An Impact Evaluation protocol for the rapid design and delivery of an experience-based co-designed mobile app to support the mental health needs of healthcare workers impacted by COVID-19

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Submitted to: JMIR Research Protocols
on: December 02, 2020

Table of Contents

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Abstract

Background: The COVID-19 pandemic has highlighted the central importance of health care workers' (HCWs) mental health and wellbeing for the successful function of the health care system. Few targeted digital tools exist to support HCWs' mental health and none appear to have been co-designed with end users.

Objective: RMHive is being developed as a mobile app to support the mental health challenges being posed by COVID-19 to HCWs using experience-based co-design (EBCD) processes. We present the Impact Evaluation protocol for the rapid design and delivery of the RMHive mobile app.

Methods: The Impact Evaluation will adopt a mixed-methods approach. Qualitative data from photo interviews undertaken with HCWs exploring needs and experiences, and semi-structured interviews conducted with governance stakeholders during design development and implementation will be integrated with quantitative user analytics data and user generated demographic and mental health data entered into the app. Analyses will address three evaluation questions related to: (1) engagement with and use of the mobile app; (2) implementation and integration; and (3) the quantifiable and qualitative impacts on individual mental health. The mobile app design and development will be described using the mobile health (mHealth) evidence reporting and assessment (mERA) guidelines. Implementation of the app will be evaluated using Normalisation Process Theory (NPT) as a framework to analyse qualitative data combined with text and video analysis from semi-structured interviews. Mental health impacts will be assessed using the Patient Health Questionnaire (PHQ4) total score and subscale scores for the Patient Health Questionnaire (PHQ2) for depression and Generalised Anxiety Scale (GAD2) for anxiety. The PHQ4 will be completed at download (baseline), then at 14 and 28 days.

Results: The anticipated use period of the app is an average of 30 days. The rapid design will occur over four months using EBCD approaches to collect qualitative data and develop app content. The Impact Evaluation will monitor outcome data for up to 12 weeks following the Minimal Viable Product release. The study received funding and institutional ethics approvals in June, 2020. Outcome data is expected to be available in March, 2021 and the Impact Evaluation published mid 2021.

Conclusions: The Impact Evaluation will examine the rapid design, development and implementation of the RMHive app and the mental health and wellbeing outcomes for HCWs. Evaluation outcomes will provide guidance for the integration of EBCD in rapid design and implementation processes. Outcomes will inform future development and roll out of the app programmatically to support the mental health needs of HCWs more widely.

(JMIR Preprints 02/12/2020:26168)
DOI: https://doi.org/10.2196/preprints.26168

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Abstract

Background

The COVID-19 pandemic has highlighted the central importance of health care workers' (HCWs) mental health and wellbeing for the successful function of the health care system. Few targeted digital tools exist to support hospital HCWs' mental health and none appear to have been led and co-designed by HCWs.

Objectives

RMHive is being led and developed by HCWs as a mobile app to support the mental health challenges being posed by COVID-19 to HCWs using experience-based co-design (EBCD) processes. We present the Impact Evaluation protocol for the rapid design and delivery of the RMHive mobile app.

Methods

The Impact Evaluation adopts a mixed-method design. Qualitative data from photo interviews undertaken with up to 30 HCWs exploring needs and experiences, and semi-structured interviews conducted with up to 30 governance stakeholders will be integrated with qualitative and quantitative user analytics data (using Think Aloud methods) and user generated demographic and mental health data entered into the app. Analyses will address three evaluation questions related to: (1) engagement with and use of the mobile app; (2) implementation and integration of the app; and (3) the quantifiable and qualitative impacts on individual mental health outcomes. The mobile app design and development will be described using the mobile health (mHealth) evidence reporting and assessment (mERA) guidelines. Implementation of the app will be evaluated using Normalisation Process Theory (NPT) as a framework to analyse qualitative data from interviews combined with text and video analysis from semi-structured interviews using a Think Aloud approach. Mental health impacts will be assessed using the Patient Health Questionnaire (PHQ4) total score and subscale scores for the Patient Health Questionnaire (PHQ2) for depression and Generalised Anxiety Scale (GAD2) for anxiety. The PHQ4 will be completed at download (baseline), then at 14 and 28 days.

Results

The anticipated use period of the app is an average of 30 days. The rapid design will occur over four months using EBCD to collect qualitative data and develop app content. The Impact Evaluation will monitor outcome data for up to 12 weeks following the Minimal Viable Product release hospital wide for all health care workers to use. The study received

funding and institutional ethics approvals in June, 2020. Outcome data is expected to be available in March 2021 and the Impact Evaluation published mid-2021.

Conclusions

The Impact Evaluation will examine the rapid design, development and implementation of the RMHive app and its impact on the mental health outcomes for HCWs. Findings from the Impact Evaluation will provide guidance for the integration of EBCD in rapid design and implementation processes. The Evaluation will also inform the future development and roll out of the app to support the mental health needs of hospital based HCWs more widely.

Key words: Mental Health; Mobile Applications; COVID-19; Health Personnel; Experience-Based Co-Design; Impact Evaluation; Digital Interventions

Introduction

Background

The mental health and wellbeing of health care workers (HCWs) should be a major public health priority [1] both during COVID-19 and beyond to support the successful functioning of the health care system. HCWs, particularly nurses and doctors, experience significant mental health challenges and these have been exacerbated through the early stages of the COVID-19 pandemic with high rates of depression (23.2%), anxiety (22.8%) and insomnia (38.9%) reported. [2] Similarly high rates of clinically significant anxiety (45%), depression (38%), and post-traumatic stress disorder (19%) have been observed during and following significant viral outbreaks and pandemics. [3] Despite the recognised impact of pandemics on the mental health and wellbeing of HCWs, few digital solutions have been developed and delivered to support hospital based HCWs mental health and wellbeing. A mobile app could provide a readily available, evidence based support for stress management, mental health and wellbeing to hospital based HCWs through the COVID-19 pandemic. By using Experience-based Co-Design approaches, this app could deliver appropriate supports across professional groups.

HCWs are often reluctant to seek appropriate and timely mental health support. [4] Perceived stigma and career impact, time challenges and a work culture that values stoicism are recognised as contributing barriers to help-seeking. [4-6] Without support, all HCWs are at increased risk of major mental health complications. [4, 7] Targeted approaches to maintain and improve HCW mental health are needed that can address barriers to help-seeking and meet HCWs 'where they are,' and 'according to their professional needs.' A HCW co-designed mobile app offering mental health support may have potential as a readily accessible, cost effective, evidence based, and scalable tool to achieve these goals. [8]

The more that a mobile app can integrate the lived experiences of HCWs through the use of co-design processes, the more likely it will respond to their needs and ideally lead to increased uptake and engagement. While digital health interventions and mobile app development utilise Human Centred Design principles (HCD) to meet user needs, [9] few embed and follow an Experience-Based Co-Design (EBCD) approach. EBCD offers power sharing and approaches that can extend HCD methods further than developing deep insights to enable users to actively shape and be co-designers of solutions. [10] EBCD has typically been used in healthcare quality improvement as a method for staff, patients and carers to

collaborate on the design of solutions drawing on narrative and story-based approaches through interview, film or other visual methods such as digital stories, coupled with facilitated co-design using design thinking and participatory approaches. The integration of the lived experience of end users via EBCD processes will ensure that outcomes are targeted and co-designed with those most likely to be impacted by an issue, change to process, or an intervention. [11, 12] EBCD provides an avenue to more deeply embed end users' experiences as the primary driver of change processes and provides a commitment to shared power arrangements and decision-making not currently addressed by the adoption of Human Centred Design (HCD) principles alone.[10] The explicit utilisation of EBCD as a way to embed lived-experience will ideally result in greater uptake of the mobile app and increased engagement. Several digital mental health support responses for HCWs have been developed to address the impact of COVID-19, [13] and while some are HCW led, peer designed, and delivered, we have been unable to identify any that have been co-designed by and for HCWs themselves. Addressing this gap may be part of what is required to improve overall uptake, engagement and use of mobile apps by individuals. The RMHive will attempt to do this by embedding HCWs in the design, development and implementation of a mobile app using EBCD.

Integrating the lived experience of HCWs in the design and development of mobile apps is important to support their mental health needs. [12] Equally important is a systematic evaluation of the development process and outcomes that can be used to support replication of mobile apps or digital interventions. This includes outlining the underlying theoretical frameworks, clear overviews of the design, development, and implementation and documentation of impact. [8, 14] Existing evaluations focus on the development and implementation of mobile apps largely from a technological perspective but can take a more limited evaluation of the wider contextual, organisational and individual factors that influence uptake and impact on outcomes. [15] A broader Impact Evaluation approach allows for socio-technical digital health perspectives to be considered in the context of intersecting factors and causal attributions across the design, development and implementation continuum for programmatic scaling up. [16] adaptive

This protocol describes the Impact Evaluation of the RMHive mobile app, being led by HCWs as an EBCD intervention for HCWs with mental health needs arising from the coronavirus pandemic. Using EBCD, HCWs from different professional groupings will be co-design partners across all phases of research from ideation to implementation. RMHive is

not being developed as a clinical or therapeutic tool. The Impact Evaluation will integrate data from the design and development and the wider implementation of RMHive and lead to the formulation of a theory of change that can explain both positive and negative impacts to guide future delivery of the mobile app across other health services and hospital networks.

Objectives

A rapid design and development cycle will be adopted using EBCD to identify experiences and create an app prototype within 3-4 months to support the mental health needs of hospital based HCWs working in the COVID-19 context. The approach adopted is analogous to rapid prototyping in design thinking, [17] through the use of rapid co-design processes. The Impact Evaluation addresses three questions using quantitative and qualitative data that will be collected across all stages:

1) What is HCWs' engagement with RMHive? (including use patterns, perceptions of content, and overall level of engagement)?

2) What contextual, socio-technical, organisational and individual features support or hinder implementation?, and

3) What are the identifiable impacts on individual HCWs' mental health through app adoption, implementation and use?

This protocol will describe the planned design, development and implementation of the RMHive mobile app using EBCD. It will describe the data to be collected to inform the Impact Evaluation and the proposed analysis plan.

Methods

Setting and locations

RMHive will undergo development, beta-testing and implementation with hospital based HCWs across Royal Melbourne Hospital (RMH). RMH is a large tertiary referral hospital that includes two major campuses; an acute care city campus and a second inner city campus providing sub-acute services including aged care and which have been heavily impacted by COVID-19. RMH is the largest provider of mental health services in Victoria with services spanning the northern and western suburbs of Melbourne. RMH is a part of the Melbourne Health network who in 2018/2019 Melbourne Health reported 10,000 staff and volunteers. In 2019, there were 79,799 presentations to the emergency department and 105,493 inpatient

admissions [18]. Design, development and beta-testing will be conducted with the emergency and cardiology departments as two settings impacted by the COVID-19 pandemic. Following completion of the beta-test phases and refinements arising from this process, RMHive will be implemented across RMH and made available to all HCWs hospital wide. While it is recognised that there may be context and profession specific needs that remain unaddressed from this preliminary rapid design process, a decision was made to roll out the app hospital wide to explore use patterns and gather feedback to inform future iterations and refinements of the app. Ethics approval for this study has been provided by the University of Melbourne Human Research Ethics Committee (Ethics ID #2056866.2).

Overview of the RMHive design, development and implementation process

The project will adopt a rapid design, development, and implementation process using EBCD to progress from HCWs needs identification and content creation through to app design and development, and beta-testing to a minimally viable product (MVP) release. An overview of the Design, Development and Implementation Framework is shown in Figure 1.

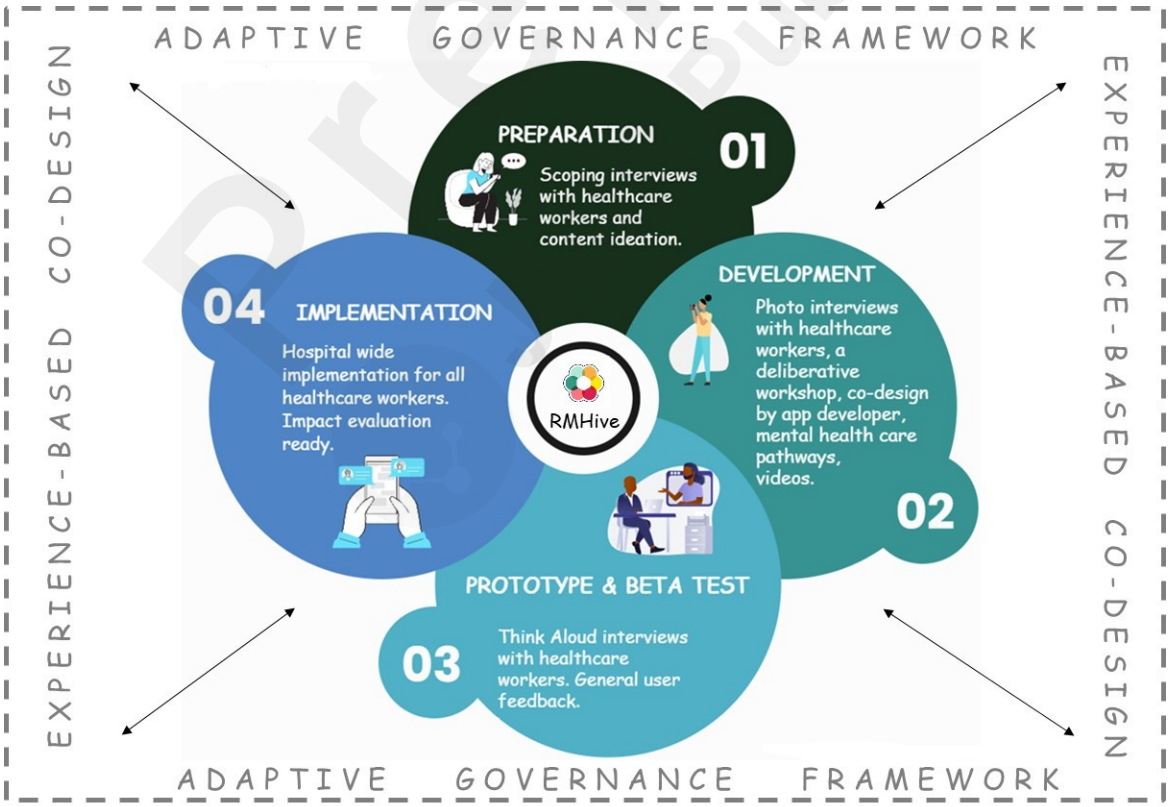

Figure 1: Planned design, development and implementation framework for RMHive

Project and governance team

An important governance principle for the research team will be adaptiveness to ensure that the design and implementation process is flexible enough to adjust to complex, unpredictable changes that may occur while undertaking the research (e.g. due to emerging events throughout the COVID-19 pandemic). An adaptive governance framework will be adopted to support the design, development and implementation of RMHive [19]. Adaptive governance provides a structured approach for decision making in complex and dynamic systems while paying attention to the needs of grass roots community members. [20] Key to adaptive governance is shared decision-making arrangements which complements the collaborative and power-sharing goals of the EBCD approach. When applied to RMHive, adaptive governance is being used to ensure HCWs from diverse professional backgrounds including clinical (nurses, doctors, psychologists, primary care specialists) and non-clinical workers (administrative staff, environmental service assistants) are continually involved in shared decision making and feedback across all phases of research and according to changing HCW community needs. This extends to providing mechanisms of accountability of the research team in the EBCD processes.

RMHive app co-design and implementation will be managed by a HCW-led project team and include HCWs in multiple project governance roles and as advisory committee members. HCW members of the project team and advisors will be invited to participate through posters and flyers posted in staff common rooms and drawn from critical care emergency and cardiology units for the first rapid design phases. It is anticipated that HCWs will most commonly be nurses and physicians as these are the two largest professional groups in the hospital. The HCW advisory group will provide input and feedback and share decision-making throughout the project. The adaptive governance framework supports feedback loops that ensure HCW input is reviewed on a continuing basis with decision making shared by HCWs on the project team meeting every 2 weeks. The project team will be multidisciplinary and incorporate experts in EBCD, implementation science, evaluation, applied ethics, mental health clinical care, project governance, mental health care research and delivery, mobile app development, digital health interventions and evaluation, and creative content production.

Preparatory phase

Prior to commencement of the co-design work, scoping interviews were conducted during the initial wave of COVID-19 in early 2020 with a small but diverse group of HCWs (N=6). This was to understand the experiences and needs of HCWs in working through the pandemic. Semi-structured interviews included scoping questions co-developed by HCWs and researchers leading the study (available upon request). HCWs reported being overwhelmed with written communication (guidelines, clinical directives, news reports) and expressed a clear preference for video rather than text based information. Using these experiences, the project team generated ideas for video-based content that reflected HCWs' experiences but which also responded to their needs. These were: 1) mental preparation and coping strategies; 2) remaining connected through hearing other experiences of working on the frontline; and 3) having 'time out' / a break from the 'dark bubble' they were living in. The broad content themes were pitched to HCW members of the implementation team and led to video content to be developed within the app.

Needs analysis and understanding context

Leveraging the expertise of EBCD researchers working on the project team, HCWs selected photo interviews (photo-elicitation) as a relevant method for understanding HCW mental health needs and lived-experiences. We have previously shown photo elicitation to be a relevant participatory visual method that can be successfully applied across different contexts and research settings [21]. Photo-interview methods enable a narrative approach to identifying needs and understanding context [21] and can assist people to articulate complex concepts, discuss sensitive topics and provide an insight into the inner worlds of feelings, emotions and thoughts. [22] Up to 30 HCWs from the emergency and cardiology departments will be invited to participate in photo interviews [21]The choice for these departments was based on the professional groups representing the largest proportion of hospital staff.

The photo interview method will involve HCWs being asked to provide the research team with a series of 3-5 digital images produced on smartphones reflecting their experience of COVID-19 including challenges associated with working on the frontline as well as experiences or behaviours that are helping them to meet these challenges The images will inform a semi-structured telephone interview to draw out key "touchpoints" related to HCWs experiences during the pandemic and the impacts on mental health. A touchpoint is a term used in EBCD to refer to the places, and the way that a person comes in touch with a

particular service, or organisation, or how an issue touches them directly (e.g. the subjective world of the person). [23] The touchpoints will be further explored in a deliberative workshop to scope content areas to be developed within the app. The workshop discussion will be analysed to identify one or two key touchpoints that will inform an additional co-design workshop to be conducted by the app developers, Curve Tomorrow (explained below). Early in the RMHive development process, a series of interviews will be conducted with a diverse range of hospital managers and leaders within RMH (N=30) to gain insights into existing mental health programs, systems, organisational context and services for HCWs' mental health. It is likely that this group will be involved in initiatives for mental health and this interview data will provide further contextual data to inform the implementation of RMHive and its Impact Evaluation.

Content creation

Video content will be developed by a University-based video producer working with a team of externally based creatives including film makers, animators and script writers based on the expressed needs and specific questions posed by HCWs in the preparatory phase. This has resulted in the creative team receiving HCW approval for four planned video series. The first series of videos will feature health experts answering questions posed by HCWs working on the frontline during the COVID-19 pandemic. The second series will include animated videos developed in conjunction with Phoenix Australia, national experts in trauma informed care, that focus on resilience and coping strategies (an issue that was raised by HCWs in the preparatory phase scoping interviews). Series 3 will include short videos based on themes identified by HCWs and which take a humorous tone based on HCW feedback that they needed a mental break from the daily challenges of COVID-19. The final series will be short films that use the audio taken from the photo interviews that address HCWs need to connect with others and film makers will creatively reflect on their experiences. HCWs identified the experience of discussing their work lives and challenges as cathartic and the content creation team has engaged eight film-makers who will be asked to respond to each audio interview with a short film in an attempt to maintain a creative dialogue between the HCWs and creative team. Closing the communication loop, HCWs will then respond to the short film with a written reflection. The films and responses are both planned to appear in the app.

A team of mental health clinicians will develop information about clinical support pathways and curate existing digital and face to face mental health support services and tools to be

included in the RMHive app. These resources will match the touchpoints identified in photo interviews with HCWs. The goal is to provide targeted pathways for mental health support depending on the needs of users, in a simple, private and focused way in response to need. HCW engagement and feedback in the preparatory phase scoping interviews of the study identified that options to self-monitor mental health would be valuable. This self-monitoring is intended as a reflective point for individuals and to provide personalised engagement opportunities in the app for the user.

The mental health team determined that the Kessler Psychological Distress Scale (K10), [24] a measure of distress commonly used by general practitioners (GPs) and in mental health settings, would be a useful tool to monitor mental health within the app. Self-monitoring mental health using mobile apps is an established effective method to increase emotional self-awareness. [25] Four general health and wellbeing questions will also be provided to prompt self-reflection regarding whether they are on track or not across four domains: mood, relationships, physical health, and productivity. In the absence of an evidence-based self-tracking tool, the four general health questions were co-developed through consensus discussions with the project lead (LB) and mental health stream leads (MO'D, CJ), and the HCW advisory group. The goal was to provide a simple, self-monitoring check-in option that could be completed as often as a user chose.

In addition to self-monitoring tools, the app will include the 4 item Patient Health Questionnaire (PHQ4) as a measure of symptom burden, functional impairment and disability. The PHQ4 comprises the Patient Health Questionnaire-2 (PHQ2) for depression and the Generalised Anxiety Scale-2 (GAD2) as brief, validated subscales. [26] These questionnaires will help to establish a baseline of HCWs mental health need (e.g. Impact Evaluation question 1) and be used to identify any changes to this during and post app use (e.g. Impact Evaluation question 3).

RMHive development, beta-testing and refinement

A co-design workshop will be conducted by the app developer and industry partner, Curve Tomorrow, using Human Centred Design principles and building on the data collected from the preparatory scoping interviews, needs analysis and content creation stages. This workshop will lead to a clickable prototype of RMHive that will be used to gather additional user feedback prior to the beta-test version of the app. Curve Tomorrow will gather phone feedback from HCWs about the clickable prototype to generate the beta-test app version. The

beta-test version will be released to one hospital unit (the Emergency Department) and feedback from users will inform the refinements that are needed for the implementation of the MVP for HCW use hospital wide release.

Think- Aloud interviews [27] will be conducted with a sub-sample of users through the beta-test to inform refinements, the identification of bugs and required fixes. Think Aloud interviews are commonly used to test new products and technologies, as simulated situations and enable a user to think out loud their thoughts and feelings as they use the app in real time. [28] The Think Aloud interviews will be audio and video recorded and outcomes summarised for beta test changes and reported in the Impact Evaluation. Key themes related to usability, and perception of content will be explored. An opt-in process to participate in Think Aloud interviews will be employed.

App architecture

RMHive will be designed to be a stand-alone app and will not be integrated into existing data repositories, human resource records or electronic medical records. The RMHive app will be developed using the Ionic app development framework with a Rails backend and will function on iOS and Android operating systems. Hosting will be via the secure cloud application platform Heroku. Data entered within the app will be anonymous to the research team and only de-identified data will be provided to the research team for analysis. In the Terms of Use, app users will be asked to provide consent for the research team to make contact for Think Aloud interviews and the impact evaluation data collection. It is planned that RMHive will be incorporated as a standalone resource into the wellbeing programs and policy response at RMH as one of a suite of support options for HCWs. Industry best practice standards for Personal Health Information and Data Security will be followed. Data will be kept secure using industry-standard encryption over the wire and at rest. Regulations to host data in Australia will be followed and data security measures will comply with the Open Web Application Security Project Healthcare guidelines, Australian Privacy Act, ISO AS/NZ 27001, ISO AS/NZ 27017, ISO AS/NZ 27018 and SOC2. The outcome paper will present a more detailed architecture in accordance with guidelines for reporting of health interventions using mobile phones. [29]

Implementation

The RMHive app will be implemented for HCW use hospital wide. An implementation

strategy will be developed to guide the wider hospital release and the effectiveness of this strategy in supporting engagement, adoption, integration, and future sustainability of the app into individual work and organisational culture will be reported on in the Impact Evaluation. A twelve-week Impact Evaluation period has been set following the release of the MVP to assess the uptake, engagement, use patterns, and impacts on mental health. This includes an assessment of the implementation enablers and challenges, and integration of data from design and development stages that will inform the three Impact Evaluation questions.

Participants and eligibility

HCWs in emergency and cardiology will participate in the preparatory phase and adaptive governance structures and frameworks, and the planned design and development processes. Up to 30 HCWs will provide photo-interview data and take part in deliberative workshops (including subsequent developer conducted co-design workshops) and up to 15 HCWs will participate in Think Aloud interviews to inform the beta-test. Governance interviews will be completed by up to 30 managers and leaders through the hospital. For wider release and implementation, all HCWs at RMH will be able to access the app and download it for use. Users will be provided an access code. In terms of understanding use and engagement with the app, 20% of HCWs who use the app for at least 7 to 30 days will be invited to participate in a Think Aloud interview. For the identification of mental health need and impacts of the app use on HCWs mental health, only data collected from the MVP stage will be included.

Sample size

Up to 10 000 HCWs at RMH will have access to the RMHive app. Our sample size for app users is calculated on an anticipated minimum rate of 10% of total staff downloading RMHive (n=1000). Of this, 50% may go on to use the app (n=500) and of this, a further 50% are anticipated to cease using the app within the first five days (n=250). Of the 250 remaining users beyond five days, an additional 30% are anticipated to continue using the app for 7 days or more (n=175) and a further 50% are likely to use the app for the full 30 day use period is expected (n=87). These figures are based on download and use patterns reported in other health related mobile apps. [30]

Harms

As the RMHive app development process will involve discussions and content about mental health and work challenges, there may be some risks to participant wellbeing. A protocolised participant distress response has been developed to support the needs of participants, and study communications will provide avenues to national and institutional support services. While RMHive is being developed to support HCW mental health, the MVP is not a clinical or triaging tool, and will not be developed to treat clinically determined symptoms of mental illness for this stage. Participants will be informed of this and will be encouraged both within the app and in study communications to seek further professional help if they feel their mental health and wellbeing needs warrant it. Some of the messages and advice within the app will be tailored to mental health screening outcomes (PHQ2 and GAD2) and provide directions to seek assistance where this is warranted. Recommended actions for K10 results for self-monitoring will be included to guide access to professional support services. Support information will be made available in study communications through the research and development process and within the app.

Impact Evaluation procedure

Conceptual framework

The RMHive development process will use EBCD concepts to embed the lived experience of HCWs within the app content and features, and adaptive governance frameworks to share power arrangements and decision-making in the co-design and implementation. This means that HCWs are embedded at all stages and processes. It is anticipated that the integration of HCW perspectives using an EBCD and adaptive governance approach will increase the engagement and ongoing use of the RMHive app and subsequently lead to sustainability for organisational use. Additionally, developmental processes that seek to engage and understand organisational governance efforts will increase the ability for RMHive to be presented as a key component of the health and wellbeing strategy across the organisation. The success of this integration and support from governance stakeholders will be evaluated with attention to the adaptive governance framework underpinning the research collaboration. [19]

Impact Evaluation questions

The three Impact Evaluation questions are outlined again in Table 1 alongside the data sources to inform these questions, and the reporting or analytical framework proposed to

answer the question. Further explanation of the planned analyses for data sources are then described.

Table 1. Impact Evaluation questions, data sources and planned analysis

Impact Evaluation question	**Data sources**	**Analytical Focus and/or Framework**
1) What is HCWs' engagement with RMHive? (including use patterns, perceptions of content, and overall level of engagement)?	- Change log from beta-test to Minimally Viable Product (MVP). - User demographics and mental health baseline measures (PHQ4, PHQ2, GAD2, K10 self-monitoring and general health self-tracking questionnaires). - App analytics data (bounce rates and patterns of use including total time using, and content use). - Qualitative Think Aloud semi-structured interview text and video data from beta-test and implementation phase.	- Descriptive overview of beta-test engagement and content changes. - Descriptive statistics on user demographics (age, gender, profession), mental health baseline scores and averages, K10 first completion averages. - Number of app downloads, use patterns, content accessed. Patterns of content engaged with, number of videos watched, time spent on content (where possible). - Thematic analysis of Think Aloud interviews text content examining (a) user perceptions of the app and content; and, (b) video analysis for app usability and feature engagement (attention to facial gestures, body language and user workflow). This data will be considered against the touchpoints identified in the photo-interviews and deliberative workshops to evaluate the question of whether the app meets HCWs needs.
2) What contextual, socio-technical, organisational and individual features support or hinder implementation?	- Qualitative governance interview data with leaders in the hospital setting. - Touchpoints that emerged from the photo-interviews and deliberative workshops during design and development that were related to contextual, socio-technical, organisational and individual barriers and	- Normalisation Process Theory using the four NPT constructs to code interview, mapping and brief survey data according to: coherence (understanding of the problem – how people make sense of HCW mental health needs and wellbeing, and the role of a mobile app in providing support), cognitive participation (engagement – how is the new technology driven forward, who buys in

Impact Evaluation question	Data sources	Analytical Focus and/or Framework
	facilitators for implementation. Review of available mental health and wellbeing programs at the hospital. - Qualitative Think Aloud semi-structured interview text and video analysis. - Web-based implementation survey of team leaders, managers and other appropriate staff distributed via hospital contacts.	to this and how is practice sustained), collective action (integration of new technology, skill-set fit, integration of new technology, what work is done to operationalise and contextually execute new technology) and reflexive monitoring (how do groups and individuals start to assess whether new approach or practice is working and what reconfigurations are undertaken by them to embed change). - Identification of themes at the different levels in qualitative interview data and deliberative workshop related to what supports or hinders app implementation and integration, these will also be mapped to NPT where appropriate. - Summary findings from brief survey of managers and team leaders regarding the implementation of the mobile app.
3) What are the identifiable impacts on individual HCW's mental health through app adoption, implementation and use?	- User demographics and mental health post app use measures for depression, anxiety and overall PHQ4 mental health. - Self-monitoring data using K10 for psychological distress - General health self-tracking questions: physical activity, relationships, productivity and wellbeing.	- Age, gender, professional role where available. Pre PHQ2, GAD2 and overall PHQ4 scores compared with post app use scores (defined as 30 days or last mental health entry on screening questionnaires). - K10 self-monitoring scores first time of app use and last user completion. - First and last entry of self-tracking general health questions. - Case studies of patterns for K10 and the four general questions will be possible for further exploration of user mental

Impact Evaluation question	Data sources	Analytical Focus and/or Framework
		health patterns over time if relevant.

Data analysis plan

Use patterns (Impact Evaluation question 1 and 3)

Participation rates (e.g. total app downloads and bounce rates) and demographic summaries of age, gender and profession will be provided using descriptive statistics. User analytics will be described in terms of time using the app; engagement with video content (yes or no responses to whether content was helpful or not); frequency of accessing individual elements of the app; time spent watching video content; links to mental health support services; and number of uses within the evaluation period. The presentation of the technological aspect of RMHive development and implementation will follow the mobile health (mHealth) evidence reporting and assessment (mERA) reporting guidelines. [29] The user analytics overview is presented in supplementary Table 1.

Engagement with the app, perceptions of content and meeting mental health needs (Impact Evaluation question 1)

The photo interview and deliberative workshop text will be thematically analysed using Braun and Clarke's approach, a theoretically flexible analysis method for qualitative data that draws out common patterns from the data that relate to the research question/s. [31] This will enable themes related to mental health need from the needs analysis to be noted and considered against themes that may emerge from the discussion of use and content in the Think Aloud interviews through the beta-test and implementation of the MVP. Video analysis will examine body language, facial expressions and discomfort or comfort in use of the app to explore engagement with the app. Voice tone will be considered for user engagement.

Contextual, socio-technical, organisational and individual factors affecting implementation (Impact Evaluation question 2)

The dynamic influence of contextual, socio-technical organisational and individual factors and their impact on the implementation of and engagement with RMHive will be assessed by using Normalisation Process Theory (NPT) [32] and the mERA reporting guidelines. [29] NPT is an implementation science theoretical framework that is used to evaluate the success of implementation through a focus on actions rather than beliefs or intentions. [32] NPT is comprised of 4 key constructs: *Coherence* which relates to the level of understanding people have about an intervention and the ways they make sense of new practices or technologies;

Cognitive Participation describing the level of engagement and commitment people have to an intervention and ways they start to embed or sustain a new practice or technology; *Collective Action* that explores how well an intervention integrates with an organisation's goals and activities, socio-technical workflows and compatibility with existing practices; and *Reflexive Monitoring* that relates to engagement in the appraisal and monitoring of the intervention and outcomes, including the extent to which individuals and groups reconfigure their practice to sustain new practices or technologies [33] The NPT framework will be applied specifically to governance interview content, the brief implementation survey and to assess the implementation strategies developed for MVP release. If there are relevant contextual or organisational themes identified from photo-interviews and the beta-test phase Think Aloud interviews, these will be coded to the NPT constructs also to support this analysis. Implementation leads (managers, team leaders and HCW members of the project team) will be provided with a link to an online based survey to identify awareness of RMHive, use and any notable barriers or challenges that have been experienced. The facilitators and barriers of RMHive uptake will be examined at an individual level through engagement with app users, and at an institutional level through ongoing governance interviews with respondents in management roles within RMH and the broader socio-cultural context. mERA will be used to describe further technical implementation. [29]

Impacts on mental health (Impact Evaluation question 3)

The Impact Evaluation will examine the profile of HCWs using RMHive, how RMHive is being used by HCWs through user analytics, and how the self-reported mental health of HCWs changes over the evaluation period.

On using the app for the first time, RMHive users will be prompted to establish a user profile and enter baseline data including the PHQ 4 including the PHQ2 and GAD2 subscales. The RMHive app will capture broad demographics including age range; gender; whether the person is in a leadership position, and broad professional group (allied health; medical; nursing; administrative; environmental services; other). Additionally, users will be prompted to enter subjective general health ratings of their mood; physical health; productivity; and relationships on a 3 point scale (on track; neutral; not on track). Descriptive statistics will be used to summarise socio-demographic and professional characteristics of participants, mental health responses, and subjective ratings collected at baseline and last completed measure. For continuous data with a skewed distribution, medians and quartiles will be used instead.

The PHQ4 [26] will be the primary study outcome as an indicator of symptom burden, functional impairment and disability and RMHive users will be prompted to complete the PHQ4 at baseline, day 14 and day 28. The PHQ4 consists of the 2 item Generalized Anxiety Disorder scale (GAD2) anxiety subscale and the 2 item Patient Health Questionnaire (PHQ2) depression subscale. The PHQ2 assesses the presence of symptoms of depression over the last two weeks using a four-point Likert scale (0=Not at all, 1=Several days, 2=More than half the days, 3=Nearly every day). Total scores are calculated by summing the two items, and range between zero and 6. The GAD2 assesses the presence of generalised anxiety symptoms over the past two weeks using a four-point Likert scale (0=Not at all, 1=Several days, 2=More than half the days, 3=Nearly every day). GAD2 has been determined to also indicate post-traumatic stress. Scores above 3 on each subscale will indicate symptoms of depression or anxiety [26, 34, 35]. The two subscales results will be reported individually, and then summed to generate a PHQ4 score which can range from 0 to 12, with higher scores indicating an increased likelihood of underlying depressive or anxiety disorder.

Users will be provided with access to the 10 standard item Kessler Psychological Distress Scale (K10) for self-monitoring upon completing their profile in the RMHive app. Respondents are asked to indicate how often in the past four weeks they have experienced certain symptoms (e.g., nervousness, hopelessness, fatigue, agitation, and depressed mood), using a five-point Likert scale (where 1=‘not at all’ and 5=‘all the time’). The total K10 score is the sum of the 10 items, ranging from 10 to 50, where higher K10 scores indicate greater higher psychological distress. If one item on the K10 is missing a response, the missing values will be substituted with the mean response of the completed items, otherwise the total score will be coded as missing. Users will be able to self-monitor their emotional state at any time and will receive reminder prompts on day 2, day 5 and then weekly through app use. Completion of the K10 will be optional throughout the study and users will be asked about the benefits or otherwise of having access to the K10 for self-monitoring in Think Aloud interviews for the wider release. K10 results will be reported using first and last completion of the measure by users. Sub-analyses will be explored based on developing user case studies to examine over time outcomes and self-monitoring trajectories.

Primary analysis will involve repeated measures ANCOVA of the PHQ4 and subscale scores from baseline to day 14 and day 28. For users where there is only baseline data, this will be used to inform the question of overall mental health need of HCWs. For users who enter data at baseline, and again at both or either day 14 and day 28 these time points will be reported as baseline, middle and post use. For users with only two completed PHQ4 scores these will be

reported as pre and post. Analysis will progress will existing data at each time point. For the secondary analysis, linear regression will be used to estimate the difference in mean change from baseline in the mean K10 emotional state tracking and last use of K10.

Data handling

De-identified data with unique record identifiers for each participant will be extracted from the data collection system in the form of comma-separated value (CSV) data files. All research data will be stored in a de-identified format and will only be accessible to named research team members involved in the analysis process approved by ethics. Data transfers from the app to the evaluation team will be conducted weekly through the beta-test and following the MVP release as CSV files. The project manager will then download the CSV data files. The project manager will then save the dummy-coded files to the central password-protected University system where they will be stored securely and backed up regularly. Aggregate user analytics will be extracted using Firebase and queries analysed through Google Analytics and exported to CSV files for reporting and analysis. The data manager will then import the CSV files into Stata 15 [36] for data processing and statistical analysis. Data will be checked to identify and where possible resolve errors prior to analyses being conducted. Steps will include labelling the variables and values, creating composite variables and creating the total scores according to the instrument's guidelines. Datasets will be merged using the unique identifier (UID) generated for each participant. De-identified data will be stored on password protected university servers with access limited to the research team for future use in accordance with the National Statement on Ethical Conduct in Human Research. [37]

Results

The RMHive program of work received funding in June 2020 and institutional ethics approval on the 9th of June, 2020. Governance structures and committees were implemented in June and data collection commenced in July. The Impact Evaluation will continue from design, development and implementation up to mid-February 2021. It is anticipated that study outcomes will be published mid-2021.

Discussion

The adverse impact of pandemics on the mental health of HCWs has been well established [2, 3] and prior research has established that mental health supports that address the needs of HCWs are required. [13] To date, the majority of mental health support tools for HCWs addressing pandemics have not incorporated the lived-experience of end users in their development or implementation. [13] This may be a reason for the limited uptake and engagement with mobile apps. Mental health support tools developed and deployed in a compressed timeframe and without an understanding of the lived experience of HCWs and their mental health needs carry an increased risk of not being delivered in a format that is readily accessible, desired, or ultimately, used by HCWs. RMHive seeks to address these risks by using EBCD to support clinicians and researchers working together in a process of shared decision making and co-design leading to an app that centres the lived experience of HCWs as a basis for responding to their mental health needs. [10] In doing so, this extends the HCD approach further to ensure active co-design by people with lived-experience and shared power.

The RMHive app is further supported by an Impact Evaluation that will provide critical insights into the contextual, socio-technical, organisational and individual factors that contribute to its implementation, engagement, and use. The Impact Evaluation [38] will expand current digital health frameworks by providing new insights into how EBCD processes inform the design, development and implementation of an app directed toward addressing HCW mental health needs. In keeping with the Impact Evaluation method, a theory of change will be produced from the evaluation to inform the future roll out and wider use of the app as a possible mental health and wellbeing intervention or support program. The impact of RMHive on HCW mental health outcomes will also be assessed. It is recognised that in this evaluation we are only focusing on near impacts of the RMHive app within the implementation context, and it is possible that the evaluation timeframe may not be sufficient for longer-term individual and organisational level changes to be observed.

To our knowledge, RMHive is the first mobile-app developed using EBCD to support the mental health of HCWs in response to a pandemic. It is hoped that RMHive will be a valuable support through the COVID-19 pandemic for HCWs who are experiencing increased challenges to their mental health and wellbeing. The Impact Evaluation outcomes will provide a valuable addition to local and international efforts to support HCWs mental health through the deployment of digital mental health tools that can be rapidly co-designed and

scaled in response to major events such as a global pandemic.

Acknowledgements

The authors would like to acknowledge Ms Roxanne Kritharidis and Ms Maria Potiriadis for providing research support to this study. The COVID Digital Asset (COVIDDA) program of work encompasses the RMHive app and is supported by a healthcare worker advisory group and an implementation group comprised of stream leads and health care worker representatives from the hospital. Additional support was provided by the Executive Steering Committee and the Digital & Mental Health Advisory Group.

Funding source

This research was funded by a grant from the Australian Government Department of Health, the Peter Doherty Philanthropic Advisory Group, Royal Melbourne Hospital and The University of Melbourne. The funders had no input into the preparation of this manuscript and will not be involved in analyses for its outcomes.

Conflicts of interest

No conflicts of interest have been identified.

Abbreviations

COVIDDA	COVID Digital Asset
CSV	comma-separated value
EBCD	experience-based co-design
GAD2	Generalised Anxiety Scale 2 item
HCD	Human Centred Design
HCWs	Health Care Worker
K10	Kessler Psychological Distress Scale
mERA	mobile health (mHealth) evidence reporting and assessment
MVP	minimally viable product
NPT	Normalisation Process Theory
PHQ4	Patient Health Questionnaire 4 item
PHQ2	Patient Health Questionnaire 2 item
RMH	Royal Melbourne Hospital
UID	unique identifier

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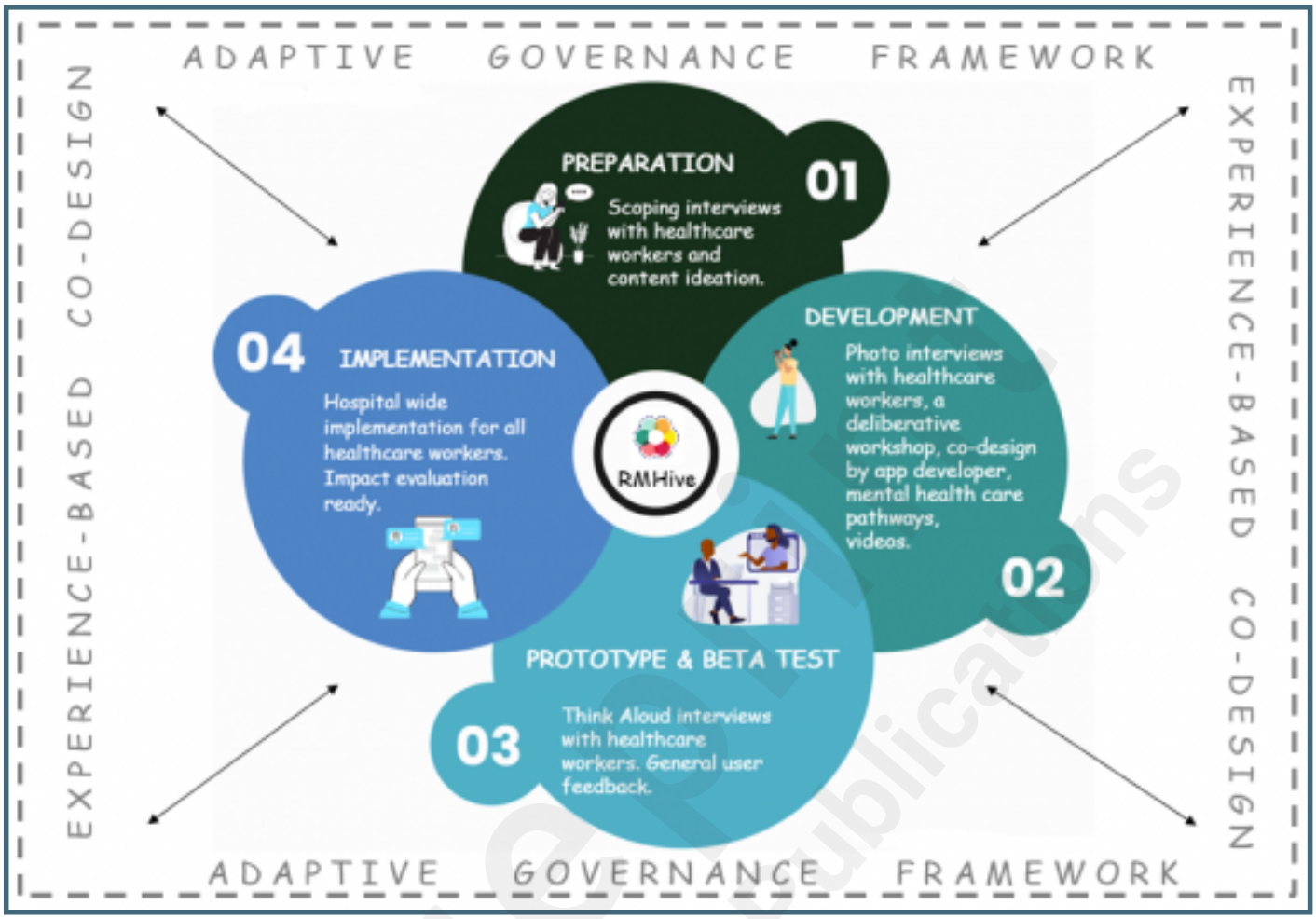
Supplementary Files

Figures

Planned design, development and implementation framework for RMHive.



Multimedia Appendixes

Supplementary Table 1. Overview of user analytics plan.
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