

An alternative to the 'light touch' digital health remote study: The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study

Sarah Margaret Goodday, Emma Karlin, Alexandria Alfarano, Alexa Brooks, Carol Chapman, Rachelle Desille, Daniel R. Karlin, Hoora Emami, Nancy Woods, Adrien Boch, Luca Foschini, Mackenzie Wildman, Francesca Cormack, Nick Taptiklis, Abhishek Pratap, Marzyeh Ghassemi, Anna Goldenberg, Sujay Nagaraj, Elaine Walsh, Stress And Recovery Participants*, Stephen Friend

Submitted to: JMIR Formative Research
on: July 19, 2021

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript.....	5
---------------------------------	----------

Preprint
JMIR Publications

An alternative to the ‘light touch’ digital health remote study: The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study

Sarah Margaret Goodday^{1,2}; Emma Karlin¹; Alexandria Alfarano³; Alexa Brooks¹; Carol Chapman¹; Rachelle Desille¹; Daniel R. Karlin^{1,4,5}; Hooria Emami⁶; Nancy Woods⁷; Adrien Boch⁸; Luca Foschini⁸; Mackenzie Wildman⁸; Francesca Cormack^{9,10}; Nick Taptiklis⁹; Abhishek Pratap¹¹; Marzyeh Ghassemi^{12,13,14}; Anna Goldenberg^{12,15}; Sujay Nagaraj^{12,15}; Elaine Walsh⁷; Stress And Recovery Participants^{*1}; Stephen Friend^{1,2}

¹YouandMe Seattle US

²University of Oxford Oxford GB

³Nationwide Children's Hospital Columbus US

⁴Tufts University School of Medicine Boston US

⁵MindMed New York US

⁶Dalla Lana School of Public Health, University of Toronto Toronto CA

⁷School of Nursing, University of Washington Seattle US

⁸Evidation Health Inc. San Mateo US

⁹Cambridge Cognition Cambridge GB

¹⁰Department of Psychiatry, University of Cambridge Cambridge GB

¹¹Center for Addiction and Mental Health Toronto CA

¹²Vector Institute Toronto CA

¹³Institute for Medical Engineering and Science, MIT Cambridge US

¹⁴Department of Electrical Engineering and Computer Science, MIT Cambridge US

¹⁵The Hospital for Sick Children Toronto CA

Corresponding Author:

Sarah Margaret Goodday

4YouandMe

2901 Third Ave Suite 330

Seattle

US

Abstract

Background: Several app-based studies share similar characteristics of a ‘light touch’ approach that recruit, enroll, and onboard via a smartphone app and attempt to minimize burden through low-friction active study tasks, while emphasizing the collection of passive data with minimal human contact. However, engagement is a common challenge across these studies reporting low retention and adherence.

Objective: To describe an alternative to a ‘light touch’ digital health study that involved a participant centric design including high friction app-based assessments, semi-continuous passive data from wearable sensors and a digital engagement strategy centered on providing knowledge and support to participants.

Methods: The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study included US frontline healthcare workers followed between May-November 2020. The study comprised 3 main components: 1) active and passive assessments of stress and symptoms from a smartphone app; 2) objective measured assessments of acute stress from wearable sensors; and 3) a participant co-driven engagement strategy that centered on providing knowledge and support to participants. The daily participant time commitment was an average of 10-15 minutes. Retention and adherence are described both quantitatively and qualitatively.

Results: 365 participants enrolled and started the study and 81.0% (297/365) of them completed the study for a total study duration of 4 months. Average wearable sensor usage was 90.6% days of total study duration. App-based daily, weekly, and every other week surveys were completed on average 69.18%, 68.37%, 72.86% of the time, respectively.

Conclusions: This study found evidence for feasibility and acceptability of a participant centric digital health study approach that involved building trust and respect with participants and providing support through regular phone check-ins. In addition to

high retention and adherence, the collection of large volumes of objective measured data alongside contextual self-reported subjective data was able to be collected that is often missing from 'light touch' digital health studies. Clinical Trial: Clinicaltrials.Gov (NCT04713111)

(JMIR Preprints 19/07/2021:32165)

DOI: <https://doi.org/10.2196/preprints.32165>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http://www.jmir.org/2021/07/e32165/"

Original Manuscript

An alternative to the 'light touch' digital health remote study: The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study

Goodday S.M.^{*1,2}, Karlin E¹, Alfarano A³, Brooks A¹, Chapman C¹, Desille R¹, Karlin D.R.^{1,4,5}, Emami H⁶, Woods N⁷, Boch A⁸, Foschini L⁸, Wildman M⁸, Cormack F^{9,10}, Taptiklis N⁹, Patrap A¹¹, Ghassemi M¹²⁻¹⁴, Goldenberg A^{12,15,16}, Nagaraj S^{12,15,16}, Walsh E⁷, *Stress and Recovery Participants, Friend S^{1,2}

¹4YouandMe, Seattle, WA, USA

²Department of Psychiatry, University of Oxford, Oxford, UK

²Nationwide Children's Hospital, Ohio, USA

⁴MindMed, Inc. New York, NY

⁵Tufts University School of Medicine, Boston, MA

⁶Dalla Lana School of Public Health, University of Toronto, Toronto, Canada

⁷School of Nursing, University of Washington

⁸Evidation Health Inc., San Mateo, CA, USA

⁹Cambridge Cognition, Cambridge, GB

¹⁰Department of Psychiatry, University of Cambridge, Cambridge, GB

¹¹The Center for Addiction and Mental Health, Toronto, Canada

¹²Vector Institute, CIFAR AI Chair, Toronto, Canada

¹³Institute for Medical Engineering and Science, MIT, Cambridge, MA, USA

¹⁴Department of Electrical Engineering and Computer Science, MIT, Cambridge, MA, USA

¹⁵The Hospital for Sick Children, Toronto, Canada

¹⁶Department of Computer Science, University of Toronto, Toronto, Canada

*Corresponding author: Sarah M. Goodday, PhD

sarah@4youandme.org

4YouandMe

Seattle, WA, USA

Acknowledgements

*Natasha Johnson, Claire Buss, Nadiyah Gary, Toni Gregory, Selena Schmit, Tricia Thomas, Aleisha Lutzen, Brooke Gambino, Klara Oh, Andrea Mizumoto, Jennifer Rand, Rebekah Kreger, Lisa Knudtson, Sarah Landon, Kimberly Ness, Margaret Fitzgibbons, Dee Ann Wolf, MaryAnn G Deiparine, Megan Page, Jeffrey T Richards, Peter McGerty, Lizbeth Rainaud, Bonnie Goff, Brittney Dahlen, Kimberly Fougere, Monica Hoefsmit, Teri Willis, Orange-Marie Miller, Katherine A Linder, Susan Miller, Alexandra L Williams, Natasha Gross, Mindy Churchwell, Whisty Taylor, Lauryn Haigh, Kimberly Whalen, Breanna Stricklin, Kristine Gerold

We would like to thank all Stress and Recovery participants for their dedication and contributions to this work, and their efforts on the frontlines during the COVID-19 pandemic.

Abstract

Background: Several app-based studies share similar characteristics of a 'light touch' approach that recruit, enrol, and onboard via a smartphone app and attempt to minimize burden through low-

friction active study tasks, while emphasizing the collection of passive data with minimal human contact. However, engagement is a common challenge across these studies reporting low retention and adherence.

Objective: To describe an alternative to a 'light touch' digital health study that involved a participant centric design including high friction app-based assessments, semi-continuous passive data from wearable sensors and a digital engagement strategy centered on providing knowledge and support to participants.

Methods: The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study included US frontline healthcare workers followed between May-November 2020. The study comprised 3 main components: 1) active and passive assessments of stress and symptoms from a smartphone app; 2) objective measured assessments of acute stress from wearable sensors; and 3) a participant co-driven engagement strategy that centered on providing knowledge and support to participants. The daily participant time commitment was an average of 10-15 minutes. Retention and adherence are described both quantitatively and qualitatively.

Results: 365 participants enrolled and started the study and 81.0% (297/365) of them completed the study for a total study duration of 4 months. Average wearable sensor usage was 90.6% days of total study duration. App-based daily, weekly, and every other week surveys were completed on average 69.18%, 68.37%, 72.86% of the time, respectively.

Conclusions: This study found evidence for feasibility and acceptability of a participant centric digital health study approach that involved building trust and respect with participants and providing support through regular phone check-ins. In addition to high retention and adherence, the collection of large volumes of objective measured data alongside contextual self-reported subjective data was able to be collected that is often missing from 'light touch' digital health studies.

Key words: stress; wearables; digital health; frontline; COVID-19

Word count: 5775

Introduction

The ubiquity of smartphones and the growing availability of wearable sensors has enabled a new era of digital health research. The increasing importance of this new form of remote health research has never been more apparent with an increasingly globalized world, and in light of the COVID-19

pandemic, which posed unprecedented challenges for the conduct of 'traditional research' involving face-to-face contact. The benefits of remote digital health research are manifold involving access to large sample sizes, cost efficiency, eliminating the necessity for travel, ease associated with passive collection of data, and most importantly the opportunities created to collect rich multimodal data involving self-reported subjective and objective measured indicators of disease at semi-continuous or high frequencies in real world settings, unbound to healthcare or research visits. Further, with the ability to enrol participants full remotely via eConsent frameworks¹ and reach by social media channels, recruitment, consent, and onboarding can be conducted entirely outside of the clinic or site through the convenience of smartphones, which in theory negates or reduces the need to assign study staff to this costly and time-consuming study task. Yet, maintaining participant engagement throughout a longitudinal study has proven a challenge²⁻⁴. The rapport built and 'safety net' provided by the in-person visit represent a difficult gap to fill, particularly with additional remote technology usability challenges.

Several large app-based studies are described in the literature⁵⁻⁷ and share similar characteristics of a 'light touch' approach that recruit, enrol, and onboard via a smartphone app and attempt to minimize burden through low-friction active study tasks, while emphasizing the collection of passive data. These studies have demonstrated the feasibility of remote recruitment across different patient and control populations. Furthermore, there is strikingly low retention and adherence rates in app-based remote studies - over half of participants tend to drop out after the first week of participation, while attrition and adherence differs significantly by important socio-demographic factors⁴. In addition to problems with engagement, there are common selection biases across studies tending to enrol white, university/college educated participants with higher rates of women⁴ reflecting non-generalizable samples. Further, patients more likely to use digital health trackers are more adherent to chronic disease medication use suggesting those unlikely to engage in some digital tools may reflect less healthy populations⁸. Predictors of low digital engagement include: lack of usability and accessibility of the digital tools, participant privacy and security concerns, perceived utility and motivation, and lack of support^{2,3,9}. While the 'light touch' approach minimizes human contact with participants through fully-remote enrolment and follow-up via an app, the lack of "human-in-the-loop" and clear value proposition for participants may inadvertently lower their engagement. Digital health cohorts being recruited via a clinic referral compared to recruitment conducted entirely through an app show higher rates of retention and adherence⁴. The 'light touch' approach also minimizes the collection of self-reported subjective data to reduce participant burden and in turn attrition that is crucial to validate objective measured information, particularly given that the field is in early phase with the need to validate objective measured sensor readouts.

The use of participant incentives and rewards still prevail as one of the most used components for a successful engagement strategy. The use of smartphones makes personalized rewards and reminders possible¹⁰. Leveraging behavioral psychology informed strategies for reward scheduling, smartphones can incentivize adherence through rewards for study task completion. Participant tailored push notifications for task reminders can be implemented and have been noted as preferred by participants in digital health research¹¹. Beyond monetary incentives and personalized reminders, treating participants differently than the traditional blinded 'subject', including them as co-drivers in the research process, could prove a powerful way to engage, retain and accelerate learning for long-term engagement. The shift to participatory research that tends to involve patient advisory groups who provide input on study design documents such as consent forms¹² and study protocols is already being conducted. However, in the context of digital health, and in the use of digital technologies, these participatory models tend to only include users after the relevant technology has been developed. These approaches can be extended further, described by some as "user centered designs" where participants and patients might be included from the very early design to implementation phases and might help shape how the technology is used¹³. As a participant centered initiative,^{14,15} in which participants can be included as equal partners in the entire research process in testing the feasibility of digital technologies for health and wellness, this form of participant co-driven research has never been more needed. Two recent app-based studies¹¹ involving a patient- and citi-

zen-centric design, achieved substantially increased retention and adherence when compared to that typically reported in such studies, which demonstrates the promise of these more patient centered approaches.

Here we describe an example of an alternative to the 'light touch' digital health study that involves active app and wearable based assessments coupled with an extensive digital engagement strategy that centered on interacting with participants as equal partners in the research process. Our objective was to demonstrate that participant centric engagement approaches aimed at providing reciprocal loops of knowledge and support between researchers and participants might enable a digital health study with improved participant experience, likelihood to retain in the study, adherence to protocols, and perhaps most importantly, respect the participants commitment of time and effort by increasing the value of the captured data.

The Stress and Recovery in Frontline COVID-19 Healthcare Workers Study

The COVID-19 pandemic has caused unprecedented stress on healthcare systems in affected countries, and in particular, on the healthcare workers working directly with COVID-19 patients. With higher risks of COVID-19 exposure, this population provides a unique example to understand how stress might impact susceptibility to infection, given evidence suggesting the damaging impact of stress on our immune system¹⁶. Yet, the accurate measurement of immediate stress responses in real time and in naturalistic settings has so far been a challenge, limiting our understanding of how different facets of acute or sustained stress increases susceptibility. Wearable technologies are showing promise for detecting shifts in the health status of individuals across multiple settings and in the detection of a wide range of multimodal measures of acute (immediate) and intermediate effects of stress¹⁷.

The COVID-19 pandemic reflected a unique natural experimental condition where frontline workers were exposed to substantial stress beyond that already present in their pre-COVID day to day work environment. Their on-shift time provided a naturally occurring "stress on" period, while their off-shift time provided a "stress off" period and an opportunity to follow an individual's recovery from stress. The aims of the Stress and Recovery study were to:

- 1) Assess the feasibility of a digital approach to collect both participant-reported subjective and objective measured longitudinal high-resolution data on immediate stress responses, intermediate signs of stress, recovery from stress, and COVID-19 infectivity by engaging frontline healthcare workers in the use of digital sensors; and
- 1) Determine the feasibility of detecting and tracking changes in immediate and intermediate stress and recovery from stress off shift in frontline healthcare workers working with patients in the COVID-19 pandemic environment.

Methods/Design

Overview

This study involved engaging US frontline healthcare workers from a variety of locations who were either working directly with COVID-19 patients, or whose work routines were shifted as a result of the COVID-19 pandemic. This study employed a participant centric design (Figure 1) that comprised three primary components and a follow-up period of 4-6 months: 1) patient reported active and passive assessments of stress and symptoms from a smartphone app; 2) objective measured assessments of acute stress from wearable sensors; and 3) a participant co-driven engagement strategy

that centered on providing knowledge and support involving regular check-in phone calls with study staff, using participant feedback in real time to improve and fine-tune the research protocol to improve participant experience, and the addition of new study sub-arms. A virtual event was held, where researchers and participants who wished to join were able to engage in an online group setting (anonymously) half-way through enrolment. This study was approved by the Institutional Review Board, Advarra (4UCOVID1901, Pro00043205) and was registered with Clinicaltrials.Gov (NCT04713111).

Recruitment and Onboarding

Frontline healthcare workers were recruited from May to August, 2020. A multi-pronged recruitment approach was developed that involved: 1) engaging trusted leaders from organizations and sites with high outreach to our target population (e.g., American Association of Critical Care Nurses); 2) engaging supervisors at selected healthcare institutions; and 3) a social media campaign (e.g., Facebook, Twitter, LinkedIn). Tailored workplace-specific recruitment materials were developed, and during the enrolment period assessed in real time how participants were learning about the existence of the study to understand the most effective recruitment strategies. Recruitment materials were distributed through workplace specific newsletters, websites, and through our social media channels.

Population

Frontline healthcare workers were invited to participate including Medical Doctors, Doctors of Osteopathy, Physician Assistants, Registered Nurses, Advanced Practice Registered Nurses, and other allied healthcare workers. Inclusion criteria were: 1) must be working directly with COVID-19 patients, slated to do so within the next two weeks or work routines have been moderately or extremely impacted by the COVID-19 pandemic; 3) Age over 18 years; 4) Able to speak, write and read English; 5) Able to provide informed consent; 6) no known SARS-CoV-2 current or past infection; and 7) must own a personal iOS mobile phone (OS11 and above) with willingness to download and use the study applications and sync phone with all study sensors.

App-based Data Assessments

Active study data were collected and managed in a REDCap (Research Electronic Data Capture^{18, 19}) database, hosted and managed by the Center for International Emergency Medical Services (CIEMS²⁰). REDCap is a secure, web-based software platform designed to support data capture for research studies. The MyCap app interface leverages REDCap and was used to produce a study app for the collection of participant-reported active data. Participants were instructed to download the MyCap app from the app store and register with the MyCap app through a unique QR code provided to them by study staff.

Via the study app, participants were prompted to complete daily, weekly, every two week, monthly, and one time measures that involved socio-demographic factors, self-reported measures of daily perceived stress, intermediate signs of stress (sleep, mood and cognition), additional health-related symptoms, influenza-like illness, individual characteristics, and cognitive active tasks (see Supplemental (Supp) Table 1). For the first half of the study ResearchKit's active tasks²¹ (Trail Making, Reaction Time, and Spatial Span Memory) were used every day, rotating the tasks each day. For the second half of the study these were replaced with Cambridge Cognition's active tasks^{22, 23} (Emo-

tional Bias test, Psychomotor Vigilance, and *n*-back test) rotating every other day. The study intended to include the Cambridge Cognition active tasks from the outset, however; their implementation was delayed while establishing the technical integration with the MyCap application.

The study sample was initially limited to iOS users because of anticipated non-functionality with the ResearchKit apps but intended to include Android users when shifting to the Cambridge Cognition tasks. However, upon pilot testing the REDCap app with the first set of enrolled Android users, it was found that the app itself had compatibility issues. Therefore, a subset of 12 Android users enrolled in the study who did not participate in the app-based assessments.

The daily burden for completing app-based assessments was estimated at an average of five minutes per day (minimum daily burden=3.5 minutes, maximum daily burden=8.5 minutes), with some daily tasks taking longer and other days shorter, which depended on the cadence of the one-time, weekly, every two week, or monthly measures. This estimate was calculated from the expected task length, not from timed participant data. A schedule was produced that spread out the one-time measures on different days within the first month, while weekly, and every two-week tasks were scheduled on different days to balance the daily burden.

Participants were given the option to download two third-party applications as part of their participation: HealthMode Cough app and RescueTime. The cough app was used to capture momentary cough during study follow-up and RescueTime as a measure of screen time (e.g., time spent in, and category of apps) as a proxy for objective stress and mood.

Wearable Assessments

Participants were mailed an Oura smart ring. The Oura Ring 2²⁴ is made of a light, durable titanium shell and includes a temperature sensor, a gyroscope, a 3D accelerometer and an infrared optical pulse sensor. There was a one-time set-up process where the participant synced their ring to the Oura smartphone app that they were instructed to download. Throughout the study, the participant was instructed to open the Oura smartphone app to sync data off the ring over Bluetooth. The sensor collects a variety of nighttime data streams such as heart rate, heart rate variability and objective sleep quality measures (Supp. Table 1). Participants were provided with their own symptom summaries via the Oura app. Participants were instructed to wear the ring only while off shift owing to potential infectivity risks generally associated with ring wearing while at work in healthcare settings, which was especially relevant as participants were actively working with patients. This did not meaningfully hamper relevant data collection because we were most interested in measuring parameters associated with recovery from stress while participants were off shift. It was expected that the daily burden associated with using sensors, remembering to charge them, and working through sensor issues to be approximately 2-4 minutes per day.

Engagement

The study engagement strategy centered on providing information and support to participants while engaging them as co-drivers of the research. This strategy had two aims: 1) to engage participants in the use of the study digital devices for optimal adherence and 2) to engage participants in the design of the study. Information was provided to participants through enabling insights into measurements of health through the study sensor apps and discussing this with participants in terms of how to interpret this information, and also what could be learned from it. Support was provided in a variety of channels through the bi-weekly check-ins, listening to participant feedback and making real-time protocol changes, and providing a variety of tools or resources in an attempt to give back (on-

line resources for stress management) and stress reducing tools. For example, participants were offered a YELL-IT tool where they could call a number and leave an anonymous voice message of their choice that could include any release that might offer benefit (ranting, yelling, journaling, etc). The records of these phone calls were immediately programmatically deleted, and the voice messages themselves were not recorded.

Check-in calls: Engagement Specialists on the research staff contacted study participants every week for the first month of study participation, and every two weeks thereafter until study completion. Engagement Specialists had clinical research backgrounds and experience with working with participants. These calls served three purposes: 1) to support participants in their study participation, troubleshoot technical problems, and build rapport; 2) to discuss, understand, and collect information on study experience; and 3) to discuss, understand and collect information on study exposure and outcome information, which in this context, was the experience of stress from working on the frontline in the COVID-19 pandemic environment. The check-in calls served as a venue to gather deep insights about the participant experience in general, specifically around interacting with digital sensors for stress and health tracking. Engagement Specialists reviewed adherence data prior to check-ins to probe participant specific study challenges. Check-in calls were expected to range in time depending on the need of the participant, but the initially allotted time was up to 60 minutes for each of these calls (see results).

Engagement Specialists conducted exit interviews by phone at the end of the study; interviews lasted approximately one hour. Participants were asked open-ended questions relating to their work in the pandemic environment and about features of the study that might help them and others in the future.

Addition of new optional sub-arms: Half-way through enrolment three new study sub-arms were employed. These included an arm with a wearable smart watch to be worn on shift, an arm with a lifestyle intervention, and an arm where hair cortisol was measured. For the wearable arm, participants were provided with Garmin Vivoactive 4 smartwatches²⁵ and were instructed to wear these continuously for four weeks (including while on shift) to capture on-shift objective measures of stress. For the intervention arm, participants were able to self-select into a physical activity sub-arm or a meditation sub-arm for four weeks using the Headspace app. For the hair cortisol arm, participants were sent hair sample collection kits with instructions to self-collect and send a hair sample back to the study team to provide a biological measure of chronic stress during the study period²⁶. (Please see Supp. Methods for a detailed description of the sub-arms).

Joint participant, investigator video meeting: A joint participant - investigator zoom call meeting half-way through enrolment was held. The purpose of this meeting was to give participants a chance to meet the study team in person (virtually), ask questions and give feedback. The study team gave study updates on progress and introduced the new optional study arms. Participants' confidentiality was maintained by using anonymous mode features of the video call platform. While participants were anonymous in the call, they could all see and hear the study team, and could participate via the chat feature to ask questions and give feedback.

Learning-by-doing: The goal of the engagement approach was to change the participant experience from feeling like only a source of data, or a blinded "subject," to a supported project co-driver and partner in the research. As this was a feasibility study, we engaged participant feedback from the study's start and implemented protocol changes during follow-up. Accordingly, participants directly helped shape the nature of how we asked app-based assessments, how we explained study related details, and how we will design future remote digital health studies. Participants were invited to be co-authors of study related published work.

Total Participation Effort

It was estimated that the total effort for study participation was on average 10-15 minutes per day. Beyond app-based assessments that on average took five minutes per day, additional activities included charging sensors, daily opening of the study apps and syncing of sensors, viewing the data from the associated apps, miscellaneous tech issues, check-in calls, and correspondence with an Engagement Specialist to schedule check-in calls and other study related activities including exit interviews and the Zoom call. This time estimate was derived by study investigators and staff communication with participants on all daily activities as described above.

Compensation and benefit

Participants were not offered any monetary incentives, nor were rewards in the form of points provided for study participation. However, participants were allowed to keep the Oura ring and the Garmin smartwatch (in sub-arm participants) at the end of their participation.

Analysis

Univariate descriptive analyses of cohort characteristics, retention and adherence are reported. Survival probabilities using the Kaplan Meier approach were calculated to display retention over the course of the study. Bivariate associations between cohort characteristics and adherence rates were conducted using chi-square, Fisher's exact (for cell counts less than five) and t-tests where appropriate. Mixed effects linear models were used to estimate changes in weekly mean adherence rates by group status using an autoregressive covariance matrix. Thematic study insights from qualitative data are described from participant and study staff feedback. Analyses were conducted using SPSS version 27²⁷.

Retention was defined as completing the minimum follow-up which was four months or retained until the end of study which was defined by a specific cut-off date. Adherence was defined as the number of tasks completed over the total number available tasks that could be completed by participant unique study time. For example, a participant with a total study time of 140 days (20 weeks) completing 100 daily surveys, 17 weekly surveys and having any Oura data upload (even if a partial day) for 130 days would have an adherence rate of 71.43% (100/140) for daily assessments, 85.00% (17/20) for weekly assessments, and 92.86% (130/140) for Oura wearable data, respectively.

Results

Description of the cohort

The final study sample included 365 participants who enrolled in and started the study (Supp. Figure 1). The median age in years was 33 (range=20-67) (Table 1). The majority of participants were female (89.04%), white (82.74%) and were registered nurses (89.04%) (Table 1). Participants were followed for a median follow-up of 112 days (range=1-170 days) during the period from May 1st, 2020 to November 20th, 2020. Primary reasons for exclusion were being an Android user, prior COVID-19 infection and no direct patient care (Supp. Figure 1). Participants were located across 27 different US states with the majority of participants working and residing (at the time of participation) in Washington (103, 34.68%), Minnesota (66, 22.22%), Massachusetts (38, 12.79%), Arizona (27,

9.09%), and Wisconsin (19, 6.34%). There were five reported cases of COVID-19 during study follow-up amongst the study participants.

Recruitment

Upon screening, participants were asked "How did you hear about our study?". Of participants screened, and enrolled into the study, over 50.00% found out about the study through a recruitment email from their work-place department or floor, while approximately 40.00% found out about the study through word of mouth. The remainder (<10.00%) found out about the study through national associations and workplace-specific newsletters and social media channels.

Retention

Of the 365 enrolled participants, 81.37% (297) completed the study. Of the 68 participants who did not complete the study, 11.76% (8) were withdrawn (study team withdrew) due to no longer meeting inclusion criteria such as no longer working with patients, furloughed, or lost study sensors; 41.18% (28) dropped out (participant decided to end participation) due to reasons such as no longer interested, not enjoying the study or study sensor, too much time commitment; and 51.47% (35) were lost to follow-up (could not be reached on re-contact). The probability of retaining in the study for one month was 98.00%, while the probability of retaining in the study half-way through study time was 92.00% (Figure 2). Retention for the three study sub-arms can be found in Supp. Figure 2.

Sample characteristics were similar in participants who started the study compared to those retained in the study. There were higher proportions of younger individuals not completing the study compared to those retained, although this was not statistically significant ($P=.157$). Other sample characteristics were similar in participants who did not complete the study compared to those retained although cell counts were low across categories (Table 1).

Adherence

Adherence calculations are presented for those participants who completed the study (Table 2). While initially excluded, twelve Android users were enrolled when the study protocol switched to Cambridge Cognition tasks from ResearchKit's active tasks because of expected sensor compatibility. However, owing to troubleshooting problems with the MyCap app, these twelve individuals (minus one participant who did not complete the study) were unable to use the study app and are excluded from app-based adherence calculations.

Participants adhered to wearing the Oura smart ring and the Garmin smartwatch for an average of 90.60% and 90.42% of study time, respectively. App-based daily, weekly, every two weeks, and monthly surveys were completed on average 69.18%, 68.37% (range across different tasks=64.44-71.86%), 72.86% (range across different tasks=72.42-73.30%), and 68.82% (range across different tasks=68.05-69.82%) of study time, respectively (Table 2). Every two-week check-in phone calls were completed for an average of 75.62% of study time (Table 2 and Figure 3). Average check-in call length was approximately 14.5 minutes and ranged from two to 70 minutes. Measures scheduled on Fridays and Saturdays had consistently lower adherence compared to other days of the week. Adherence was higher for the ResearchKit active tasks (80.59%) compared to the Cambridge Cognition tasks (56.49%). However, the ResearchKit tasks were integrated within the study app and were shorter in duration, while the Cambridge Cognition tasks had to be completed via an external web-based link which may have contributed to lower adherence on these tasks. Weekly average

adherence on daily app measures across age categories were similar, and not statistically significant ($F=.20$, $P=.894$), although there was a trend where higher age categories demonstrated higher adherence on Oura ring use ($F=2.49$, $P=.060$). Adherence across other sample characteristics was not explored owing to very small sample sizes across categories.

Average adherence in the week after the joint participant-investigator Zoom call was held showed large increases for app-based daily surveys (82.93%), Cambridge Cognition tasks (88.97%) and in Oura ring usage (97.89%).

Engagement impact on adherence

While this study was not designated to explicitly test different aspects of the engagement approach on study acceptability and experience, to explore whether study related events had an impact on adherence, weekly average adherence on active daily app-based surveys in participants enrolled prior to the joint participant/investigator Zoom call and therefore had the opportunity to participate ($n=246$) and participants enrolled after the Zoom call and therefore did not participate ($n=39$) were calculated. As seen in Supp. Figure 3, participants who were enrolled later in the enrollment period and did not have the opportunity to participate in the joint investigator/participant zoom call showed lower weekly average adherence (mean=0.66, standard deviation [SD]=0.22) on daily app-based tasks compared to those enrolled prior to this meeting (mean=0.71, SD=0.21), although, this was not statistically significant over study time ($F=3.06$, $p=0.81$) (Supp. Table 2).

Learning-by-doing

Insights learned during study follow-up

Knowledge was gained from the check-in calls with Engagement Specialists and from the Engagement Specialists themselves through discussions with participants that fuelled insights into study improvements. Insights learned can be found in Supp. Table 3. Protocol changes implemented can be found in Supp. Table 4. Key themes centered on: privacy (particularly on the surveillance nature of some app features (e.g., RescueTime), usability, perceived utility, and knowledge of how to interpret sensor readouts, particularly the objective data (e.g., heart rate and Heart rate variability). Dedicating check-in calls to explain the purpose of individual measures and how data are used by third-party applications helped with these challenges. While not an initial purpose of check-in calls, in discussing stress and symptom experience with participants, these calls also served as an outlet for some participants to discuss with someone outside their place of employment their COVID-19 frontline experience. Accordingly, these calls may have produced an inadvertent interventional effect.

Discussion

This study tested the feasibility of a participant centered digital health study with a daily burden of 10-15 minutes in frontline healthcare workers. In our study sample of frontline healthcare workers, we found support for the feasibility and acceptability of this approach with 81% retention, while average adherence for wearable sensor usage and daily app-based assessments was approximately 90% and 70% of study time, respectively. This contrasts to typical reported retention and adherence rates in digital medicine studies that tend to be lower than 50%⁴ and that had much lower daily burdens, although the underlying populations of these studies are different which makes direct comparisons difficult. In addition to high retention and adherence, the collection of large volumes of objec-

tive data along-side contextual self-reported subjective data was able to be collected that is often missing from the 'light touch' digital health study.

The COVID-19 pandemic has highlighted the increasing importance of being able to operate, communicate, and conduct research remotely and digitally. Yet, historically remote digital studies have been hampered by low retention and engagement of participants. This poses obvious challenges for the usability and generalizability of digital data and is also an early warning signal. Poor engagement at the research phase provides clues into the challenges we will face at the healthcare implementation phase. The engagement approach developed here involved three components: 1) supportive check-in calls with Engagement Specialists during follow-up; 2) a learning-by-doing approach that leveraged direct feedback from participants collected during check-ins to fuel real time study improvements and participant experience; and 3) new study features, and a virtual investigator - participant event. Findings from this feasibility study suggest these participant-centered strategies offer enough value to sufficiently engage participants without monetary/reward-based incentives. While participants were offered to keep their Oura ring and Garmin watch at the end of participation, no monetary incentives or point-based rewards systems were used. Both the increase in adherence after the joint participant/investigator Zoom call and higher daily adherence among those with the opportunity to participate in the Zoom call suggests that potential self-awareness and benefit from the sensors alone are not the only reason for sustained adherence to protocols. Further, this approach enabled the collection of rich objective measured data along-side participant self-reported subjective data. The common 'light touch' digital health study often lacks adequate contextual self-reported subjective data to ground and validate the objectively collected information which poses challenges in interpreting the data. These findings suggest that engaging participants in the appropriate way can enable a high burden study and the subsequent collection of needed contextual self-reported subjective data.

Digital sensors that can return symptoms back to the user, enable a two-way learning experience in which participants learn about themselves in real time, and provide insights to researchers, in contrast to traditional methodologies that collect data from participants in blind or shielded ways, where the data are then unveiled at the end of the study. The former enables accelerated learning at the pilot research phase: a learning-by-doing approach that leverages digital tools to enable participants to actively partake in and shape their digital research experience through tracking their own health data and discussing these data with study investigators in real time. However, the impact of tracking objective measures of health is largely unknown in terms of how being enabled to track personal objective data impacts the user. Further, wearable sensor companion apps have embedded nudges and prompts to shift behaviour based on the collected data. Some participants noted frustration with both the returning of the Oura ring collected symptom summaries, and associated feedback prompts as these were non-actionable, particularly in a healthcare professional population. On the contrary, others viewed these returned symptoms and nudges positively. Commonly, participants noted a desire to have more knowledge about interpreting the sensor readouts and were curious about other participants' data. Beyond digital literacy, there is complex knowledge and support required in the use of digital tools for stress and health tracking. The field is in an early phase of understanding how individuals from diverse populations will interact with digital technologies at home and in everyday life that will be needed for the successful implementation of digital approaches into health systems and for their use in transforming individualized care. Support in the use of these tools is a current gap. The notion of a 'digital expert' or counsellor, not dissimilar to genetic counsellors and like the Engagement Specialists used here, may be one approach to bridge this gap both for digital research and digital healthcare.

Limitations

The study population included predominantly white healthcare professionals who are non-representative of non-white and non-healthcare provider populations in having higher than average knowledge of research and higher health literacy. It is unclear how the engagement approach might work in other populations. On the other hand, this population is a busy, high stress population. In light of this, one could argue that this particular population would be difficult to engage in a high-friction study owing to work-life constraints. A non-probability sample was included, therefore selection biases may be present where participants enrolled may be more likely to engage or have interest in the use of wearable sensors for health tracking compared to those who were uninterested. A control group of participants who did not receive the adjacent engagement strategy were not included; therefore, we cannot imply causality of this approach or parse the different possible drivers of success on retention and adherence results. Future work should test these engagement approaches with control groups of financial incentives only, and no incentives to further determine their effectiveness across different populations.

The participant centered, learning-by-doing approach used here worked well for a feasibility study where the primary purpose is to learn about how well a methodology, or a tool will work for health-related purposes. However, these approaches may not be well suited to other types of studies that require more controlled data collection such as in randomized controlled trials. Enabling participants to track their own health outcomes while they are under study may increase risk of bias in the controlled study context through participant's awareness of symptoms, particularly through companion app nudges and prompts. Although, this hallmark challenge in traditional controlled studies largely reflects a risk to altering perceptions of the outcome of interest which is how symptoms are traditionally measured. As we embark on a potential new era of enabling individuals to be aware of their own measured objective signs of stress and disease, the importance of this traditional challenge becomes less clear. An additional possibility is that the implemented engagement approach may have produced a positive interventional effect from either the returned symptoms, or the every two-week check-in calls, which could modulate the stress signal in the data.

Additional challenges of this approach encompass a time burden on researchers and staff. Both investigators and staff were highly engaged during the study follow-up. Each check-in call took on average 15 minutes, with some calls taking as long as an hour. However, in the context of traditional research where research staff conduct in person assessments, and manually enter data, it remains unclear how much extra time burden this approach actually produces. This learning-by-doing approach may also be difficult to implement depending on research ethics board review timelines. The Institutional Review Board used here enabled rapid review of modifications enabling quick and efficient amendments to the protocol. Finally, this approach may not be scalable for large digital health studies, and it is unclear how effective it might be in other populations - future work should explore this.

Conclusions

Digital technologies could facilitate a new era of participant driven models in research and medicine²⁸. As datafication, the process of digitizing most aspects of human life, continues to intensify, the need to incorporate insights from the individuals who are the source of those data grows increasingly important. A common shortcoming of the 'light touch' digital health study is lacking adequate ground truth data in the form of participant-reported subjective information. Given the early state of this field, ground truths to validate measurements of health are crucial yet are so often missing. While statistical power is important, it is unclear whether an increase in size of study can counter the benefits seen from the depth of collecting additional contextual information. Incorporating a learning-by-doing digital approach facilitates a closed loop research process whereby partici-

pants can offer rich self-reported context for objectively measured data, while researchers can learn in real time and offer knowledge and support back to participants. In order for this to work, trust and respect between participant and researcher is essential as it should always be and could serve as a model to be leveraged for the implementation phase of digital medicine.

Conflicts of Interest

SF holds <0.05% stock in Oura Health

References

1. Friend SH. App-enabled trial participation: Tectonic shift or tepid rumble? *Sci Transl Med*. 2015; 7: 297ed10.
2. Simblett S, Greer B, Matcham F, et al. Barriers to and Facilitators of Engagement With Remote Measurement Technology for Managing Health: Systematic Review and Content Analysis of Findings. *J Med Internet Res*. 2018; 20: e10480.
3. O'Connor S, Hanlon P, O'Donnell CA, Garcia S, Glanville J and Mair FS. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. *BMC Med Inform Decis Mak*. 2016; 16: 120.
4. Pratap A, Neto EC, Snyder P, et al. Indicators of retention in remote digital health studies: a cross-study evaluation of 100,000 participants. *NPJ Digit Med*. 2020; 3: 21.
5. McConnell MV, Shcherbina A, Pavlovic A, et al. Feasibility of Obtaining Measures of Lifestyle From a Smartphone App: The MyHeart Counts Cardiovascular Health Study. *JAMA Cardiol*. 2017; 2: 67-76.
6. Pratap A, Grant D, Vegesna A, et al. Evaluating the Utility of Smartphone-Based Sensor Assessments in Persons With Multiple Sclerosis in the Real-World Using an App (elevateMS): Observational, Prospective Pilot Digital Health Study. *JMIR Mhealth Uhealth*. 2020; 8: e22108.
7. Bot BM, Suver C, Neto EC, et al. The mPower study, Parkinson disease mobile data collected using ResearchKit. *Sci Data*. 2016; 3: 160011.
8. Quisel T, Foschini L, Zbikowski SM and Juusola JL. The Association Between Medication Adherence for Chronic Conditions and Digital Health Activity Tracking: Retrospective Analysis. *J Med Internet Res*. 2019; 21: e11486.
9. Vo V, Auroy L and Sarradon-Eck A. Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies. *JMIR Mhealth Uhealth*. 2019; 7: e13817.
10. Nahum-Shani I, Smith SN, Spring BJ, et al. Just-in-Time Adaptive Interventions (JITAs) in Mobile Health: Key Components and Design Principles for Ongoing Health Behavior Support. *Ann Behav Med*. 2018; 52: 446-62.
11. Druce KL, Dixon WG and McBeth J. Maximizing Engagement in Mobile Health Studies: Lessons Learned and Future Directions. *Rheum Dis Clin North Am*. 2019; 45: 159-72.
12. Andrews JE, Moore JB, Weinberg RB, et al. Ensuring respect for persons in COMPASS: a cluster randomised pragmatic clinical trial. *Journal of medical ethics*. 2018; 44: 560-6.
13. Birnbaum F, Lewis D, Rosen RK and Ranney ML. Patient engagement and the design of digital health. *Acad Emerg Med*. 2015; 22: 754-6.
14. Kaye J, Curren L, Anderson N, et al. From patients to partners: participant-centric initiatives in biomedical research. *Nat Rev Genet*. 2012; 13: 371-6.

15. Anderson N, Bragg C, Hartzler A and Edwards K. Participant-Centric Initiatives: Tools to Facilitate Engagement In Research. *Appl Transl Genom*. 2012; 1: 25-9.
16. Pruett SB. Stress and the immune system. *Pathophysiology*. 2003; 9: 133-53.
17. Goodyday S and Friend S. Unlocking stress and forecasting its consequences with digital technology. *npj Digital Medicine*. 2019; 2: 1-5.
18. PA Harris RT, BL Minor, V Elliott, M Fernandez, L O'Neal, L McLeod, G Delacqua, F Delacqua, J Kirby, SN Duda. REDCap Consortium, The REDCap consortium: Building an international community of software partners. *J Biomed Inform*. 2019.
19. P.A Harris RT, R Thielke, J Payne, N Gonzalez, J.G. Conde. Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009; 42: 377-81.
20. <http://ciems.org/>.
21. <http://researchkit.org/docs/docs/ActiveTasks/ActiveTasks.html>.
22. Penton-Voak IS MM, Looi CY. Biased facial-emotion perception in mental health disorders: a possible target for psychological intervention? *Curr Direct Psychol Sci*. 2017; 26: 294-301.
23. Cormack F, McCue M, Taptiklis N, et al. Wearable Technology for High-Frequency Cognitive and Mood Assessment in Major Depressive Disorder: Longitudinal Observational Study. *JMIR Ment Health*. 2019; 6: e12814.
24. <https://ouraring.com/>.
25. <https://www.garmin.com/>.
26. Russell E, Koren G, Rieder M and Van Uum S. Hair cortisol as a biological marker of chronic stress: current status, future directions and unanswered questions. *Psychoneuroendocrinology*. 2012; 37: 589-601.
27. IBM. Corp. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp, 2019.
28. Erikainen S, Pickersgill M, Cunningham-Burley S and Chan S. Patienthood and participation in the digital era. *Digit Health*. 2019; 5: 2055207619845546.

Abbreviations

REDCap - Research Electronic Data Capture

Supp - Supplemental

CIEMS - Center for International Emergency Medical Services

SD - standard deviation

Author Contributions

SG wrote the manuscript and conducted the analysis, EM assisted with the analysis, SF along with all authors contributed to the design of the study, all authors contributed to the editing of the final manuscript

Figure 1. Study design

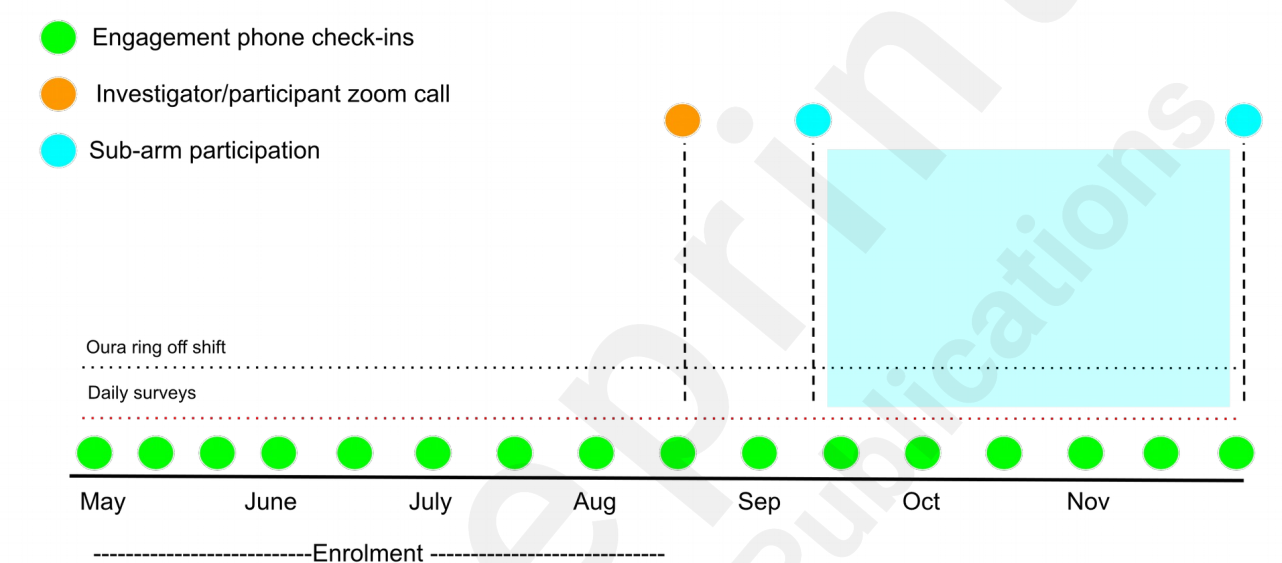
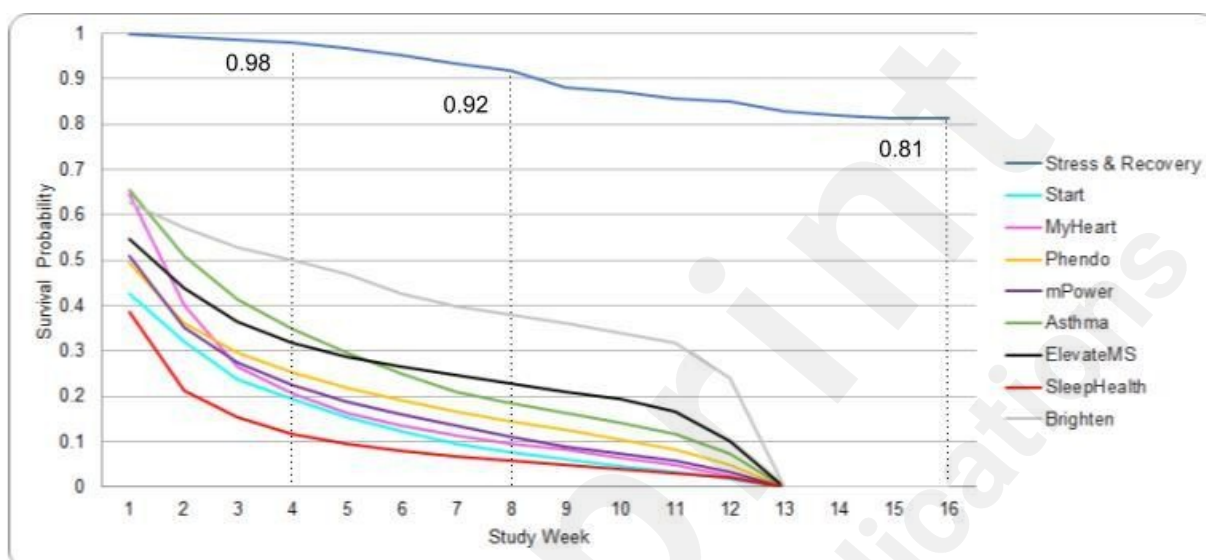


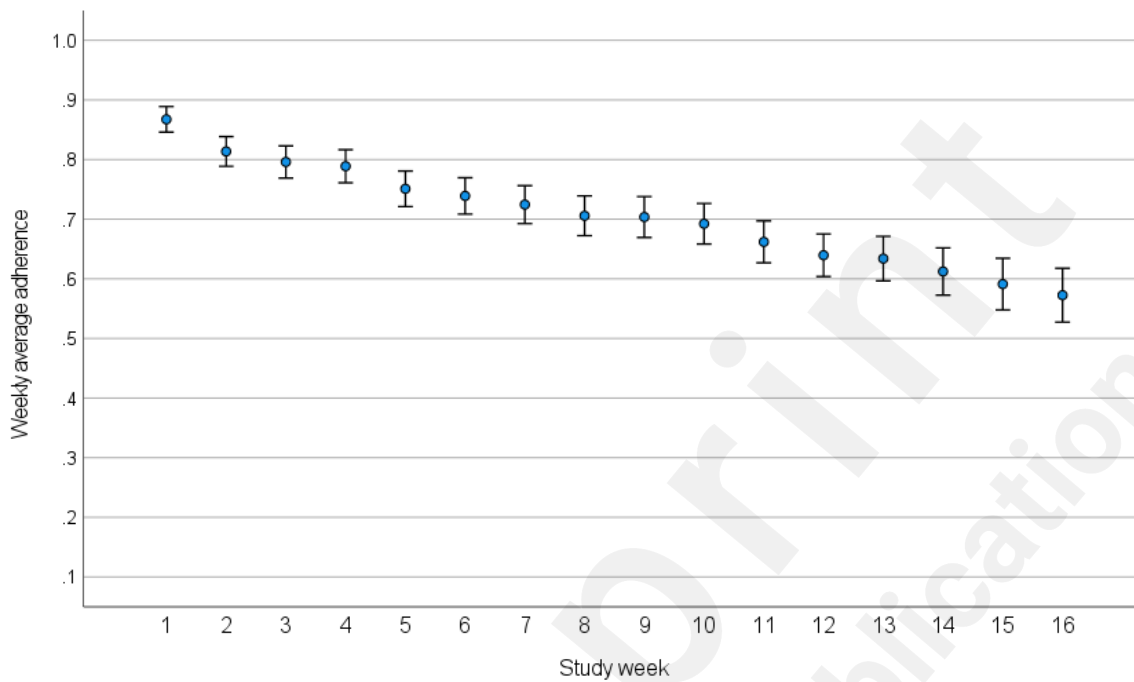
Figure 2. Survival probability of retaining in the study



Additional data from Patrap et al., 2020⁴. Kaplan Meir survival curves for the Stress and Recovery study and for 8 additional digital health app-based studies as described in Patrap et al., 2020⁴. Please interpret with caution. The survival probabilities from the 8 studies included in Patrap et al., 2020⁴ included a mix of different study populations some including chronic disease populations and some, healthy populations with different study durations.

Figure 3. Weekly average adherence and standard errors for daily app-based tasks (A) and Oura ring usage (B) in retained participants (n=297)

A)



B)

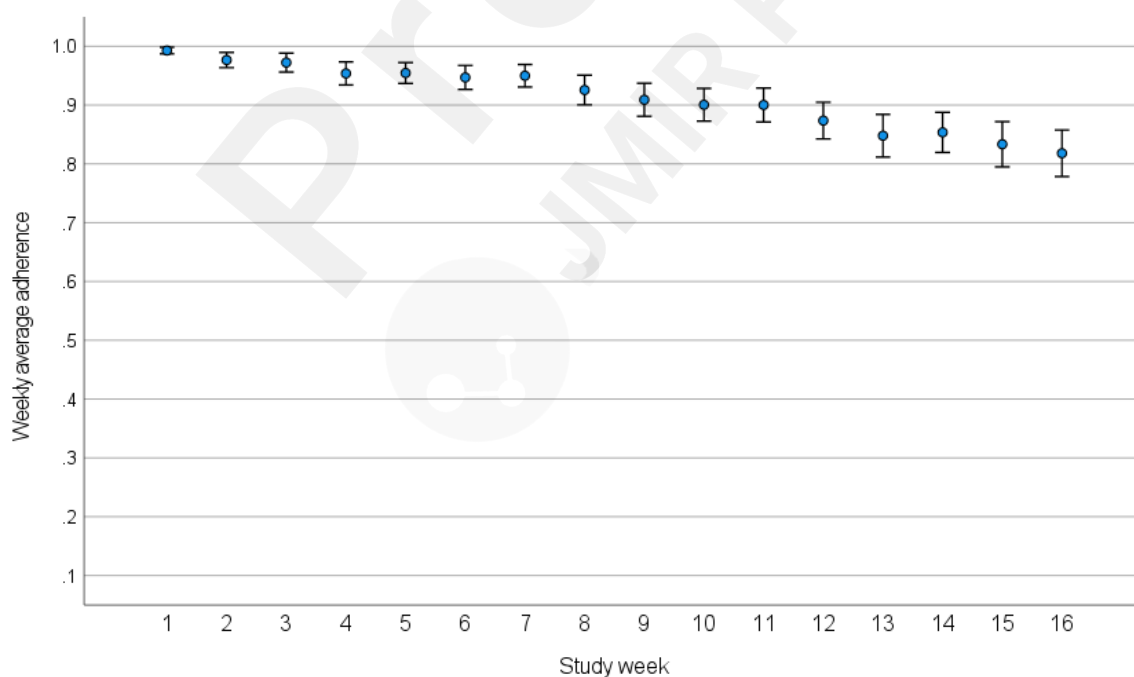


Table 1. Characteristics of the cohort among those who enrolled, completed the study, and did not finish

	Enrolled and started the study	Retained ¹	DNF ²	P-value (Retained vs DNF)
N	365	297	68	
Age (years)				
18-25	47 (12.88%)	37 (12.46%)	10 (14.71%)	.157 ³
26-35	168 (46.03%)	129 (43.43%)	39 (57.35%)	
36-45	78 (21.37%)	67 (22.56%)	11 (16.18%)	
46+	72 (19.73%)	64 (21.55%)	8 (11.76%)	
Gender				
Female	325 (89.04%)	264 (88.89%)	61 (89.71%)	.846 ³
Male	40 (10.96%)	33 (11.11%)	7 (10.29%)	
Race				
White	302 (82.74%)	242 (81.48%)	60 (88.24%)	.348 ⁴
Black or African American	8 (2.19%)	8 (2.69%)	0 (0.00%)	
Asian / Pacific Islander	27 (7.40%)	22 (7.41%)	5 (7.35%)	
Native American or American Indian	2 (0.55%)	1 (0.34%)	1 (1.47%)	
More Than One Race	21 (5.75%)	19 (6.40%)	2 (2.94%)	
Unknown / Not Reported	5 (1.37%)	5 (1.68%)	0 (0.00%)	
Ethnicity				
Hispanic or Latino	12 (3.29%)	9 (3.03%)	3 (4.41%)	.685 ⁴
Not Hispanic or Latino	343 (93.97%)	279 (93.94%)	64 (94.12%)	
Unknown / Not Reported	10 (2.74%)	9 (3.03%)	1 (1.47%)	
Occupation				
Registered Nurse	325 (89.04%)	264 (88.88%)	61 (89.71%)	.388 ⁴
Medical Doctor	5 (1.37%)	5 (1.68%)	0 (0.00%)	
Medical Assistant	10 (2.74%)	7 (2.36%)	3 (4.41%)	
Emergency Medical Services	2 (0.55%)	1 (0.34%)	1 (1.47%)	
Other ⁵	23 (10.96%)	20 (6.73%)	3 (4.41%)	

¹Retained includes complete follow-up of 4 months or by study end cut off date

²DFN Includes participants lost to follow-up, dropped out, or withdrawn

³Pearson Chi-Square Tests

⁴Fishers Exact Tests

⁵Other occupations include: Social Workers, Respiratory Therapist, Surg/Cardio Tech, Dentist, Registered Dietitian, Medical Student

Table 2. Adherence rates by study activity

	Full Study Period
Study app Surveys (n)	286 ⁶

Daily Survey ¹	69.18%
Weekly Surveys	68.37%
Bi-Weekly Surveys	72.86%
Monthly Surveys	68.82%
ResearchKit tasks (n) ²	164*
Cognitive Active Tasks	80.59%
Cambridge Cognition (n) ³	289
Cognition Tasks	56.49%
ES Check-Ins (n)	297
Bi-Weekly Check-Ins ⁴	75.62%
Oura Smarttring (n) ⁵	296
Oura Ring Usage	90.60%
On Shift Wearable Sub-arm (n)	95
Garmin Smartwatch Usage	90.42%*

ES: Engagement Specialist

¹All study app survey completion calculations exclude 12 participants (11 retained) with Android sensors who have no study app data

²ResearchKit active tasks were switched to Cambridge Cognition tasks on 7/6/2020, therefore, some participants did not receive at least 1 ResearchKit tasks as reflected by a smaller study sample size

³The higher sample size reflects a few Android users who were able to access the web-based Cambridge Cognition links

⁴ 2 participants of 297 retained completed 0 check-ins

⁵1 retained participant never synced their ring to the app

⁶Excluding 11 participants who were Android users and unable to use the study app