorganisms among patients and providers have been widely disseminated.[5,6] Despite this, adherence with hand hygiene guidelines remains low.[7] Additionally, hand hygiene adherence has been shown to vary by hospital location, provider type, and specific hand hygiene moments - with adherence rates lower among physicians (versus nurses), and before (versus after) patient contact.[7] Numerous behavioral model studies have demonstrated that hand hygiene perceptions, beliefs and attitudes - such as perceived social pressure from superiors, colleagues and administrators, the belief in role modeling for other colleagues, the belief that healthcare-associated infection (HAI) can be severe for patients and that hand hygiene is effective at preventing HAI, and having a positive attitude towards hand hygiene - are associated with hand hygiene adherence.[8-10] While numerous interventions focusing on improving hand hygiene among healthcare providers have been introduced, success

has been limited. Further, it is not well understood which components of multi-faceted interventions are most effective in achieving optimal hand hygiene adherence.[11] As recently emphasized in the ongoing COVID-19 pandemic, vigilant hand hygiene remains one of the most important elements of preventing infectious disease transmission and innovative strategies for effectively improving hand hygiene among healthcare providers are still needed. Strategies promoting hand hygiene in Veterans Health Administration (VHA) hospitals have the potential to reduce HAI risk and improve Veteran health.

Negative components of well-being including fatigue, depression, burnout (physical or mental collapse caused by overwork or stress), and anxiety/stress have increased in recent years among healthcare providers. The COVID-19 crisis will likely continue to present unique challenges to healthcare systems and further degrade provider well-being. Healthcare provider burnout is prevalent, increasingly common across healthcare settings, and may negatively influence providers' ability to maintain safe practices. Professional burnout and dissatisfaction with work-life balance has increased among physicians in recent years; with more than half of physicians reporting at least 1 sign of professional burnout.[12] Additionally, symptoms of burnout are greater among physicians compared to the general working population,[12,13] regardless of physician career stage.[13] Importantly, poor well-being and burnout are associated with increased risk of patient safety incidents, poorer quality of care due to reduced professionalism, decreased patient satisfaction,[14-18] and decreased productivity.[19] Burnout among nurses is also prevalent and poses similar threats to quality of care. Factors such as unit-level management, social capital, workload, and nursing burnout are associated with job satisfaction, turnover intentions, patient satisfaction, patient falls, HAIs, and medication errors.[20] High levels of burnout among nurses is associated with lower ratings of quality of care independent of practice environment, suggesting that reducing nurse burnout may be an effective strategy for improving quality of care in hospitals.[21] A study of nurses from a Veterans Affairs (VA) hospital showed that increased nurse burnout was associated with the perception of lower patient safety.[22] After adjustment for patient acuity and nurse and hospital characteristics, associations between nursing burnout and increased HAI have been reported.[23] Importantly, nurse burnout has been shown to be negatively associated with adherence to hand hygiene, highlighting an opportunity for interventions promoting well-being among nursing staff.[24]

There are cognitive biases in clinical settings. A large body of literature demonstrates the existence of cognitive bias among clinicians,[25] which may impact decision making. A key factor known to induce cognitive bias is a stressful and demanding work environment.[26,27] Clinical practice requires healthcare providers to prioritize many responsibilities and shift quickly between patient care and administrative tasks. These shifts cause distractions, which can impact performance and increase stress. Dealing with these types of stressors often compels providers to adopt quick and reactive behavior rather than responding with a focused or efficient approach. As illustrated by Daniel Kahneman's seminal work on dual-process theory,[28,29] a decrease in cognitive effort leads to reliance on System 1 thinking, which is fast, reflexive, and vulnerable to bias and error.[30,31] This results in a lack of System 2 thinking, which is slower and involves more analytical decision-making. Under stress, individuals are known to make decisions before all available options are systematically considered.[32]

We believe that dual-process theory, though with known limitations,[33] is a helpful heuristic model for understanding how busy healthcare providers make decisions. Stressful situations likely result in providers relying heavily on System 1 thinking. When healthcare providers are busy at work, they don't have natural moments to pause, be present, and switch from System 1 to System 2 thinking. Not having that pause can lead to cognitive biases, which can result in decisions that are not fully informed by System 2 thinking. The practice of mindfulness teaches presence.

Mindfulness increases System 2 critical thinking and has shown promise in clinical settings. Mindfulness is an intervention known to be successful in decreasing biased decision-making and increasing higher-order, System 2 cognitive processing.[34] Several studies in the psychology literature link mindfulness to enhanced executive functioning.[35] Additionally, mindfulness facilitates insight problem-solving[36] and ethical decision-making.[37] Noone and colleagues demonstrated that mindfulness enhanced the ability to analyze and evaluate evidence and arguments.[38] This makes mindfulness an ideal intervention to facilitate presence, which can result in switching from System 1 to System 2 thinking, thereby impacting decision-making. Mindfulness could prompt providers to engage in System 2 thinking and improve patient safety by prompting providers to shed preconceived cognitive and implicit[39] biases through nonjudgmental awareness. Several articles have pointed to mindfulness as a potential intervention to increase patient safety and decrease diagnostic error.[30,40] Mindfulness is also known to reduce cognitive bias.[41,42] The mechanism involves a regulation of one's attention and awareness towards the present moment.[43] In recent years, mindfulness-based interventions have been applied to clinical practice, demonstrating success in reducing symptoms of stress, burnout and depression among attending physicians, residents, interns, medical students and nurses.[44-54]

PRELIMINARY STUDIES

Members of the proposed study team have conducted numerous studies on hand hygiene adoption, improvement and sustainability.[55-61] This includes a systematic literature review on brief mindfulness interventions involving healthcare providers.[44] Our review found that brief, mindfulness-based interventions modified to accommodate busy provider schedules yielded improvements in levels of stress, anxiety, mindfulness, resiliency, and burnout among hospital-based physicians and nurses.[44] A recent meta-analysis has shown that online mindfulness interventions can be more convenient and cost-effective, while yielding substantial reductions in stress and moderate improvements in mindfulness.[62] Prior proof-of-concept work has shown that brief online modules and peer- supported group sessions among healthcare professionals lead to changes in the intended direction for perceived stress, burnout, mindfulness, resilience, and in providing calm, compassionate care.[63-65] Additionally, increased doses of online training are associated with more frequent and sustainable mind-body practices.[66] In a recent survey, physicians have reiterated the importance of social and organizational support in maintaining physician health.[67]

Official direct observation data from the VA Ann Arbor Healthcare System (VAAAHS) from fiscal year 2019 (October 2018 - September 2019) shows average hand hygiene compliance was 90%, with compliance slightly lower on room entry (89%)

than exit (92%). By comparison, covert secret shopper data at VAAAHS during fiscal year 2019 found lower hand hygiene compliance at both room entry (85%) and exit (81%). During fiscal year 2019 at the Michael E. DeBakey VA Medical Center (MEDVAMC), the average hand hygiene adherence based on random direct observations was 77%. Although not readily available, we can reasonably assume that covert observations at MEDVAMC would yield slightly lower adherence rates, as seen at VAAAHS. These data demonstrate that opportunities to improve hand hygiene adherence exist at the proposed study sites. Additionally, the act of performing hand hygiene might not always correspond to properly performing hand hygiene. Preliminary data on hand hygiene duration at the proposed study sites is lacking and the proposed study will allow for assessments of proper hand hygiene (20 seconds of rubbing).

While baseline data on provider composite measures of well-being are not readily available for the proposed study sites, data from the VA All Employee Survey from 2019 demonstrate degrees of physician and nurse burnout exist at both of the proposed sites. At both sites, physician and nurse survey respondents on average reported feeling burned out from their work (physical exhaustion domain) from at least once a month to several times per month. While the responses for emotional exhaustion were slightly more favorable, respondents still reported worrying that their job was hardening them emotionally at least once per month. Additionally, the current and ongoing COVID-19 pandemic has imposed unprecedented demands on healthcare workers that will likely contribute to detrimental and lasting impacts on provider well-being.[68-70] As such, implementing and assessing initiatives to enhance and sustain hand hygiene practices and promote provider well-being will continue to be important in quality healthcare.[70,71]

In a hand hygiene-based mindfulness intervention pilot study of almost 1,300 hand hygiene observations, we found significantly improved adherence to hand hygiene practices after a mindfulness intervention (Table 1). Additionally, the intervention led to a nearly 4% increase in observed mindfulness behaviors.[72] Qualitative findings from the study indicated that physicians held favorable views of the idea of practicing mindfulness in clinical settings and that doing so could result in improved physician well-being and provider-patient relationships.[72] These findings give us confidence that practicing mindfulness in clinical settings is feasible, can modify clinician behavior to improve hand hygiene and combat HAI, and has the potential to improve provider well-being.

Table 1: Mindfulness Intervention Impact on Hand Hygiene[72]

Observations	Intervention N	Intervention Change from Baseline % (95% CI)	Control N	Control Change from Baseline % (95% CI)	P-value
Hand Hygiene					
Physician Type					
Attending	132	14.1 (-1.1, 29.5)	113	-5.7 (-15.9, 4.5)	0.035
Senior Resident	90	24.7 (5.4, 44.0)	81	0.2 (-15.5, 15.9)	0.064
Intern	136	10.0 (-2.6, 22.6)	215	4.2 (-6.4, 14.9)	0.007
Medical Student	267	4.7 (-4.4, 14.0)	265	7.7 (0.2, 15.1)	0.003
Mindful Moments[a]	621	3.7 (1.3, 6.0)	662	0.9 (-0.4, 2.3)	0.021

Key: CI = confidence interval; [a]Mindful Moments were observed moments of pause during hand hygiene or before entering the patient room, such as closing eyes or taking a deep breath.

INNOVATION & IMPACT

Deploying mindfulness during hand hygiene as a novel approach to optimize hand hygiene adherence and duration and improve provider well-being, thereby potentially reducing risk of HAI in Veterans: The act of hand hygiene prior to entering and upon exiting a patient's room presents a prompt to practice mindfulness. A moment-by-moment awareness of the various steps of hand hygiene (e.g., pausing, noticing the sound and feeling of water and soap flowing onto the hands or alcohol gel being massaged into the palms) creates an ideal opportunity for moments of reflection during busy clinical duties, and could help create an environment where providers can develop clarity, insight, and increase presence and awareness. Promoting integration of hand hygiene and mindful moments presents opportunities to utilize brief but sufficient time periods as a means of both pausing to be mindful and promoting proper duration of hand hygiene (i.e., rubbing for 20 seconds).[7,73]

Our conceptual model of how an increase in mindfulness can impact provider well-being and Veteran outcomes is illustrated in Figure 1. Encouraging, and ultimately embedding, learned mindfulness behaviors within hand hygiene moments among providers has the potential to improve provider well-being. Moreover, the positive, internal feedback experienced through mindful hand hygiene moments may directly boost and sustain hand hygiene adherence and duration, thereby decreasing risk of pathogen transmission. Improvements in provider well-being and hand hygiene have the potential to jointly reduce

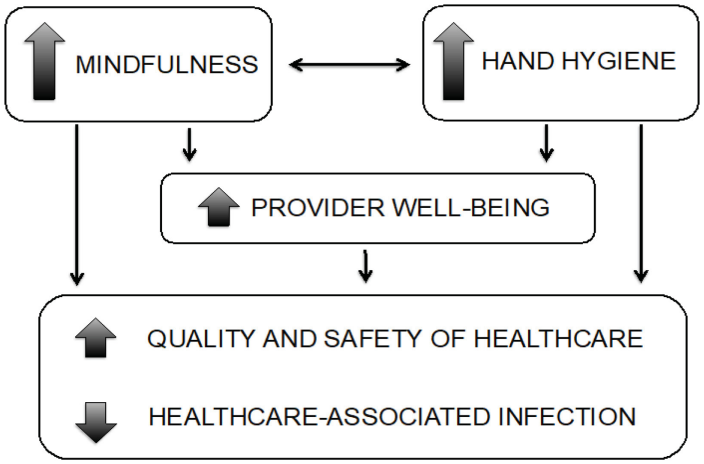

Figure 1. Hand Hygiene-Based Mindfulness Intervention Conceptual Model

HAI and improve the quality and safety of healthcare delivered to Veterans. Additionally, although beyond the scope of what we plan to assess in the proposed study, an increase in mindfulness has the potential to directly reduce HAIs through promoting focused decision-making (e.g., the decision of whether or not to place a urinary or central catheter).

There are several aspects of this proposal that are novel with respect to mindfulness. First, building on the successes demonstrated and qualitative information gained in our pilot project assessing the impact of brief mindfulness on hand hygiene adherence and mindful behavior,[72] we plan to expand the mindfulness intervention duration and bolster the intervention content with self-directed mindfulness training and practice via online educational modules, mobile app based tools and reminders, and increased facilitated group discussions on mindfulness. The mindfulness mobile app we propose to use has previously been deployed among Veterans as a tool for reducing stress and maintaining healthy coping practices. Extending the mobile app's scope of impact from Veterans to providers has not been studied, will be an excellent use of VHA resources, and will substantially contribute to the patient safety literature. Second, in addition to monitoring potential differences in hand hygiene adherence and mindfulness, we will be monitoring differences in hand hygiene duration and perceptions. Third, although numerous prior studies have evaluated the impact of mindfulness-based interventions on levels of provider burnout, anxiety, and stress, the proposed study will be the first study that we are aware of that will formally evaluate the impact of self-directed and group-facilitated mindfulness practices specifically reinforced during repetitive moments of hand hygiene on provider well-being. Finally, we will engage Veterans to provide insights and suggestions on all phases of the proposed provider-facing intervention. This work, if successful, will form the foundation of larger-scale implementation and dissemination projects to further benefit VHA healthcare providers and Veteran patients in the United States (US).

3.0 Objectives

This study has three specific aims:

1) To evaluate the effectiveness of a hand hygiene-based mindfulness intervention on provider hand hygiene adherence, duration, and perceptions.
2) To evaluate the effectiveness of a hand hygiene-based mindfulness intervention on measures of provider mindfulness and well-being.
3) To identify the barriers, facilitators, and perceptions of a hand hygiene-based mindfulness intervention in the hospital.

The overall goal is to optimize provider hand hygiene adherence, improve provider well-being and enhance the quality and safety of care delivered to Veterans. Our hypothesis is that an intervention focused towards healthcare providers on promoting the use of hand hygiene as a moment to practice mindfulness will result in improved levels of mindfulness practices, well-being, and use of proper hand hygiene among providers.

4.0 Resources and Personnel

The study will be conducted with participants at the Lieutenant Colonel (LTC) Charles S. Kettles VA Medical Center (Ann Arbor VAMC) – the main hospital in the VAAAHS - and at the MEDVAMC. All activities at both active study sites (Ann Arbor VAMC and MEDVAMC) will be conducted in accordance with the VA Central Institutional Review Board (IRB) approved protocol. While there is a co-investigator (Jason Owen, PhD) located at the VA Palo Alto Healthcare System, there will not be any subject recruitment at that site. Instead, Dr. Owen will assist with scientific expertise and oversee development and use of the Mindfulness Coach mobile app – described in more detail below. The modifications to the app itself to tailor for use with healthcare providers will be done with Vertical, as they helped develop the original app and are familiar with VA data security requirements. We will also contract with Ohio State University for use of their online mindfulness training modules as part of our intervention. The Ann Arbor VAMC will be the coordinating site, with all data being stored and analyzed together at the VAAAHS Center for Clinical Management Research (CCMR).

ANN ARBOR VAMC PERSONNEL (ANN ARBOR, MI)

M. Todd Greene, PhD, Principal Investigator Dr. Greene, an epidemiologist, is a Research Health Science Specialist at the VA Ann Arbor CCMR and an Associate Research Scientist in the University of Michigan (U of M), Division of Hospital Medicine. Dr. Greene is the Program Manager for the Ann Arbor VA/U of M Patient Safety Enhancement Program. His research interests include epidemiologic methods, hospital acquired infections, and patient safety and quality of care enhancement. Dr. Greene has knowledge of study design, implementation, and data analysis of both clinical observational studies and randomized controlled trials. As a Principal Investigator, Dr. Greene will work closely with Dr. Saint in sharing primary responsibility for this project as described in the leadership plan. His specific responsibilities will include serving as the corresponding Project Director/Principal Investigator (PD/PI) for the project and supervising the project staff. Dr. Greene will be responsible for the organization and daily operation of the project and will have primary responsibility for design and assessment, as well as all logistics related to data collection and data management. Dr. Greene will participate in the data collection activities associated with the project, including the both quantitative and qualitative data. Dr. Greene will work closely with Dr. Saint and co-investigators in developing and conducting the intervention and interpreting findings. Dr. Greene will also take the lead with dissemination of final results.

Sanjay Saint, MD, MPH, co-Principal Investigator Dr. Saint is the Chief of Medicine at the LTC Charles S. Kettles VAMC, the George Dock Professor of Internal Medicine at the U of M, Director of the VA/U of M Patient Safety Enhancement Program, and a core faculty member of the VA CCMR Health Services Research & Development. His professional interests are in enhancing patient safety by preventing healthcare-associated complications; translating research findings into practice; and medical decision-making (including cognitive errors). Dr. Saint will work with Dr. Greene to

supervise the project staff, make budgetary decisions, lead project development and implementation, and disseminate the final results. Dr. Saint will also supervise the qualitative team as well as chair all stakeholder advisory panel meetings.

Molly Harrod, Ph.D., Co-Investigator Dr. Harrod is a trained medical anthropologist and a Research Health Science Specialist at the VA CCMR, where she is Director of the Qualitative Core. Dr. Harrod's expertise is in conducting interviews, engaging in observations, and coding and analyzing qualitative data. Dr. Harrod will supervise the qualitative analysis for this project and provide expertise in medical anthropology. She will: 1) develop the qualitative methods and interview guides; 2) participate in interviews and data collection; 3) supervise Ms. Quinn in identifying and coding common themes from the qualitative data using a VA approved qualitative analysis program like MaxQDA; and 4) assist with manuscript preparation.

Nathan Houchens, MD, Co-Investigator Dr. Houchens is the Associate Chief of Medicine at the Ann Arbor VAMC and an Assistant Professor in the Department of Internal Medicine at the U of M Medical School. Dr. Houchens' research interests include communication in healthcare settings, empathy, resilience, medical education, and mindfulness. For this project Dr. Houchens will serve, along with Dr. Sheffield, as a site mindfulness champion at the Ann Arbor VAMC and assist with development and implementation of the intervention. He will also co-lead the mindfulness meetings with intervention participants. He will also participate in the interpretation of the results and dissemination of study findings.

Virginia Sheffield, MD, Co-Investigator. Dr. Sheffield is a Clinical Assistant Professor with the Department of Medicine at the VA Ann Arbor Healthcare System, and with the Division of Hospital Medicine at the University of Michigan. Her interests are in diversity, equity, and inclusion, and medical education. For this project she will serve as a site mindfulness champion at the VAAAHS and assist with development and implementation of the intervention. She will co-lead the intervention mindfulness meetings with Dr. Houchens. She will also participate in the interpretation of the results and dissemination of study findings.

David Clive, Research Assistant David Clive will serve as a research assistant at the Ann Arbor, MI site. He will be carefully trained in protection of human subjects and will work closely with the project manager. For this project he will communicate with local staff about the project, recruit participants, obtain informed consent, conduct hand hygiene observations, collect survey data, and perform data entry.

Jason Engle, Research Assistant. Mr. Engle is a recent graduate of the University of Michigan School of Public Health, with a degree in Epidemiology. He has worked with Dr. Saint and the Patient Safety Enhancement Program for approximately 5 years as a research assistant. For this project, Mr. Engle will work under the direction of the project manager Ms. Fowler. He will be responsible for creating study databases, communicating with local staff about the project, recruiting participants, obtaining

informed consent, conducting the blinded hand hygiene observations, collecting survey data, and performing data entry for the project.

Karen Fowler, MPH, Project Manager Ms. Fowler is an Epidemiologist with 20 years of experience in project management with the VA CCMR. She has been working with Dr. Saint for the past 10 years on patient safety related projects, including the VA Ann Arbor Patient Safety Center of Inquiry and several national healthcare-associated infection prevention collaboratives. For this project, Ms. Fowler will help coordinate activities between all project investigators and staff. She will prepare IRB applications and materials for project team meetings. She will supervise the research assistant activities and coordinate the Ann Arbor qualitative team visits to the study sites and participate in the qualitative interviews, as well as coordinate intervention implementation activities. She will also help prepare presentations, reports, and manuscripts for this project.

Serene Jacob, MSN, Research Nurse. Ms. Jacob is a Research Nurse for the VA Ann Arbor Healthcare System Medicine Service. She has worked at the VA Ann Arbor for 14 years in various roles. She is also a clinical instructor at Washtenaw Community College and the University of Michigan, instructing nursing students. For this project Ms. Jacob will help with subject recruitment, data collection, study observations, and serving as a nurse mindfulness champion.

Latoya Kuhn, MPH, Project Manager Ms. Kuhn also has 20 years of experience in project management with the VA CCMR. She is a senior project manager with the VA/U of M Patient Safety Enhancement Program. For this project, Ms. Kuhn will assist Ms. Fowler will management of all project activities as needed. This will include coordination of activities between sites, supervision of research assistants and data collection, management of IRB, and prepare presentations, reports, and manuscripts for this project.

Erica Paulos, MA Data Analyst. Ms. Paulos is a new data analyst with the VA/University of Michigan Patient Safety Enhancement Program. She has completed postgraduate studies in mathematics at Harvard University and a Master of Arts in Economics at the University of Michigan. She will take over as the data analyst for this project from Mr. Ratz and will be responsible for all statistical analyses under the direction of Dr. Greene. Ms. Paulos will begin on the project in May 2023.

David Ratz, MS Data Analyst Mr. Ratz is an experienced data analyst with the VA/University of Michigan Patient Safety Enhancement Program. He has expertise in statistical methods and will serve as the data analyst for this project. He will be responsible for all statistical analyses under the direction of Dr. Greene. Mr. Ratz's effort will not begin until Year 2 after data collection has begun for the project.

IPA: Martha Quinn, MPH, Qualitative Analyst. Ms. Quinn is a Senior Research Area Specialist in Evaluation and Policy at the U of M School of Public Health. Her expertise is in conducting interviews, and coding and analyzing qualitative data. Ms. Quinn will support the qualitative analysis for this project under the direction of Dr. Harrod. She will work on the project under an Intergovernmental Personnel Agreement (IPA). She will: 1) lead the qualitative interviews at all sites; 2) take primary responsibility for the coding and qualitative analysis of the interview data using a VA approved qualitative analysis software like MAXQDA; and 3) assist with manuscript preparation.

MICHAEL E. DEBAKEY VAMC PERSONNEL (HOUSTON TX)

Barbara Trautner, MD, Site PI/Co-Investigator Dr. Trautner is a staff physician clinician-investigator at the MEDVAMC and an investigator at the Center for Innovations in Quality, Effectiveness, and Safety (IQuESt). Dr. Trautner is a Professor at Department of Medicine at Baylor College of Medicine. She also has secondary appointments with the Department of Surgery and the Department of Virology and Molecular Biology at Baylor College of Medicine. Dr. Trautner will serve as the site principal investigator for MEDVAMC in Houston, Texas. As site PI, she will be the primary supervisor for the research assistants who will be conducting subject recruitment and data collection at the MEDVAMC. She will also advise on the recruitment and data collection procedures at the Houston VA, in collaboration with Dr. Prathit Kulkarni. Dr. Trautner will also participate in developing the intervention and will participate in the interpretation, application, and dissemination of the study findings.

Prathit Kulkarni, MD, Co-Investigator Dr. Kulkarni is the Assistant Chief of Medicine at the Michael E. DeBakey VA Medical Center. He is an Infectious Diseases physician whose research interests include antimicrobial stewardship, infection control, healthcare epidemiology, quality improvement, and medical education. For this project, Dr. Kulkarni will assist Dr. Trautner with conducting the study at the Houston VAMC. He will assist with intervention development, supervision of research assistants, and leading the in-person mindfulness sessions to intervention participants. He will also assist with manuscript preparation and dissemination activities.

Laura Dillon, Research Assistant Laura Dillon will serve as a research assistant at the Houston, TX site. She will be carefully trained in protection of human subjects and will work closely with the project manager. For this project she will communicate with local staff about the project, recruit participants, obtain informed consent, conduct hand hygiene observations, collect survey data, and perform data entry.

Michelle Espiritu, Research Assistant Michelle Espiritu will serve as a research assistant at the Houston, TX site. She will be carefully trained in protection of human subjects and will work closely with the project manager. For this project she will communicate with local staff about the project, recruit participants, obtain informed consent, conduct hand hygiene observations, collect survey data, and perform data entry.

VA PALO ALTO HEALTHCARE SYSTEM PERSONNEL (PALO ALTO, CA)

Jason Owen, PhD, MPH, Co-Investigator. Dr. Owen is a Clinical Psychologist and mobile team lead with the VA National Center for PTSD's Dissemination & Training Division in Palo Alto, CA. He is the co-director of the VA's Center for Mobile Apps Research Services (CMARRS). He has extensive experience with developing and programming of mobile applications (apps) and conducting research using applications. Dr. Owen is also responsible for app-related data associated with VA mobile apps and led the development of the VA App Connect platform for conducting mobile app analytics, engagement tracking, and research integration. For this project, Dr. Owen will help us develop the mindfulness-based intervention. Specifically, he will help direct the customization of the application for use with providers and will assist in the collection of de-identified app analytics data and send to the VA Ann Arbor CCMR for analysis. He will also participate in manuscript and report preparation.

5.0 Study Procedures

5.1 Study Design

Research Design: A multi-center, repeat-measures randomized controlled mixed-methods trial.

Study Population: The proposed study will focus on Internal Medicine physicians who are part of inpatient care teams and nurses providing care on medical and medical/surgical units at LTC Charles S. Kettles VAMC in Ann Arbor, MI and MEDVAMC in Houston, TX. Medical students, surgical physicians, and physicians on sub-specialty teams will not be included. At both participating facilities the inpatient care teams are predominately composed of 1 attending, 1 senior resident, 2 interns, and up to 3 medical or physician assistant students. Interns and senior residents are usually assigned to a team for 4-week blocks (occasionally 2 weeks), while attendings rotate approximately every 2 weeks. The Ann Arbor VAMC has 3 medical or medical/surgical inpatient units, while MEDVAMC has 5 units. At both facilities each nursing unit employs between 20-30 nurses. We will aim to recruit approximately 30 attendings, 72 residents and 40 nurses at Ann Arbor VAMC. As MEDVAMC is larger, with a greater number of inpatient care teams and nursing units than the Ann Arbor VAMC, we will aim to recruit approximately 40 attendings, 72 residents and 90 nurses. Our target study sample size is a total of 344 physicians and nurses (167 intervention/177 control). For Aim 3, we plan to interview approximately 8 physician team members and 4-6 nurses from the intervention arm at each site.

General Study Overview and Outcome Measures:

A summary of the proposed study activities at each participating site is presented in **Table 2** below.

Table 2: Overview of Study Activities at Each Study Site

Study Detail	Physicians	Nurses
Target	Attendings, senior residents and interns on inpatient medicine teams	Nurses on medical or medical/surgical units
Teams/Units Participating	2 teams each month for 12 months randomized to intervention or control arm at each site	2 units (1 intervention; 1 control) at Ann Arbor VAMC & 4 units (2 intervention; 2 control) at MEDVAMC randomized once & followed for 12-months
Estimated number of participants	107 intervention and 107 control	20 intervention and 20 control at Ann Arbor VAMC; 40 intervention and 50 control at MEDVAMC
Habituation Period	1 month	1 month
Habituation assessment	• Unit-based hand hygiene observations	• Unit-based hand hygiene observations
Pre-Intervention Assessment	• Survey (FFMQ, WBI, select PSHW)	• Survey (FFMQ, WBI, select PSHW)
Intervention Period	2-4 weeks	1 month
Intervention Assessment	• Hand hygiene observations • Survey given at end of intervention (FFMQ, WBI, select PSHW) • Mobile app data and usage • Completion of STREAM mindfulness modules • Transcripts from intervention guided discussions • Qualitative interviews with ~8 physicians per site	• Hand hygiene observations • Survey given at end of intervention (FFMQ, WBI, select PSHW) • Mobile app data and usage • Completion of STREAM mindfulness modules • Transcripts from intervention guided discussions • Qualitative interviews with ~4-6 nurses per site
6-month Follow-up	• Emailed survey (FFMQ, WBI, select PSHW)	• Survey emailed or given in person (FFMQ, WBI, select PSHW)
Sustainability follow-up	• Select hand hygiene observations for ~10 weekdays at 3-12 months follow-up	• Hand hygiene observations for 1 month at 12 months follow-up

Habituation Period - To collect baseline data on hand hygiene adherence and duration and to habituate providers to the presence of observers, 1 month of covert, unit-based hand hygiene observations will be conducted. At the end of year 1, we will report out on observed hand hygiene rates. Observation of hand hygiene adherence will include hand hygiene prior to patient room entry and after exiting the patient room (**Appendix A**). In US hospitals, the entry/exit method has been demonstrated to be feasible for observed hand hygiene adherence monitoring by overcoming line-of-sight issues and other barriers.[74] Hand hygiene observers will not enter patient rooms or interfere in patient care. Observation of hand hygiene duration will be done when providers exit patient rooms, as observing hand hygiene duration upon room entry will not be feasible

since observers will not enter patient rooms.

Pre-Intervention Assessment - To evaluate mindfulness and hand hygiene, inpatient medicine teams and nurses from medical and medical/surgical units at each participating hospital will be included. Following informed consent, physicians from selected teams and nurses from selected units will be asked to complete a survey containing validated scales measuring dispositional mindfulness, well-being, and hand hygiene perceptions (**Appendix B**). The Five Facet Mindfulness Questionnaire (FFMQ)[75] is a validated instrument with favorable psychometric properties and consists of 39 questions. Additionally, participants will be asked to complete the Well-Being Index (WBI). The 9-question WBI assesses distress across a variety of dimensions including fatigue, depression, burnout, stress, and quality of life, and has been validated for use in physicians,[76] residents,[77] and nurses.[78] Participants will also be asked to complete 8 questions on HAI and hand hygiene perceptions selected from the Perceptions Survey for Healthcare Workers (PSHW) developed by the World Health Organization.[79] Similar to other studies on hand hygiene perceptions guided by the constructs based on the Theory of Planned Behavior,[8-10] the selected PSHW questions cover behavioral, normative, and control beliefs, as well as self-reported hand hygiene adherence. Participants will also be asked whether they meditate or perform any form of internal reflection prior to the study, as this may influence performance during the intervention. Questionnaire completion will take approximately 10 minutes. When feasible, surveys will be distributed in person with a postage-paid return envelope. Each survey will be labeled with a unique study ID number to allow us to track response. When we are unable to distribute the surveys in person – for example, when a physician rotates to another facility during residency – the surveys will be distributed using an electronic survey tool such as Qualtrics or RedCap. As physicians will need to access the survey's from outside the VA firewall (if they have rotated to another facility), we will use programs hosted by the University of Michigan. The informed consent document will include that survey data may be collected outside the VA firewall, however no personal identifiable information will be collected with the surveys to protect confidentiality. Subjects will always have the choice to complete the survey on paper if they would prefer.

Randomization – At each study site the participating physician teams and nursing units will be randomly assigned into one of two study arms (intervention/control). For physician teams, this will occur on a rolling basis for 12 months with 2 physician teams randomly selected at each site each month for participation (1 intervention, 1 control). Once randomized, an email will be sent to the initial attending of the team introducing the study and asking them to reply to the email if they would prefer to opt out and not have their team participate in the randomized controlled trial. If the attending physician from a team refuses to allow their team to participate, the next team identified from the randomized list will be approached to participate. If a new attending joins the team mid-month, they will be approached to participate in the study, but will be automatically assigned to the same randomization group as the rest of their team.

Similarly, a total of 2 medical/surgical units from VAAAHS (1 intervention, 1 control) and 4 medical/surgical units from MEDVAMC (2 intervention, 2 control) will be randomly selected to participate in the nurse portion of the project. The nurse manager for each

selected unit will then be approached to obtain approval for the unit to participate. If a nurse manager declines, the next unit on the list will be selected.

For both physicians and nurses, an independent statistician will allocate the teams and units in a concealed fashion, using a computer-generated randomization schema. The physicians and nurses from the intervention groups will receive both independent and group-facilitated mindfulness education, will be encouraged to use a mindfulness mobile app as a practice reminder and additional resource, and instructed to integrate moments of mindfulness with repeated episodes of hand hygiene during the course of caring for patients. The control groups will receive no such education or intervention and will continue as usual.

Mindfulness Intervention: We will work with a site-specific principal investigator (PI) and research assistants to facilitate intervention delivery. At each participating site, we will employ a train-the-trainer format and a member of the study team will serve as a mindfulness champion**.** They will be trained in mindfulness techniques, including completion of an online course and attending virtual meetings to standardize intervention methods between sites. Study PIs will also check in with mindfulness champions at each site on a monthly basis. The intervention will be delivered separately to physicians and nurses. For physicians, the intervention will be offered to attendings, senior residents and interns within the teams randomized to receive the intervention. The intervention will be offered to all nurses within the units randomized to receive the intervention. Components of the intervention are listed below.

Self-Directed Components - Participants will be asked to complete self-directed, online mindfulness training modules developed by the Ohio State University Mind-Body Skills Training for Resilience, Effectiveness, and Mindfulness (STREAM) program.[80] At the beginning of the intervention period, the curriculum will be described to participants as a way to help health professionals become more personally resilient and to be more effective in helping patients. The mindfulness training will include three modules: (a) Introduction to Mindfulness: The Body Scan, (b) Mindfulness in Daily Life, and (c) Mindfulness: Mindful Breathing and Sitting. As the modules were designed to be non-linear and acquiring skills sequentially to advance through modules is not necessary, participants will be allowed to complete the modules in any order. Participants will also be allowed and encouraged to repeat modules as desired. Each module includes a case, embedded self-reflection exercises, descriptions of the evidence supporting the skill, hyperlinks to peer-reviewed research, links to free MP3 recordings to experience the practice and develop a new skill, and links to resources. This interactive, experiential learning was designed to help participants develop new skills quickly and easily. We will recommend that each skill be practiced five times for a week or more before moving ahead to the next skill. Each module takes approximately 20 minutes to complete. Participants can download or print certificates of module completion. The STREAM staff will generate and provide the study team with reports of participant module usage and completion to be tracked as a measure of intervention engagement. Instructions for participants to access these modules can be found in Appendix Q. Participants will be asked to complete these modules during off-duty hours, and as such will be offered $25 for each module they complete (Maximum of $75) as remuneration

to encourage completion of this key aspect of the intervention.

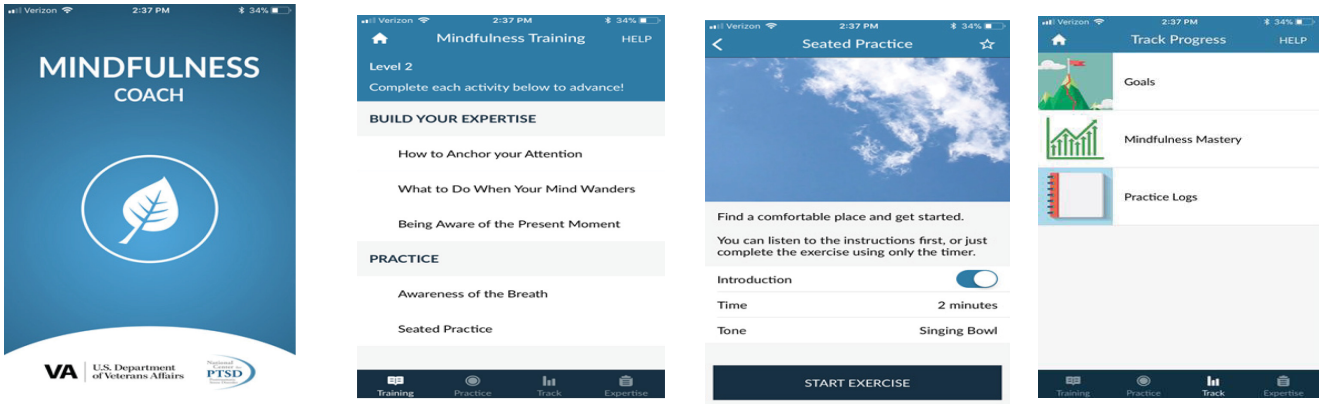

Figure 2: Mindfulness Coach 2.0 Mobile App Interface

The self-directed component will also include a mobile app to serve as an additional self-directed mindfulness practice tool and reminder. We will collaborate with researchers at the National Center for Posttraumatic Stress Disorder, Dissemination & Training Division at the VA Palo Alto Health Care System, to modify and incorporate the Mindfulness Coach (Figure 2). This mobile app contains information on the benefits of mindfulness, mindfulness exercises, strategies for overcoming barriers to practicing mindfulness, mindfulness practice reminders, and the ability to track progress. Mindfulness Coach, available for both iOS and Android platforms, is a free, anonymous, evidence-informed app. The app was originally designed to help Veterans with Posttraumatic Stress Disorder and related mental health concerns and has been updated by incorporating feedback from VA providers and Veterans about their app experiences. We will be employing a research version of the app in coordination with our app development team partners. Nurse participants will be offered the standard Mindfulness Coach Explorer app, while physician participants will be offered a slightly modified version of the mobile app – titled “Mindfulness for Clinicians”. Following randomization, study staff will provide information to participants in the intervention arm to introduce the app, guide participants through features, and encourage use of the app as a tool and reminder for practicing mindfulness. Instructions for how to access the mobile application can be found in Appendix R. Additional reminders to practice mindfulness and incorporate mindfulness during hand hygiene moments will be sent to participants during the intervention period through regular, auto-generated email notifications. The research version of the app also includes push notifications regarding new coaching messages. Deidentified and encrypted app-use metrics will be captured via invitation codes, which unlocks the app and transmits which screens are accessed and duration. App data will be used as a measure of intervention engagement.

Group-Facilitated Components - At each site, the site lead/mindfulness champion will lead guided discussions with participants that will focus on how principles of mindfulness can be used to influence a clinician’s state of mental presence, allowing for moments of clarity, insight, and reflection, and potentially enhanced provider and patient safety. Group discussions will address how principles of mindfulness can be

implemented to generate reflective pauses during moments of hand hygiene while providing clinical care. Discussion leads may share personal anecdotes and clinical examples of instances where stopping to be aware of physical and emotional state influenced decision-making, patient care, and personal feelings. As the group-facilitated discussions are also intended to foster a sense of interpersonal support, participants will be encouraged to participate in the discussion, provide insights on learning and practicing mindfulness, share experiences, and ask questions on integrating mindfulness into clinical and hand hygiene practices. Discussions will also address questions and feedback on the self-directed components discussed above. For physician participants, group-facilitated discussions lasting approximately 15 minutes will be offered every other week throughout the intervention phase at each site. For nurse participants, group-facilitated discussions lasting up to 30 minutes will be offered every week throughout the intervention phase at each site. Given the circumstances brought on by the COVID-19 pandemic and to offer greater flexibility, these discussions will be conducted either in person or virtually through a VA approved online conferencing program such as Microsoft Teams or Zoom to promote participation and implementation fidelity across sites. These discussions will be audio recorded and transcribed as described in the qualitative data and analysis section below. Attendance at these meetings will be tracked as a measure of intervention engagement. Meeting logistics for the discussions will be addressed at each site accordingly and participants will be encouraged to attend as many discussions as possible.

Promotion of Mindful Hand Hygiene Moments Component - Mindfulness is a moment-by-moment practice that, to be effective, should be reinforced regularly. Our intent is to create a mindfulness movement within rounds to slow the brain between patients and become present to each new interaction. Each mindful hand hygiene moment is a step towards greater provider well-being that can be renewed day after day and patient after patient. Because it is difficult to find moments to practice mindfulness during busy clinical days, hand hygiene will be promoted as the primary recurring prompt to pause, take a few deep breaths, be present, and accept whatever arises without judgment or reaction before entering and upon exiting a patient's room. During this pause, a moment to reflect, crystallize thoughts, be fully present in the moment and visualize what may happen in the next encounter, while acknowledging and accepting internal emotions or feelings will be suggested. After randomization, study staff will provide participants in the intervention arm a guide for a moment of mindfulness during hand hygiene (**Appendix C**). Intervention participants will be offered personal sized hand hygiene dispensers to help promote hand hygiene. To integrate the mindful moments with appropriate hand hygiene, participants will be encouraged to mindfully perform hand hygiene for at least 20 seconds.[6] Under the train-the trainer format, mindfulness champions at each site will teach and promote mindfulness during hand hygiene during group discussions and other frequent co-worker encounters. Study staff will also provide further guidance and reminders via regular emails at the beginning and end of each week during the intervention period. Pending pilot results assessing multiple factors (e.g., alert fatigue) reminders may also be integrated into the Mindfulness Coach app modifications.

Intervention Assessment - Following randomization to the intervention or control arm, physician teams will be observed for hand hygiene for the remainder of their time on

that service rotation on weekdays (3-4 weeks). For the physician teams, which rotate each month, this process will be repeated monthly for 1 year with up to 24 patient-care teams from each participating site. Nurses from both the intervention and control medical/surgical units will be observed for hand hygiene for one month. Observers will be blinded to randomization of the physician teams and thus intervention status. Since nurses remain assigned to one unit for a much longer period of time, nursing units will only participate once during the study. This will result in two nursing units from VAAAHS and four nursing units from MEDVAMC participating. At the completion of the observations, the physicians and nurses will again be asked to complete FFMQ, WBI, and select PSHW questions. To assess sustainability of well-being, mindfulness, and hand hygiene perceptions, we will ask participants to repeat FFMQ, WBI, and select PSHW questions at 6-month post-intervention follow-up points. To assess sustainability of hand hygiene among physicians, select hand hygiene observations at 3 to 12 months post-intervention (based on team schedules) will be conducted. To assess hand hygiene sustainability among nurses, unit-based hand hygiene practices will be reassessed at 1-year post-intervention. To examine changes across survey time points, crosswalk files will be utilized. Participant names will not be on the survey. A study team member will assign the survey respondents an identification number to link repeat surveys.

As part of the intervention we will also collect measures of fidelity. This will include information from the Mindfulness Coach/Mindfulness for Clinicians mobile application including usage and responses from any assessments included in the app about the participant's level of mindfulness. We will also collect data on completion of the Ohio State University STREAM Mind Body modules. This data will be completely de-identified. Both programs do not collect any personal identifiers. Instead, participants will be asked to register with a study assigned code. The de-identified user data for each code will be shared back with the study team to assess fidelity.

Data Collection and Management: Field observational data collection will include hand hygiene adherence and duration using standardized templates for data collection. Research assistants will perform the observations and data entry. The research assistants will be blinded to the randomization of the physician teams, however, they will know which nursing units were assigned to the intervention. Study staff will covertly observe members of inpatient physician teams and nurses within specific units in their performance of hand hygiene as they enter and exit a patient's room. Hand hygiene dispensers are located outside of patient's rooms in the hallways and most staff use these dispensers before entering and upon exiting patient rooms which will be visible from the hallway. Hand hygiene data will include whether a member washes their hands with soap and water, uses alcohol-based hand rub, or does not perform hand hygiene. In the event the observer is unable to visualize hand washing due to the location of the washbasin in the patient's room or the rapid changes between providers as hand hygiene is performed, the observer will record this event as unknown. If a team member does not enter the patient's room or the patient is not in the room, this will be recorded as no room entry. Hand hygiene duration will be captured for room exit observations for all nurse observations and for half of the attending observations. Duration will be recorded as the elapsed time of rubbing hands after dispensing hand

sanitizer product onto hands. The data collection tools (**Appendix A**) will capture whether the person observed is an attending, resident, intern, or nurse but will not include any individual names. Information on team or unit name will be collected so the data analyst can later identify the observation as intervention or control. Photos of all physician team members are posted on each inpatient unit or available online, which will allow research assistants to identify physician level (attending, senior resident, or intern). Since the research assistants will be blinded to intervention status of physicians and physicians will change teams during the follow-up observations, we will identify individual physician participants with a unique study ID on the data collection forms. Observers will not enter patient rooms.

Data acquisition over the course of the study will span intervention/control groups that include inpatient physician care teams (up to 48 each at Ann Arbor VAMC and MEDVAMC) and nurses on medical/surgical acute care units (2 units at Charles S. Kettles VAMC and 4 units at MEDVAMC). Each physician team generally cares for approximately 10 patients per day, but this rate varies based on patient volume. For physician team observations hand hygiene will be observed for the attending, senior resident, and interns when entering a patient's room. We will rotate observations on exiting patient rooms, with half of the observations focusing on hand hygiene of the physician team, and the other half focusing on the duration of hand hygiene by the attending. The number of observations per day may vary depending on the composition of the team and the structure of the morning team rounds. One or more team members may be missing on any given day due to planned days off or other commitments. Further, some teams review patient information in a conference room instead of visiting each patient as a large group. In this scenario, we will still observe the attending and other team members present during patient visits after table rounds.

There could be a risk of a Hawthorne effect with conducting hand hygiene observations. Three basic, non-technological methods to help avoid or decrease the Hawthorne effect include: 1) letting healthcare workers habituate to unobtrusive and/or frequent observation; 2) using indirect methods to monitor hand hygiene adherence, such as monitoring consumption of hand sanitizer products; and 3) covertly observing hand hygiene adherence.[81] To minimize the risk of Hawthorne effects for this project, research assistants will conduct wash-in period observations within units as a means of habituating physicians and nurses to being observed. Additionally, research assistants will not follow the inpatient teams. Instead, all observations will be done covertly from a randomly chosen location on one of the hospital units each day. As such, we anticipate that research assistants will be able to capture hand hygiene moments for 4-6 patient encounters per observation day. Due to the variable number of patients, team attendance and daily rounding structure, each day we expect to observe approximately 8-24 before room entry and 4-12 after room exit hand hygiene moments, with an additional 2-3 measures of attending hand hygiene duration upon leaving the room. With roughly 10 observational days per attending team (M-F, no weekend or holiday observations) during the intervention period and up to 24 attending teams, we estimate we will collect the following physician data per arm at each site: 1,920-5,670 room entry hand hygiene moments, 960-2,880 room exit hand hygiene moments, and 480-720 measurements of hand hygiene duration.

Covert observations within randomly selected areas within units will also be conducted for observing hand hygiene among nurse participants. Observations will be conducted for 1 month before the intervention and 1-month after the intervention. On all participating units, observations of nurse hand hygiene while entering and exiting patient rooms will be conducted. Hand hygiene duration among all nurses will also be captured upon room exit. Nurses will be observed for approximately 4 hours per day during the first part of their shift, as all nurses typically check in with each patient at the start of their shift. From covert locations within the unit, the observers will only be able to observe approximately 10 rooms at a time. They will move their location in the unit each day to ensure representation from different nurses. The number of times a nurse enters each patient room will vary, but we estimate at minimum each nurse will enter each room once per hour. Therefore, observing 10 patient rooms for 4 hours per day, with 2 observation points per entry would lead to approximately 80 hand hygiene moments observed per day per unit. Observing 3 units per arm for approximately 44 days total would lead to an estimated 7,040 nurse hand hygiene observations per study arm in total. As hand hygiene duration will also be recorded upon room exit, and estimated total of 3520 hand hygiene duration observations per study arm will be observed. In addition to the 1-month post-intervention observation period, we will also observe and collect 1 month of data on hand hygiene moments at 1-year post-intervention in the intervention and control units at both sites.

Collected data will be transferred from the paper observation data tool into a study database. The data analyst and project manager will be able to link these covert observations accordingly to intervention or control groups based on team and unit name.

Study surveys will be distributed in person using a paper survey and a postage-paid business reply envelope where feasible. Electronic surveys containing questions from FFMQ, WBI, and PSHW surveys will be generated. Study participants will be directed to a link to the survey tool (for the pre- and post-intervention, as well as 6-month post-intervention follow-up periods) and responses will be saved to a database managed by the study team.

Qualitative data will be collected to better understand the perception of the intervention and assess any barriers or facilitators encountered (**Appendix D**). The primary subjects will be nurses and physicians that participated in the intervention. For this evaluation we will conduct individual or group interviews with approximately 6 nurses and 8 physicians at each site, for a total of 12 nurses and 16 physicians. In addition to the interviews, we will also audio record the site lead/mindfulness champion guided discussions with participants. During these guided discussions it is expected that participants will talk about their insights on learning and their own personal experiences practicing mindfulness during the intervention. All guided discussions, along with the interviews, will be recorded using Audacity software, Microsoft Teams, or Zoom for Government. The discussions and interviews will be conducted in person wherever feasible, however when not feasible, we will use Microsoft Teams, Zoom for Government, or phones to conduct these meetings virtually. The audio recordings will be transcribed and de-identified for analysis. Transcripts will be reviewed and data central to the aims of this study will be extracted and analyzed.

Additional data on fidelity to the intervention will be collected. This will include de-identified usage data from the OSU STREAM modules as well as the Mindfulness Coach/Mindfulness for Clinicians app. For both of these, participants in the intervention will login using a specific project code. No personal identifiers will be collected by either program. De-identified data on usage including the number of people who accessed each module and usage of the Mindfulness Coach/Mindfulness for Clinicians app will be shared with study staff at VA CCMR to evaluate fidelity.

All study data will be stored on a VA Ann Arbor CCMR secure server, accessible only by study staff. To protect subject confidentiality, unique study ID numbers will be used for all study surveys and study databases in lieu of names. Only study staff will have access to the cross-link file that could connect subjects to their ID number. Study documents including signed informed consent documents and data collection/observation sheets will be stored in a locked filing cabinet at each study site. We will follow approved VA guidelines, Records Control Schedule RCS 10-1, for the disposition of records following closure of the study.

RISKS

There are no physical risks associated with this research. However, as with any study, there is a risk to participants of inadvertent disclosure of personal information or a loss of confidentiality. We believe this risk is extremely low; we describe the multiple measures that we will take to protect our participants below. Additionally, participants may find it uncomfortable to answer some of the questions on the survey or during the interviews. They will be informed that they can skip any question. Finally, to minimize the risk of coercion, all potential subjects will be offered the opportunity to decline study participation with no penalty to VA employment, and will be informed that they may decide not to continue participation at any time.

The principal investigators, Drs. Greene and Saint, take ultimate responsibility for ensuring the safety of the participants. Specifically, we intend to take several steps to ensure subject confidentiality and protect against the potential risks related to loss of confidentiality, and stress related to interviews.

Throughout the study, IRB and privacy guidelines will be followed to ensure the privacy and integrity of the information we collect. Any breach of confidentiality will be immediately reported to the PD/PI and to the participating IRBs. In addition, any complaints/concerns expressed to the study staff will be immediately reported to the PD/PI and the IRB in accordance with existing policies and expectations.

Aim 1: Hand hygiene observation data will not include any names in an attempt to protect subject confidentiality. The observation forms will record the team name or unit, the role of the individual, and what type of hand hygiene was performed (if any) upon entering and exiting a patient room. Duration of hand hygiene will also be recorded for all nurses and for attending physicians for half the observations. We will therefore be able to conduct analysis by intervention arm and physician type (attending, senior resident, or intern physician), or nurse. If the data collection forms were released, it might be possible to identify an individual's hand hygiene compliance with the information collected. The research assistants will store the forms in a lock box during

transport to protect confidentiality. Once in a study office, the hand hygiene observation data will be entered into a study database on a secure VA server, with access only to study team members. The paper observation forms will be stored in a locked filing cabinet.

Aim 2: All potential participants will be clearly informed that their participation is completely voluntary. Thus, an alternative course of action for each of them would be to not participate. Subjects will be asked to complete surveys with questions on mindfulness and well-being at multiple time points throughout the study. These surveys will be labeled with a unique study ID so study staff can link the survey to the subject. The crosswalk file that would identify the participants will be stored on a secure VA server with access to only study staff. The baseline survey will primarily be distributed in paper form when participants are recruited, after they have provided informed consent. The data from these surveys will be entered into a study database on a secure VA server and then stored in a locked filing cabinet. We will also distribute surveys electronically to those we are unable to approach in person. For example, nurses on the control units will be emailed an invitation to participate in the study survey instead of in person (**Appendix E**). A reminder email will also be sent to non-respondents on the nurse control units to encourage participation (**Appendix F**). We will also email the 1-month and 6-month post-intervention (7 months from baseline) surveys to nurses on the intervention units, as well as physicians during follow-up since many resident physicians will rotate to other hospitals (**Appendix G**). Similar to the nurse control's, reminder emails will be sent to non-respondents at 1-week and 2-weeks after the initial mailing to encourage survey completion (**Appendix F**). We will use an online survey program like Qualtrics which can be accessed outside of the VA firewall, since physicians may be completing the survey on a non-VA computer. The electronic surveys will not contain any individual identifiers. They will be labeled only with the unique study ID number and will ask questions about mindfulness, well-being and hand hygiene perceptions.

There could be added risks associated with using the Mindfulness Coach/Mindfulness for Clinicians app in the intervention. The Mindfulness Coach/Mindfulness for Clinicians app was developed by VA researchers for use with Veteran patients, and it already meets VA privacy and security standards. The mobile app will provide education and exercises to practice mindfulness. We will collect usage data and responses to a self-assessment from the app. The mobile app does not itself collect any individual identifiers. When subjects are enrolled, they will be given a unique study id that will allow the study team to identify data collected from the app, using a crosswalk file. Files that link the interviewee with the study ID will be securely stored in an access restricted folder on a secured VA server in a separate location from the study data.

Aim 3: We plan to record and transcribe the interviews and guided discussions in the intervention arm. The participants will be told they can ask for the recorder to be turned off at any time and they may skip questions that they may not wish to answer or end participation at any time. Psychological and social risks might be possible if confidentiality were breached for the interviews or discussions. To protect the interviewee's confidentiality, the audio recordings will be labeled using unique study ID codes only. Participant names, other individual names, and facility names will not

appear in any of the transcripts. If such information is volunteered (despite instructions) by the participant in a taped session, it will be removed by the transcriptionist. Files that link the participant with a study ID will be securely stored in a restricted access folder on a secure server at Ann Arbor VA CCMR. The original audio recordings, and study transcripts will be electronically stored in restricted access folders on secure servers that can only be accessed by specified study personnel. At the end of the study, the linking information will be removed from the transcripts to protect confidentiality. All reports and transcripts from the qualitative recordings will be completely stripped of any identifiers to protect the confidentiality of all participants. No information that could identify a respondent will be reported. There are no physical risks associated with this aim.

Any reports or manuscripts on this project will contain only aggregate, de-identified data.

BENEFITS:

This research study has an excellent risk/benefit ratio. While risks to participants are minimal, the benefits are great. Although the participants may not receive any direct benefit, participation in the study could improve hand hygiene adherence and provider well-being. This in turn could help prevent HAIs and improve the quality of care delivered to Veterans. If successful, this intervention could be spread throughout VHA to improve both provider well-being and patient safety.

5.2 Recruitment Methods

Recruitment and Informed Consent

Aim 1: Participation in the randomized controlled trial portion of the study will involve obtaining a signed informed consent document from subjects. This process is described under Aim 2 below.

We will seek a waiver of informed consent to conduct the hand hygiene observations for Aim 1 on each unit and with each physician team that participates in the trial. To help minimize a Hawthorne effect we will make these observations covertly by standing in the hallway and not following any one individual or team. If asked about our presence on the unit we will respond that we are there to study hospital workflow. The data collected will be de-identified, only indicating the role of the person observed (attending, senior, intern, or nurse). Hand hygiene is something that the hospital is already monitoring periodically and collecting hand hygiene data for this study will not put the observed healthcare providers at any increased risk.

Aim 2: The providers will be recruited through multiple methods to increase the participation rate.

- Nurses: We estimate there will be approximately 20-30 nurses on each unit. We will recruit from 2 units at the Ann Arbor VAMC (approximately 20 intervention; 20 control) and 4 units at the MEDVAMC (approximately 40 intervention; 50 control), for a total of approximately 130 nurse participants. Nurses will be provided information about the study during unit meetings and through study flyers posted in the break room (**Appendix H & I**).
    - Nurses on the control units will only be asked to complete the 3 study surveys over a 7-month period. This can be done with a waiver of documented consent. Nurses on the control units will be given a study information letter with a paper survey and return envelope or emailed the study information letter with a link to complete the survey electronically (**Appendix E**). If they complete the survey, they are implying consent. A reminder email will be sent at 1-week and 2-weeks to non-respondents to encourage participation (**Appendix F**).
    - Nurses on intervention units will be sent an introductory email (**Appendix J**) with information about the study and asking to set up a time and place to discuss the study in more detail. If we are unable to reach the nurses through email, study staff will approach the nurses during their work shift and ask to set up a time to meet to discuss the study in private. Recruitment will occur in a private room or office using the attached recruitment script (**Appendix K**).
- Physicians: We estimate enrolling approximately 35 attending physicians, 24 senior residents, and 48 intern physicians into each arm of the study, which will result in a total of 214 physicians in total. All physicians from physician teams will be asked to participate in the randomized controlled trial and provide a signed informed consent. Each month one team at the Ann Arbor VAMC and 2 teams at MEDVAMC will be randomized to intervention and an equal number at each site will be randomized to control. A flyer describing the study (**Appendix S**) will be emailed (**Appendix T**) to teaching attendings to introduce the study. Before the beginning of the month, the initial attending physician on each selected team will be sent an email describing the study and giving them the option to opt out of their team being approached to participate (**Appendix L**). A time and place will be scheduled to discuss the study in more detail and obtain informed consent from the attending (**Appendix M**). Unless the attending indicates they do not want their team participating, the rest of the team will be sent an email describing the study (**Appendix L**). Then study staff will approach the senior resident and interns in the team rooms and ask to speak with them about the study (**Appendix M**). If there are others in the team room, the study staff will ask the residents to follow them to a private room to discuss the study in greater detail. If they are willing to participate, they will be asked to sign an informed consent document. The primary participants are the attending physicians on each team. If the initial attending declines allowing their team to participate, another team will be randomly selected and approached for participation. If any physicians choose to not participate, they will not be asked to participate in the intervention activities (if randomized to the intervention) or to complete the study surveys (both study

arms). However, hand hygiene data will still be collected using a waiver of informed consent. When a new attending starts on a team that has already been randomized, they will be recruited in a similar manner as the initial attending (email, followed by in person recruitment). If the 2nd attending on the team declines participation, the team is still considered enrolled, however the new attending will not be asked to participate in the intervention (if on an intervention team) or complete the study surveys.

Aim 3: Interviews and Guided Discussions

- Interviews: Select participants in the intervention arm will be asked to participate in the qualitative evaluation interviews to provide feedback about the intervention. We estimate enrolling 4-6 nurses and 8 physicians from each site. The providers will be recruited via email (**Appendix N**) or in-person communication with study staff. If they agree, a day, time, and location for the interview will be arranged. At the Ann Arbor VAMC, these interviews can be conducted in person, or by phone if needed. Members of the team from Ann Arbor plan to travel to MEDVAMC to conduct these interviews in person as well, since more information can be obtained through direct observation and face to face interactions. However, if travel restrictions are in place or if someone is unable to attend an in-person meeting, the interview can be scheduled to occur either over the phone or using a VA approved conferencing program like Microsoft Teams or Zoom for Government. The Ann Arbor qualitative team will provide a study information letter and review the purpose of the interview before obtaining verbal informed consent. As we will be audio recording – will will ask verbal permission to audio record at the start of the interview using the attached audio recording permission script (**Appendix O**). We will ask for a waiver of informed consent for this aim of the study as it poses minimal risk and a signed consent would be the only link between the subject and their interview, which would increase their risk of loss of confidentiality.
- Guided Discussions: The signed informed consent that is obtained from all nurses and physicians in the intervention will include permission to record the guided discussion sessions. In addition, the mindfulness champion will ask all attendees at each guided discussion session if they are willing to have the session recorded and that they can ask to have the recorder turned off at any time for any reason (**Appendix P**).

All subjects will be VA employees or trainees. As participation in this program will require extra time outside of their normal work duty to complete the three mindfulness educational modules, we will offer $25 remuneration per completed module (maximum of $75 for the project). Each participant will be given a unique code to access these training modules. Consultant Kathi Kemper will email the project manager every 1-2 weeks with a list of which modules were completed and the associated unique codes. The staff in Ann Arbor will then check the cross-link file to identify to which subjects those codes correspond. The gift cards will then be mailed to the participants for each completed module or distributed in person where feasible. This is to help promote completion of this key part of the intervention. Participants will be told they will not be

eligible for remuneration if they complete the modules during their normal working hours. However, this will be done on an honor system as project staff will have no way to confirm when the modules were completed or what is the participant's normal tour of duty. There will be no remuneration for any other aspect of the project.

5.3 Informed Consent Procedures

Subjects will be recruited for the project as described in section 5.2. We will seek a waiver of informed consent to conduct the hand hygiene observations for Aim 1.

All physician participants (i.e., those that are assigned to either the intervention or control arm of the study) will be asked to provide written informed consent with a HIPAA authorization. The informed consent document will describe the randomized controlled trial including both arms of the study (intervention activities and control). It will also include information about the survey data that they would be asked to provide at baseline, 1-month, and 6-month post-intervention time-points. This method of consent will allow the research assistants who will be obtaining the informed consent and also conducting the hand hygiene observations to be blinded to the intervention status of each participant.

For nurse participants, we will seek a waiver of documented informed consent for the nurses on the units randomized as control. These nurses will only be asked to complete surveys about mindfulness (**Appendix B**) at baseline, 1, month, 6 months post-intervention. Completion of surveys falls under exemption category 2. Completing the survey will imply their consent for their responses to be included in the study. The nurses on the units randomized to the intervention will be asked to provide written informed consent to participate in the intervention which will outline all aspects of the intervention as well as the surveys. This change in consent strategy between the nurses and physician is because the research assistants will know which units are assigned to intervention and control. It is not feasible to blind the research assistants to the intervention status of the nursing units, but we will be able to blind them to the status of the physicians. As such, we are requesting the waiver of documented consent for the control nurses only to reduce burden in the hopes of increasing participation of this group.

For the physicians (both intervention and control) and the nurses on the intervention units, consent will be obtained in a private room or office. Trained research staff will explain the study and answer any questions. If the eligible subjects choose to participate, they will then be asked to provide a signed informed consent which will cover the appropriate aspects of the study.

For the interviews of a sample of intervention participants for Aim 3, the qualitative team will provide a study information letter and review the purpose of the interview before obtaining verbal informed consent. We will ask for a waiver of documented informed consent for this portion of the study as it poses minimal risk and a signed consent would be the only link between the subject and their interview, which would increase their risk of loss of confidentiality. All study research staff will be trained in appropriate human subjects protection and the informed consent process. To minimize

the risk of coercion, all potential subjects will be offered the opportunity to decline study participation with no penalty to VA employment, and will be informed that they may decide not to continue participation at any time. As our subjects are VA staff, there will not be any protected health information collected as part of this project.

5.4 Inclusion/Exclusion Criteria

Aims 1 and 2:

For the nurse portion of the trial, 1 inpatient hospital unit at Ann Arbor VAMC and 2 units at MEDVAMC will be randomized to receive the intervention and an equal number of units at each site will be randomized to receive the control. All nurses on the selected units will be asked to participate in the voluntary study. Inclusion criteria are all nurses on the identified units. There are no exclusion criteria.

For the physician portion of the trial, we will focus on inpatient physician teaching teams, which typically include 1 attending physician, 1 senior resident, and 2-3 intern physicians (Year 1 residents). Inclusion criteria are physicians on inpatient medical teams. Exclusion criteria are medical students, surgical attendings, and physicians on sub-specialty teams. Attending physicians may be on service multiple times per year. Attendings will be allowed to participate in multiple months, however, once a physician has been randomized to the intervention arm, they will no longer be eligible to participate in the control arm of the study.

Aim 3:

In this aim we will conduct a qualitative evaluation to better understand the perception of the intervention and assess any barriers or facilitators encountered. The primary subjects will be nurses and physicians that participated in the intervention. Inclusion criteria for this aim is being a nurse or physician that participated in the intervention. There are no exclusion criteria.

5.5 Study Evaluations

The following evaluations will be conducted. Details can also be found in section 5.1 - Study Design.

Field observational data collection will include hand hygiene adherence and duration using standardized templates for data collection (**Appendix A**). Collected data will be transferred from the paper observation data tool into a study database.

All participants will be asked to complete a survey containing validated scales measuring dispositional mindfulness, well-being, and hand hygiene perceptions. The FFMQ[75] is a validated instrument with favorable psychometric properties and consists of 39 questions. Additionally, participants will be asked to complete the WBI. The 9-question WBI assesses distress across a variety of dimensions including fatigue, depression, burnout, stress, and quality of life, and has been validated for use in physicians,[76] residents,[77] and nurses.[78] Participants will also be asked to complete 8

questions on HAI and hand hygiene perceptions selected from the PSHW developed by the World Health Organization.[79] Similar to other studies on hand hygiene perceptions guided by the constructs based on the Theory of Planned Behavior,[8-10] the selected PSHW questions cover behavioral, normative, and control beliefs, as well as self-reported hand hygiene adherence. Participants will also be asked whether they meditate or perform any form of internal reflection prior to the study, as this may influence performance during the intervention. Questionnaire completion will take approximately 10 minutes. No personal identifiable information will be collected. Paper survey distribution will be used wherever feasible, but electronic versions using Qualitrics will be available for physicians that have rotated to locations outside of the VA. Study participants will be directed to a link to the survey tool (for the pre- and post-intervention, as well as 6-month post-intervention follow-up periods) and responses will be saved to a database managed by the study team.

Participants from the intervention groups will receive both independent and group-facilitated mindfulness education, will be encouraged to use a mindfulness mobile app as a practice reminder and additional resource, and instructed to integrate moments of mindfulness with repeated episodes of hand hygiene during the course of caring for patients. The control groups will receive no such education or intervention and will continue usual care.

Details of each intervention component and measures of fidelity are as follows:

- Participants will be asked to complete self-directed, online mindfulness training modules developed by the Ohio State University Mind-Body STREAM program. The mindfulness training will include three modules: (a) Introduction to Mindfulness, (b) Mindfulness in Daily Life, and (c) Mindful Breathing and Sitting. Participants will be given a unique code to use to access these training modules. The modules will not store or collect any personal identifying information. Consultant Dr. Kemper will share access data with the Ann Arbor project staff by that access code which will be used to measure fidelity to the intervention.
- As part of the self-directed component participants will be encouraged to use the VA Mindfulness Coach or Mindfulness for Clinicians mobile app. Participants can choose to download this app to their personal devices. Co-investigator Jason Owen at the VA Palo Alto Healthcare System will collect de-identified data on app usage and share with the Ann Arbor team to measure fidelity to the intervention. The mobile app does not collect any personal identifiers.
- The group-facilitated component will include discussions focused on how principles of mindfulness can be used to influence a clinician's state of mental presence, allowing for moments of clarity, insight, and reflection, and potentially enhanced provider and patient safety. Discussions will also address questions and feedback on the self-directed components discussed above. For physician participants, group-facilitated discussions lasting approximately 15 minutes will be offered every other week throughout the intervention phase at each site. For nurse participants, group-facilitated discussions lasting up to 30 minutes will be offered every week throughout the intervention phase at each site. In addition to

recording these discussions for use in the qualitative study evaluation, attendance at these discussions will be recorded to assess fidelity.

5.6 Data Analysis

Quantitative Statistical Analysis (Aims 1 and 2): Differences in hand hygiene adherence and duration between intervention and control groups will be assessed using Fisher's exact test and t-test, as appropriate. Risk differences in adherence to duration of hand hygiene will be calculated for both intervention and control groups. Because the primary outcomes for Aim 1 (i.e., hand hygiene adherence and duration) are expected to occur frequently, we will use generalized linear models to evaluate differences in hand hygiene adherence and duration for the intervention versus control group, with the Poisson distribution (log link) and robust error variance. Models will account for provider type and level, and will incorporate clustering by physician team (and separately for nursing unit). Statistical significance will be calculated for the intervention (intervention vs. control) coefficient.

As a secondary outcome for Aim 1, we will assess changes and differences in hand hygiene perception based on response to select questions from PSHW. For Aim 2, mindfulness will be based on responses to FFMQ and well-being will be based on responses to WBI. FFMQ and WBI scales will be scored according to the published algorithms. Descriptive statistics will be used to summarize participant scores from pre- and post-intervention, as well as 6-month post-intervention follow-up assessments. Within-group paired-samples t-tests will be used to test for improvement in participant scores across the baseline, post-intervention (~14 days for physicians and 1-month for nurses), and 6-month post-intervention follow-up periods, for the intervention and control groups separately. Analyses will use list-wise deletion for missing data. Participants not completing all surveys will still be included in any analysis for which they provide data. For all analyses, p values less than 0.05 will be considered significant and all tests will be two-tailed. Analysis of covariance (ANCOVA) models will then be used to assess relative changes in mindfulness, well-being, and hand hygiene perceptions across groups, the most direct test of discriminant validity. In these models, post-test scores will be predicted by group status controlling for pre-test scores.

Power - Based on a range of 10%-15% significant percent change in hand hygiene adherence from our pilot data,[72] we are anticipating an expected increase in hand hygiene adherence due to the intervention from approximately 80% at baseline to 88%-92% at follow-up. We will have 79.8% power to detect this 10% increase based on a fixed total sample size of 334 with a two-sided alpha of 0.05, assuming an average of 60 observed hand hygiene opportunities per provider per measurement time point (i.e., intervention and follow-up), and taking into account clustering of data within site/team/unit (assumed Intraclass Correlation Coefficient=0.4).[82] For assessing differences in the select PSHW questions we will have 70.1% power to detect an effect size of 0.15.[83] For assessing differences in FFMQ and WBI scores, we will have >95% power to detect effect sizes ranging from 0.3 to 0.75 as found in prior studies.[65,84,85]

Qualitative Phase (Aim 3): In Aim 3, we will begin the process of identifying the facilitators and challenges of incorporating mindfulness into clinical practice and developing a deeper understanding of perceptions and experiences related to using mindfulness in the clinical setting. We will employ a case-study methodology, conducting semi-structured interviews. First, we will conduct interviews with intervention participants (attending physicians, senior residents, interns, and nurses) at each site. We will ask participants about their experience with mindfulness and opinions about using it as a possible tool to promote hand hygiene, infection prevention, and provider well-being. Interviews will occur at the conclusion of selected intervention phase observation periods. We will invite members of the intervention arms to discuss their experience of attempting mindful hand hygiene, the concept of mindfulness for healthcare providers in the inpatient setting, the hand hygiene-based mindfulness intervention components (i.e., online modules, mindfulness app, group-facilitated discussions, mindful hand hygiene moments), challenges to performing mindfulness, and the potential benefits for providers and patients. Based on the literature and our prior experience, data saturation is generally achieved after interviewing 10-12 individuals at a site. We plan to interview approximately 8 physician team members and 4-6 nurses at each site. Interviews will include a semi-structured interview guide (**Appendix D**) to stimulate discussion of the realities and challenges of practicing mindfulness through hand hygiene in the clinical setting. Second, qualitative data will also be collected and evaluated from each site's group-facilitated guided discussions. During these guided discussions it is expected that participants will talk about their insights on learning and their own personal experiences practicing mindfulness during the intervention. All guided discussions, along with the interviews, will be recorded, de-identified, and transcribed for analysis. These recordings will be transcribed internally by staff at the VA Ann Arbor CCMR offices. The interviews and transcripts will be stored on secure VA CCMR servers with access limited to approved project staff. Transcripts will be reviewed and data central to the aims of this study will be extracted and analyzed. We will use the 7 aspects of Mindful Practice[86] as they may relate to hand hygiene as a guide for data interpretation.

All interviews will be conducted by 2 to 3 members our team and will generally include the study Principal Investigator Greene, other study co-investigators PD/PI Saint, or Co-Investigators Houchens and Sheffield, non-clinician qualitative experts Harrod or Quinn, and project support staff (the project manager or research assistant). All interviews will be audio-recorded and transcribed for analysis; field-notes and site materials will be preserved. Participants will be informed when the audio recording is in process and may request to stop the audio recording at any time.

A descriptive-content analysis will be conducted on the qualitative data from interviews and group discussions.[87] Three to four members of the study team will begin by independently reading a sample of interview and group discussion transcripts and together develop a preliminary coding scheme to help guide the analysis. A codebook will be created that includes both deductive codes, identified prior to coding based on key study categories, and inductive codes that emerge directly from the data. Two members of the study team will use this codebook, which will be revised periodically as additional codes emerge, to independently review and code all transcripts. If new codes emerge, previously coded transcripts will be re-analyzed to ensure consistency in the

application of codes. The two coders will meet regularly, and with other study team members as needed, to discuss and resolve any discrepancies in coding until agreement is reached. We will use a VA approved qualitative analysis program like MAXQDA (VERBI Software, Berlin, Germany) will be used to manage and organize the qualitative data. Once all of the data have been coded and entered into MAXQDA, members of the larger study team will identify key themes. All recordings and transcripts will be stored on a secure VA CCMR server, with access limited to approved study staff.

5.7 Withdrawal of Subjects

Subjects may choose to withdraw at any time without any penalty. We will use the data collected up until the point of withdrawal. There are no anticipated circumstances for subject withdrawal without subject consent.

6.0 Reporting

Because this is a minimal risk study with no patient involvement, we do not anticipate any serious adverse events. Study subjects will be physicians and nurses who will be asked to complete either paper or electronic surveys, participate in group led discussions, complete online training modules, and use an optional mobile application on mindfulness. Hand hygiene compliance will be monitored covertly. Intervention participants will be encouraged to practice mindfulness and use hand hygiene as a moment of mindfulness. Serious adverse events (SAEs) to be monitored include the following: 1) a breach of a participant's confidentiality or privacy that involves potential risk to that participant or others, 2) deviations from VA IRB regulations and policies, and 3) unanticipated problems that involve social or economic harm instead of the physical or psychological harm associated with (UAPs) adverse events. SAEs will be prospectively tracked according to the following plan: reports of SAEs and protocol deviations will be made by the study team member who discovers the event, the site PI, or site project manager (if applicable) to the primary site (Ann Arbor) project manager. The primary site project manager and PI will report the event to the Central IRB (Primary Site IRB). Any SAEs and UAPs meeting the definition of serious will be reported within 5 business days of discovery to the Central IRB. AEs and UAPs that do not meet the definition of serious are to be reported to Ann Arbor project manager as they are discovered, and will be reported to the Central IRB in summary at the time of continuing review/project closure. Protocol deviations/violations that are likely to substantially adversely affect 1) the rights, safety, or welfare of a participant; 2) a participant's willingness to continue participation; or 3) the integrity of the research data, including VA information security requirements will all be reported within 5 working days of being made aware of the occurrence. Dr. Saint will be involved with all decisions related to the health and safety of subjects for this project. We will also submit annual progress reports to the HSR&D Data Safety and Monitoring Board.

7.0 Privacy and Confidentiality

- Will you be accessing REAL SSNs? **NO**

The study will not use or disclose any protected health information (PHI). To protect subjects' confidentiality, all study materials will be labeled using unique study ID codes only. For example, participant names or other individual names will not appear in any of the surveys or interview transcripts. If such information is volunteered (despite instructions) in a taped session or in a survey, it will be removed by the transcriptionist and/or other research staff. Files that link the interviewee with a study ID will be securely stored in a restricted access folder on a secure VA CCMR server. The original audio recordings and study transcripts will also be electronically stored in restricted access folders on secure servers that can only be accessed by specified study personnel. At the end of the study, the linking information will be removed from the transcripts to protect confidentiality. Any notes taken during the interviews and/or guided sessions will be typed up and stored on the secure CCMR Server in the study folder. Hard copies of the notes will be stored in locked filing cabinets in the CCMR Suite on the 3rd Floor of Building 16 at the North Campus Research Complex. Once the handwritten notes are typed up and checked for accuracy, the hard copies will be destroyed using the VA shredding service. For all study data, we will follow approved VA guidelines, Records Control Schedule RCS 10-1, for the disposition of records following closure of the study.

8.0 Communication Plan

Communication will occur through regular study team meetings. These monthly meetings will include discussion of the events since the prior meeting, and specifically if any problems/events have occurred. The PIs and the study team will work to address any problems/events to reduce the likelihood of occurrence in the future, to keep the risk to subjects as low as possible, and to maximize the potential study benefits. These team meetings will also be utilized to ensure that all relevant IRB policies and study procedures are being followed. These include: (1) all participants understand, agree to and provide informed consent (written or verbal as approved by the IRB) before participating; (2) strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; (3) all data collection is completely confidential; (4) consent forms and identifying information are kept separate from the actual participant data; (6) all identifying information is kept locked at all times and sensitive computer files are maintained on a secured VA server; and (7) participants are informed in writing how to contact the site PD/PI, the study coordinator, and IRB office with any questions and/or concerns. Additional communication about the project will be conducted over email. Dr. Greene, Dr. Trautner, and the project manager will remain in close contact regarding all multi-site study activities including recruitment procedures, recruitment status, intervention implementation, data collection and subject follow-up.

9.0 References

1. Ellingson K, Haas JP, Aiello AE, et al. Strategies to prevent healthcare-associated infections through hand hygiene. Infect Control Hosp Epidemiol 2014;35 Suppl 2:S155-78.
2. Kirkland KB, Homa KA, Lasky RA, et al. Impact of a hospital-wide hand hygiene initiative on healthcare-associated infections: results of an interrupted time series. BMJ Qual Saf 2012;21:1019-26.
3. Mathai E, Allegranzi B, Kilpatrick C, et al. Prevention and control of health care-associated infections through improved hand hygiene. Indian J Med Microbiol 2010;28:100-6.
4. Allegranzi B, Pittet D. Role of hand hygiene in healthcare-associated infection prevention. J Hosp Infect 2009;73:305-15.
5. Boyce JM, Pittet D, Healthcare Infection Control Practices Advisory Committee, et al. Guideline for hand hygiene in health-care settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HIPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Am J Infect Control 2002;30:S1-46.
6. World Health Organization. WHO guidelines on hand hygiene in health care: First global patient safety challenge clean care is safer care. Geneva, Switzerland; 2009. Available from: https://www.who.int/infection-prevention/publications/hand-hygiene-2009/en/. Accessed 28 February 2020.
7. Erasmus V, Daha TJ, Brug H, et al. Systematic review of studies on compliance with hand hygiene guidelines in hospital care. Infect Control Hosp Epidemiol 2010;31:283-94.
8. Pittet D, Simon A, Hugonnet S, et al. Hand hygiene among physicians: performance, beliefs, and perceptions. Ann Intern Med 2004;141:1-8.
9. Whitby M, McLaws ML, Ross MW. Why healthcare workers don't wash their hands: a behavioral explanation. Infect Control Hosp Epidemiol 2006;27:484-92.
10. Sax H, Uckay I, Richet H, et al. Determinants of good adherence to hand hygiene among healthcare workers who have extensive exposure to hand hygiene campaigns. Infect Control Hosp Epidemiol 2007;28:1267-74.
11. Gould DJ, Moralejo D, Drey N, et al. Interventions to improve hand hygiene compliance in patient care. Cochrane Database Syst Rev 2017;9:CD005186.
12. Shanafelt TD, Hasan O, Dyrbye LN, et al. Changes in burnout and satisfaction with work-life balance in physicians and the general US working population between 2011 and 2014. Mayo Clin Proc 2015;90:1600-13.
13. Dyrbye LN, West CP, Satele D, et al. Burnout among U.S. medical students, residents, and early career physicians relative to the general U.S. population. Acad Med 2014;89:443-51.
14. Panagioti M, Geraghty K, Johnson J, et al. Association between physician burnout and patient safety, professionalism, and patient satisfaction: A systematic review and meta-analysis. JAMA Intern Med 2018;178:1317-31.
15. Salyers MP, Bonfils KA, Luther L, et al. The relationship between professional burnout and quality and safety in healthcare: A meta-analysis. J Gen Intern Med 2017;32:475-82.

16. Dewa CS, Loong D, Bonato S, et al. The relationship between resident burnout and safety-related and acceptability-related quality of healthcare: a systematic literature review. BMC Med Educ 2017;17:195.
17. Dewa CS, Loong D, Bonato S, et al. The relationship between physician burnout and quality of healthcare in terms of safety and acceptability: a systematic review. BMJ Open 2017;7:e015141.
18. Hall LH, Johnson J, Watt I, et al. Healthcare staff wellbeing, burnout, and patient safety: A systematic review. PLoS One 2016;11:e0159015.
19. Dewa CS, Loong D, Bonato S, et al. How does burnout affect physician productivity? A systematic literature review. BMC Health Serv Res 2014;14:325.
20. Van Bogaert P, Timmermans O, Weeks SM, et al. Nursing unit teams matter: Impact of unit-level nurse practice environment, nurse work characteristics, and burnout on nurse reported job outcomes, and quality of care, and patient adverse events--a cross-sectional survey. Int J Nurs Stud 2014;51:1123-34.
21. Poghosyan L, Clarke SP, Finlayson M, et al. Nurse burnout and quality of care: cross-national investigation in six countries. Res Nurs Health 2010;33:288-98.
22. Halbesleben JR, Wakefield BJ, Wakefield DS, et al. Nurse burnout and patient safety outcomes: nurse safety perception versus reporting behavior. West J Nurs Res 2008;30:560-77.
23. Cimiotti JP, Aiken LH, Sloane DM, et al. Nurse staffing, burnout, and health care-associated infection. Am J Infect Control 2012;40:486-90.
24. Manomenidis G, Panagopoulou E, Montgomery A. Job Burnout Reduces Hand Hygiene Compliance Among Nursing Staff. J Patient Saf 2019;15:e70-e3.
25. Saposnik G, Redelmeier D, Ruff CC, et al. Cognitive biases associated with medical decisions: a systematic review. BMC Med Inform Decis Mak 2016;16:138.
26. Yu R. Stress potentiates decision biases: A stress induced deliberation-to-intuition (SIDI) model. Neurobiol Stress 2016;3:83-95.
27. Starcke K, Brand M. Decision making under stress: a selective review. Neurosci Biobehav Rev 2012;36:1228-48.
28. Morewedge CK, Kahneman D. Associative processes in intuitive judgment. Trends Cogn Sci 2010;14:435-40.
29. Kahneman D. Thinking, Fast and Slow. New York, NY: Farrar, Straus and Giroux; 2013.
30. Croskerry P. From mindless to mindful practice--cognitive bias and clinical decision making. N Engl J Med 2013;368:2445-8.
31. Norman G, Sherbino J, Dore K, et al. The etiology of diagnostic errors: a controlled trial of system 1 versus system 2 reasoning. Acad Med 2014;89:277-84.
32. Keinan G. Decision making under stress: scanning of alternatives under controllable and uncontrollable threats. J Pers Soc Psychol 1987;52:639-44.
33. Evans JS, Stanovich KE. Dual-process theories of higher cognition: advancing the debate. Perspect Psychol Sci 2013;8:223-41.
34. Brewer J. The Craving Mind: From Cigarettes to Smartphones to Love - Why We Get Hooked and How We Can Break Bad Habits. New Haven, CT: Yale University Press; 2017.

35. Chambers R, Lo BCY, Allen NB. The impact of intensive mindfulness training on attentional control, cognitive style, and affect. Cogn Ther Res 2008;32:303-22.
36. Ostafin BD, Kassman KT. Stepping out of history: mindfulness improves insight problem solving. Conscious Cogn 2012;21:1031-6.
37. Ruedy NE, Schweitzer ME. In the moment: The effect of mindfulness on ethical decision making. J Bus Ethics 2010;95:73-87.
38. Noone C, Bunting B, Hogan MJ. Does mindfulness enhance critical thinking? Evidence for the mediating effects of executive functioning in the relationship between mindfulness and critical thinking. Front Psychol 2015;6:2043.
39. Burgess DJ, Beach MC, Saha S. Mindfulness practice: A promising approach to reducing the effects of clinician implicit bias on patients. Patient Educ Couns 2017;100:372-6.
40. Sibinga EM, Wu AW. Clinician mindfulness and patient safety. JAMA 2010;304:2532-3.
41. Kiken LG, Shook NJ. Mindfulness increases positive judgements and reduces negativity bias. Soc Psychol Personal Sci 2011;2:425-31.
42. Hafenbrack AC, Kinias Z, Barsade SG. Debiasing the mind through meditation: mindfulness and the sunk-cost bias. Psychol Sci 2014;25:369-76.
43. Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. J Pers Soc Psychol 2003;84:822-48.
44. Gilmartin H, Goyal A, Hamati MC, et al. Brief Mindfulness Practices for Healthcare Providers - A Systematic Literature Review. Am J Med 2017;130:1219 e1- e17.
45. Goodman MJ, Schorling JB. A mindfulness course decreases burnout and improves well-being among healthcare providers. Int J Psychiatry Med 2012;43:119-28.
46. Montanari KM, Bowe CL, Chesak SS, et al. Mindfulness: assessing the feasibility of a pilot intervention to reduce stress and burnout. J Holist Nurs 2019;37:175-88.
47. Botha E, Gwin T, Purpora C. The effectiveness of mindfulness based programs in reducing stress experienced by nurses in adult hospital settings: a systematic review of quantitative evidence protocol. JBI Database System Rev Implement Rep 2015;13:21-9.
48. Verweij H, van Ravesteijn H, van Hooff MLM, et al. Mindfulness-based stress reduction for residents: A randomized controlled trial. J Gen Intern Med 2018;33:429-36.
49. Lebares CC, Hershberger AO, Guvva EV, et al. Feasibility of formal mindfulness-based stress-resilience training among surgery interns: A randomized clinical trial. JAMA Surg 2018;153:e182734.
50. van Dijk I, Lucassen P, Akkermans RP, et al. Effects of mindfulness-based stress reduction on the mental health of clinical clerkship students: A cluster-randomized controlled trial. Acad Med 2017;92:1012-21.
51. Lamothe M, Rondeau E, Malboeuf-Hurtubise C, et al. Outcomes of MBSR or MBSR-based interventions in health care providers: A systematic review with a focus on empathy and emotional competencies. Complement Ther Med 2016;24:19-28.

52. Phang CK, Mukhtar F, Ibrahim N, et al. Effects of a brief mindfulness-based intervention program for stress management among medical students: the Mindful-Gym randomized controlled study. Adv Health Sci Educ Theory Pract 2015;20:1115-34.
53. West CP, Dyrbye LN, Erwin PJ, et al. Interventions to prevent and reduce physician burnout: a systematic review and meta-analysis. Lancet 2016;388:2272-81.
54. Melnyk BM, Kelly SA, Stephens J, et al. Interventions to Improve Mental Health, Well-Being, Physical Health, and Lifestyle Behaviors in Physicians and Nurses: A Systematic Review. Am J Health Promot 2020;34:929-41.
55. Petrilli CM, Mantengoli E, Saint S, et al. The effect of merging two infectious diseases units on hand hygiene in Italy. J Infect Prev 2017;18:144-7.
56. Sakihama T, Honda H, Saint S, et al. Hand hygiene adherence among health care workers at Japanese hospitals: A multicenter observational study in Japan. J Patient Saf 2016;12:11-7.
57. Sakihama T, Honda H, Saint S, et al. Improving healthcare worker hand hygiene adherence before patient contact: A multimodal intervention of hand hygiene practice in Three Japanese tertiary care centers. J Hosp Med 2016;11:199-205.
58. Lieber SR, Mantengoli E, Saint S, et al. The effect of leadership on hand hygiene: assessing hand hygiene adherence prior to patient contact in 2 infectious disease units in Tuscany. Infect Control Hosp Epidemiol 2014;35:313-6.
59. di Martino P, Ban KM, Bartoloni A, et al. Assessing the sustainability of hand hygiene adherence prior to patient contact in the emergency department: A 1-year postintervention evaluation. Am J Infect Control 2011;39:14-8.
60. Saint S, Bartoloni A, Virgili G, et al. Marked variability in adherence to hand hygiene: a 5-unit observational study in Tuscany. Am J Infect Control 2009;37:306-10.
61. Mody L, Saint S, Kaufman SR, et al. Adoption of alcohol-based handrub by United States hospitals: a national survey. Infect Control Hosp Epidemiol 2008;29:1177-80.
62. Jayewardene WP, Lohrmann DK, Erbe RG, et al. Effects of preventive online mindfulness interventions on stress and mindfulness: A meta-analysis of randomized controlled trials. Prev Med Rep 2017;5:150-9.
63. Romcevich LE, Reed S, Flowers SR, et al. Mind-body skills training for resident wellness: A pilot study of a brief mindfulness intervention. J Med Educ Curric Dev 2018;5:2382120518773061.
64. Kemper KJ, Yun J. Group online mindfulness training: proof of concept. J Evid Based Complementary Altern Med 2015;20:73-5.
65. Kemper KJ. Brief online mindfulness training: immediate impact. J Evid Based Complementary Altern Med 2017;22:75-80.
66. Kemper KJ, Rao N, Gascon G, et al. Online Training in Mind-Body Therapies: Different Doses, Long-term Outcomes. J Evid Based Complementary Altern Med 2017;22:696-702.

67. Brooks E, Early SR, Gendel MH, et al. Helping the healer: population-informed workplace wellness recommendations for physician well-being. Occup Med (Lond) 2018;68:279-81.
68. Lai J, Ma S, Wang Y, et al. Factors associated with mental health outcomes among health care workers exposed to Coronavirus Disease 2019. JAMA Network Open 2020;3:e203976.
69. Bohlken J, Schomig F, Lemke MR, et al. [COVID-19 Pandemic: Stress Experience of Healthcare Workers - A Short Current Review]. Psychiatr Prax 2020;47:190-7.
70. Dewey C, Hingle S, Goelz E, et al. Supporting clinicians during the COVID-19 pandemic. Ann Intern Med 2020;172:752-3.
71. Ayanian JZ. Mental health needs of health care workers providing frontline COVID-19 care. In: JAMA Health Forum; 2020.
72. Gilmartin H, Saint S, Rogers M, et al. Pilot randomised controlled trial to improve hand hygiene through mindful moments. BMJ Qual Saf 2018;27:799-806.
73. Gilmartin HM. Use hand cleaning to prompt mindfulness in clinic. BMJ 2016;352:i13.
74. Chang NC, Reisinger HS, Jesson AR, et al. Feasibility of monitoring compliance to the My 5 Moments and Entry/Exit hand hygiene methods in US hospitals. Am J Infect Control 2016;44:938-40.
75. Baer RA, Smith GT, Hopkins J, et al. Using self-report assessment methods to explore facets of mindfulness. Assessment 2006;13:27-45.
76. Dyrbye LN, Sotile W, Boone S, et al. A survey of U.S. physicians and their partners regarding the impact of work-home conflict. J Gen Intern Med 2014;29:155-61.
77. Dyrbye LN, Satele D, Sloan J, et al. Ability of the physician well-being index to identify residents in distress. J Grad Med Educ 2014;6:78-84.
78. Dyrbye LN, Johnson PO, Johnson LM, et al. Efficacy of the Well-Being Index to Identify Distress and Well-Being in U.S. Nurses. Nurs Res 2018;67:447-55.
79. Perception Survey for Health Care Workers. World Health Organization,, 2009; Available from: https://www.who.int/gpsc/5may/Perception_Survey_for_Health_care_Workers.doc?ua=1. Accessed October 20, 2020.
80. Mind-Body Skills Training for Resilience, Effectiveness, and Mindfulness (STREAM). The Ohio State University College of Medicine, 2016; Available from: https://mind-bodyhealth.osu.edu/. Accessed May 20, 2020.
81. Wu KS, Lee SS, Chen JK, et al. Identifying heterogeneity in the Hawthorne effect on hand hygiene observation: a cohort study of overtly and covertly observed results. BMC Infect Dis 2018;18:369.
82. Shim JY, Park S, Kim GE, et al. Does physician leadership influence followers' hand hygiene compliance? Open Forum Infect Dis 2019;6:ofz236.
83. Kitsanapun A, Yamarat K. Evaluating the effectiveness of the "Germ-Free Hands" intervention for improving the hand hygiene practices of public health students. J Multidiscip Healthc 2019;12:533-41.
84. Benzo RP, Anderson PM, Bronars C, et al. Mindfulness for healthcare providers: The role of non-reactivity in reducing stress. Explore (NY) 2018;14:453-6.

85. Lomas T, Medina JC, Ivtzan I, et al. A systematic review and meta-analysis of the impact of mindfulness-based interventions on teh well-being of healthcare professionals. Mindfulness 2019;10:1193-216.
86. Kiyoshi-Teo H, Krein SL, Saint S. Applying mindful evidence-based practice at the bedside: using catheter-associated urinary tract infection as a model. Infect Control Hosp Epidemiol 2013;34:1099-101.
87. Forman J, Damschroder L. Qualitative Content Analysis. In: Jacoby L, Siminoff L, eds. Empirical Methods for Bioethics: A Primer (Advances in Bioethics, Vol 11). Bingley: Emerald Group Publishing Limited; 2007:39-62.