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Health Information Technology System ("Roadmap 2.0") in the Context of Hematopoietic Cell Transplantation

MULTISITE ROADMAP 2.0 INTERVENTION

Protocol UMCC Number: 2019.106
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Principal Investigator: Sung Won Choi, MD, MS
1500 E. Medical Center Drive, D4118 MPB
Ann Arbor, MI 48109-5718
Phone: 734-615-5707
Fax: 734-615-0464

Coordinating Site: University of Michigan

Participating Sites: University of Michigan
Oregon Health and Science University
University of Minnesota

Biostatistician: Thomas Braun, PhD

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PROTOCOL SYNOPSIS

A RANDOMIZED TRIAL OF ROADMAP 2.0

Principal Investigator: Sung Won Choi, MD, MS

Study Design: This is a prospective study to investigate the use of a mobile health technology-mediated intervention in caregivers and patients undergoing allogeneic/autologous hematopoietic cell transplantation (HCT). The study will use a two-arm randomized controlled design. Each of the participants will be randomized to an active intervention arm or to a control arm. The random allocation of participants to the intervention arm or control arm establishes the basis for testing the statistical significance or difference between the groups in the measured outcome (caregiver health-related quality of life [HRQOL], assessed by the PROMIS Global Health scale).

Primary Objective: The primary objective is to test the statistical significance or difference between the intervention arm and the control am in the measured outcome of caregiver HRQOL, assessed by the PROMIS Global Health scale, at day 120 post-HCT.

Exploratory Objectives: Exploratory objectives will be to assess: i) caregiver and patient HRQOL, as assessed by PROMIS measures: Profile 29+2, Companionship, Self-Efficacy for Managing Symptoms, Self-Efficacy for Managing Daily Activities, Positive Affect and Well-Being, and Emotional Support; ii) caregiver and patient HRQOL, as assessed by the Perceived Stress Scale; iii) patient (ages 8-17 years) and parent proxy for pediatric patients (ages 5-17 years) HRQOL, as assessed by measures of PROMIS Sleep Disturbance and Profile 25; iv) physical activity through physiological data capture using the wearable sensor; v) health care utilization (i.e., total count of hospital days, ED visits, readmissions, and ambulatory care clinic visits);vi) overall survival within the first 120 days post-HCT; vii) the overall feelings and helpfulness of the app measured through the MARS survey and qualitative interviews and; viii) the understanding of how circadian rhythms through the social rhythms app affect health and wellbeing; IX) caregiver and patient HRQOL, as assessed by Resilience, Optimism and Gratitude scales; X) caregiver and patient negative and positive dyadic interaction, as assessed by measures of the Dyadic Relationship Scale.

Eligibility Criteria: Caregivers (age ≥ 18 years) of patients undergoing allogeneic or autologous HCT; patients (age ≥ 5 years) who meet eligibility to undergo allogeneic/autologous HCT. Caregivers must be able to read and speak English, agree to participate as caregiver-patient dyads, and sign informed consent and assent forms. Caregivers and patients must possess his/her own smartphone or tablet to participate.

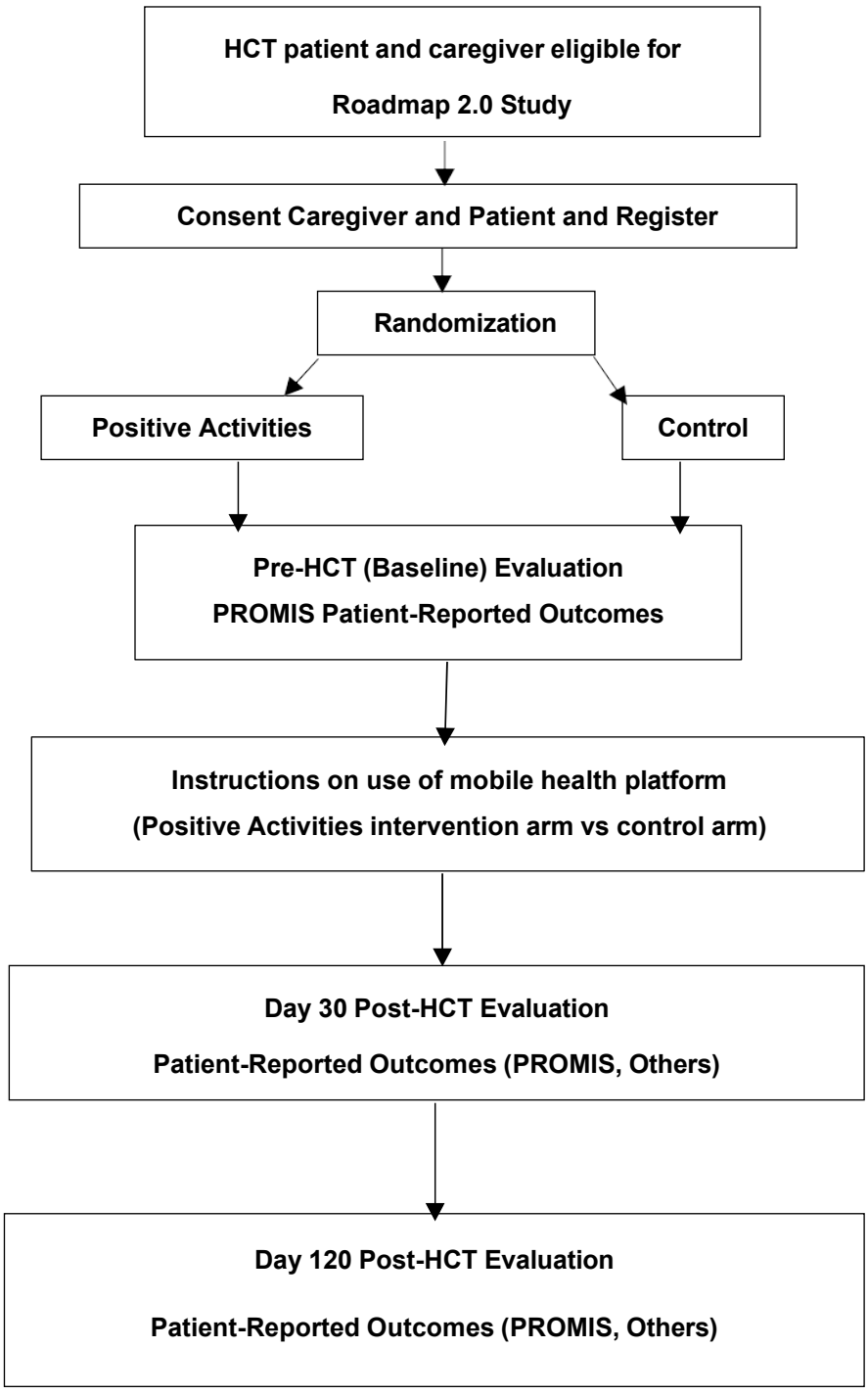
Treatment Description: The participants (caregiver-patient dyads) will be randomized to an active intervention arm (mobile platform + Positive Activities) or to a control arm (mobile platform + control). Blocked randomization will be used to limit bias and achieve an equal distribution of participants to the control and treatment arms. The study (intervention vs control) will be delivered from the time for admission of the patient's HCT through day 120 post-HCT. Participant data will be collected pre-intervention (baseline), during the intervention (day 30 post-HCT), and at the end of the intervention (day 120 post-HCT).

Intervention arm (Positive Activities): Caregivers and patients randomized to the treatment arm will be instructed on how to operate Roadmap 1.0 on an iPad (Michigan inpatients only) and Roadmap 2.0 (with Positive Activities for caregivers only) and Social Rhythms app on a mobile phone or tablet (inpatient and outpatient), download the app on the mobile device or tablet, be provided an access code, and to use Roadmap 2.0 with Positive Activities freely throughout the intervention period. The caregiver will receive a wearable sensor device (Fitbit); the patient will receive a wearable sensor device (Fitbit). The caregiver will download the Roadmap 2.0 app with Positive Activities, the patient will download the Roadmap 2.0 app without positive activities. Both the caregiver and patient will download the wearable sensor device (Fitbit) app onto their mobile phones or tablet. Both the caregiver and patient will download the Social Rhythms app and perform uploads at the survey intervals; baseline, day 30, and day 120.

Control arm: Participants will receive usual care only, defined as standard-of-care information provided according to institutional guidelines. The caregiver and patient will download the Roadmap 2.0 app without the Positive Activities and the caregiver and patient will also each receive a Fitbit device. Both caregiver and patient will download the wearable sensor device (Fitbit) app onto their mobile phones or tablet. Of note,

	neither caregiver or patient in the control arm will receive Roadmap 1.0. Both the caregiver and patient will download the Social Rhythms app and perform uploads at the survey intervals; baseline, day 30, and day 120.
Accrual Objective:	We will enroll a total of 300 caregiver-patient dyads (600 participants). The study will enroll a total of 40 pediatric dyads, which will consist of pediatric patients (age 5-17 years) and their adult caregiver (age ≥ 18 years). Pediatric dyads will account for 80 subjects. Adult patients (age ≥ 18 years) undergoing HCT and their caregivers (adult dyads), will account for 260 of the 300 planned dyads (520 subjects). At least 166 adult dyads will be allogeneic HCT recipients.
Accrual Period:	The estimated accrual period is 5 years.
Study Duration:	Participant intervention will be followed for 120 days post-HCT. Subjects will remain in follow-up for 1 year post-HCT. The study team will have access to the electronic medical records for 1 year post-HCT.

STUDY SCHEMA: SCHEDULE OF EVENTS



TIME AND EVENTS TABLE

	Pre-HCT	Post-HCT	
	Prior to Admission to Transplant Unit	Day 30	Day 120
Deemed eligible to undergo HCT by the Institutional Transplant Teams	X		
Consent to Study	X		
Training of wearable senor; download app	X		
Training of Roadmap 2.0 and Social rhythms app; download app (if randomized to intervention arm)	X		
Questionnaires	X	X	X
Social Rhythms	X	X	X
Qualitative Interviews*	X	X	X

Intervention Arm vs Control Arm

INTERVENTION ARM

USUAL CARE:
Routine patient care ("usual care") provided by usual means = laboratory studies, medications, health care providers, clinical trial information delivered through verbal communication and/or handwritten materials during inpatient rounds or routine clinic visits

WEARABLE SENSOR (Fitbit):
Caregiver and Patient download wearable sensor app onto each of their own mobile phones/tablet (iOS, Android) to track activity and sleep

ROADMAP 1.0 (Michigan Medicine only):
Caregiver iPad (inpatient only) *

ROADMAP 2.0:
Caregiver downloads Positive Activities Components onto her/his mobile phone/tablet (iOS, Android) to use freely throughout inpatient and outpatient (through day 120 post-transplant). The patient also downloads the Roadmap app, but will only see the control version of the app.

Social Rhythms:
Both patient and caregiver will use this app to upload retroactive Fitbit data.

CONTROL ARM

USUAL CARE:
Routine patient care ("usual care") provided by usual means = laboratory studies, medications, health care providers, clinical trial information delivered through verbal communication and/or handwritten materials during inpatient rounds or routine clinic visits

WEARABLE SENSOR (Fitbit):
Caregiver and Patient download wearable sensor app onto each of their own mobile phones/tablet (iOS, Android) to track activity and sleep

ROADMAP 2.0:
Caregiver and Patient will download Roadmap 2.0 app but will only have access to component D of the app. (See appendix B of the protocol).

Social Rhythms:
Both patient and caregiver will use this app to upload retroactive Fitbit data.

1.0 BACKGROUND AND SIGNIFICANCE

1.1 Public Health Impact of Caregiving

Millions of individuals depend on family caregivers to manage their care.[1] While family caregivers are a central part of health care,[2] they often are invisible in our health care system – so much that they are sometimes referred to as "hidden patients."[3] The economic value of unpaid hours of care by family caregivers was estimated at $470 billion in 2013, and their contributions continue to intensify.[4] Indeed, with the aging population in the U.S. and the rising need for caregivers, efforts to foster caregiver health and well-being are essential for sustaining long-term care.[5] Caregivers assist patients with a wide range of activities, including managing complex medical tasks, organizing care plans, and advocating on their behalf.[3] These demands are time- and labor-intensive and they place caregivers at high-risk for injury and adverse events.[3, 6-8] Addressing the needs of at-risk caregivers is an urgent public health priority.[1]

1.2 Caregiving in the Clinical Context of Hematopoietic Cell Transplantation (HCT)

HCT is an intense, but potentially curative therapy for a number of life-threatening blood diseases.[9] Given the high-risk associated with HCT, a dedicated caregiver is necessary and expected for at least the first 100 days post-transplant.[10] However, HCT caregivers are often unprepared for this role; it is not surprising that HCT caregivers experience significant levels of anxiety and distress, especially during the peri-transplant period.[11, 12] Psychoeducational, skills training, and therapeutic counseling interventions have been shown to benefit caregiver health and well-being.[13] However, major barriers in translating successful interventions to clinical practice have included: **i)** limited understanding of the mechanism of action of an intervention, and **ii)** need for expert trainers, intensive training, and monitoring.[3] Interventions that are mechanism-focused, low-cost, and sustainable are needed.[14]

1.3 Mobile Health Technology to Support Caregiving Efforts in a Scalable Manner

Our ability to capture the hazards of caregiving (i.e., adverse physical and mental health consequences)[15] accurately and in real-time has been limited by assessments that have traditionally relied on long-term recall and self-report of symptoms. Mobile health technology remains relatively new in the clinical research space, but it is spreading quickly, and its costs are declining.[16] It can serve as a platform for delivery of multi-component interventions as well as capture of continuous, real-time measures (e.g., sleep, physical activity). The extreme BMT setting[17] provides an ideal 'model' to rigorously test a mobile health intervention due to: **i)** high level of engagement by BMT caregivers; **ii)** intense and rapidly evolving caregiving needs of medically fragile patients; and **iii)** long hospital course followed by frequent outpatient follow-up that allow for high-resolution data collection with minimal additional burden.[18]

1.4 Conceptual Framework to Address the Positive Aspects of Caregiving Efforts

Caregiver burden is defined as the "negative reaction to the impact of providing care on the caregiver's social, occupational, and personal roles."[19] Much focus has been placed on the wide range of *negative* implications associated with caregiving[20] (e.g., depression, anxiety).[21] Despite this, a majority of caregivers have recognized the benefits of caregiving.[22, 23] The imbalance of focusing primarily on negative aspects may limit our ability to develop new assessment and intervention methods.[24] Thus, a 'corrective focus' is needed in caregiving research to expand our knowledge on the *positive* aspects of caregiving.[25, 26] Research on self-management suggests that self-efficacy, a positive aspect, can promote caregiver health, well-being, and positive health behaviors (i.e., improved sleep and physical activity).[27, 28] Carbonneau's evidence-based conceptual framework on the positive aspects of caregiving suggests that self-efficacy may be correlated with a caregiver's ability to positively perceive the caregiving role.[29]

1.5 Positive Activity Interventions to Highlight the Positive Aspects of Caregiving

The positive aspects of caregiving, such as self-efficacy and positive attitudes toward the caregiver role, may explain how caregivers can positively engage patients in self-care activities.[30] Caregivers with better self-efficacy and well-being (e.g., health-related quality of life [HRQOL]) may positively impact patients' health outcomes.[31-33] Simple strategies aimed at enhancing positive thoughts, emotions, and behaviors have been shown to be effective and highly scalable.[34-36] Positive activity interventions, such as daily positive reflection, gratitude journals, and conducting acts of kindness, have been used in heart disease, cancer, diabetes, and chronic pain.[37-42] Our preliminary data suggest that BMT caregivers desire these activities to reduce stress and improve well-being.

1.6 Biomarkers Relevant to Caregiving Efforts

Caregivers experience significant stress, anxiety, and poor sleep that lead to physiological changes.[43] Indeed, long-term caregiving has been associated with increased physical morbidity.[44] While caregiver interventions have been shown to reduce emotional distress and increase well-being in caregivers,[45] less is known about the impact of physiological changes on caregiver health and well-being.[15] Caregiver assessments have relied on snapshot self-report measures (i.e., patient-reported outcomes [PROs]).[46] Recent advances in wearable sensors facilitate non-invasive collection of continuous, real-time measures (e.g., sleep, physical activity). These highly time-resolved, *objective* parameters correlated with *subjective* PROs may help us identify the mechanism of action of an intervention. Further, newer data science techniques may enable data patterns, relationships, and interpretation in ways that were not previously possible.[47]

1.7 Study Rationale

The scientific premise of this protocol stems from the literature presented in the Background and Significance and the large body of prior work by the study PI and Co-Is who have extensive experience examining the information needs of BMT caregivers and patients. An intensive ethnographic study conducted over nearly three years in the adult HCT population showed that caregivers gain most of their knowledge of the HCT care process via *scaffolding*, a process by which health care providers (e.g., nurses, physicians) progressively guide caregivers to perform new or difficult tasks.[48, 49] Importantly, the execution of safe health care practices by HCT caregivers requires support from the health care team, health care system (institution), and the community (social resources).[49] The transition from hospital to home heightens caregiver anxiety, particularly as responsibility for routine medical tasks, previously performed by nurses (e.g., line care, dressing changes, administration of medications), shift to the caregiver.[49] The risks of life-threatening events, such as line infections, are substantial.[50]

HCT caregivers at the University of Michigan were engaged in a project that aimed to improve patient safety by implementing bundled checklists performed by health care providers; this ultimately led to significant reductions in central line infections.[51] Patient, caregiver, and health care provider focus groups also were conducted to discuss how to better educate future caregivers and patients about BMT; these discussions revealed their desire to be active participants in research, supporting today's emphasis on family-centered care.[52-54] Specifically, caregivers and patients expressed a need for more information and support throughout the BMT trajectory.[50, 52] Additional qualitative research in the form of *observations, interviews, and artifact collections* showed that technology could support caregivers at three levels: **i)** institutional scaffolding and navigating the health care system; **ii)** managing day-to-day caregiving tasks; and **iii)** transitioning to the outpatient/home setting.[55] These data led to an R21-funded project directed by Sung Won Choi (PI) who developed BMT Roadmap via methods in human-computer interaction.[56]

1.8 Roadmap 1.0 Development

The app was developed on an iPad tablet as a multi-component mobile app to provide patient-specific information, education, and skills- building exercises for caregivers (**Table 1**).[48-52, 55-57] Patients, caregivers, and health care providers participated in *iterative cycles of user-centered design, development, and testing*. To date, >80 BMT caregivers have enrolled in IRB-approved studies to assess the feasibility of implementing BMT Roadmap.[58] PROs were collected at baseline, discharge, and day 100. The most viewed modules were laboratory results and medications.[59-63]

Table 1. BMT Roadmap Components

Patient-Specific Informational Resources	
Disease Characteristics	Infectious disease markers, blood type, donor type, donor characteristics, BMT regimen
Laboratory Studies	Results of laboratory studies updated in real-time
Medications	Medication list grouped according to indication (i.e. antibiotic, anti-emetic), dosing and schedule
Clinical Trials	Easy-to-read description of clinical trials and copies of consent
Provider Directory	Photos of healthcare providers in yearbook style
Patient-Specific Educational Resources	
Glossary	Commonly used words/terms and definitions used in the BMT journey
Phases of Care	Roadmap metaphor with detailed description of each phase of BMT
Symptoms/Side Effects	Description of commonly reported medication side effects
Patient-Specific Skills Building	
Videos	Video modules of central line care, dressing changes, cleaning, bathing
Discharge Checklist	Interactive list of 9-item discharge criteria to assess "Readiness"

Roadmap 1.0 Use. The app was rated highly useful and easy-to-use;[59-64] caregiver anxiety[65] decreased; caregiver well-being or HRQOL[66, 67] improved; and caregiver activation[68] was increased at discharge compared with baseline.[59] *Following memos and coding for content analyses*, major themes emerged, including: **i)** Roadmap usefulness, ease-of-use, and likeability; **ii)** positive aspects of caregiving (e.g., benefits); and **iii)** desire to expand BMT Roadmap directed to the caregiver with 'caregiver-specific resources' and 'positive activities' components (**Table 2**).[59-64, 69]

Table 2. Caregiver-Specific Resources and Positive Activities Components

Caregiver-Specific Resources	
Peer-to-Peer Contact	BMT Roadmap to connect families; Resource links to BMTInfoNet or nbmtLink to connect families
Coping Techniques	Instructions on self-care, meditation and relaxation techniques (positive coping skills: write, draw, paint)
Intrinsic Motivation	Instructions to help caregivers identify goals (values framing)
Physical Activity Tips	Instructions of exercises varying in intensity; walking/jogging courses
Healthy Sleeping Tips	Instructions on healthy sleeping principles (sleep journal)
Caregiver-Specific Positive Activities	
Positive Piggy Bank	Every evening, the family caregiver (CG) will think about the things that made him/her happy; write down one of these moments on a piece of paper, fold up the piece of paper and drop in piggy bank. At the end of 30 days, CG will "close the account" and open the piggy bank and read and savor all of the deposited memories
Pleasant Activity Scheduling	Set aside a small block of time each day for a positive activity (e.g., watching a favorite show, bubble bath, having ice cream with friend). This is an "appointment" just as serious as any other appointment.
Gratitude Journal	Every day for 30 days the CG will write down 3 things for which the CG is grateful – 3 new things/day.
Random Acts of Kindness	One day of the week, do 5 acts of kindness – including something kind for oneself. Self-care is important (e.g., bubble bath, massage, walk in park, popsicle)
Savoring	CG will be asked to spend a few minutes each day savoring two everyday experiences (e.g., coffee, sunshine, call from friend). CG is to be mindful while savoring the experience and use all of the senses to solidify the memory.
Signature Strengths	CG will identify the top 7 character strengths using a brief questionnaire (e.g., kindness, creativity, perseverance, bravery, intelligence). The CG will use one of these strengths in a new way every day over a week.

1.9 Positive Activity Interventions

Positive activity interventions have been developed to improve well-being (i.e., HRQOL) and physical health through well-studied constructs (e.g., positive daily reflection,[37, 40, 70, 71] gratitude,[38, 39, 72, 73] savoring[74]). To assess caregiver interest and opinions about these interventions, we conducted semi-structured interviews with BMT caregivers (N=17). Caregivers rated activities on a scale of 1–10. All the positive activities in **Table 2** were viewed as potentially useful and meaningful. The three most highly rated activities were Random Acts of Kindness, Savoring, and Positive Piggy Bank. The Positive Piggy Bank was developed and tested by Afton Hassett (Co-I). For this activity, participants reflect over a day's events and identify events that made them happy. One such event is noted on a slip of paper, savored, and then deposited in a piggy bank. After 30 days, participants withdraw the slips of paper from the piggy bank, read them, and recall the happy memories.

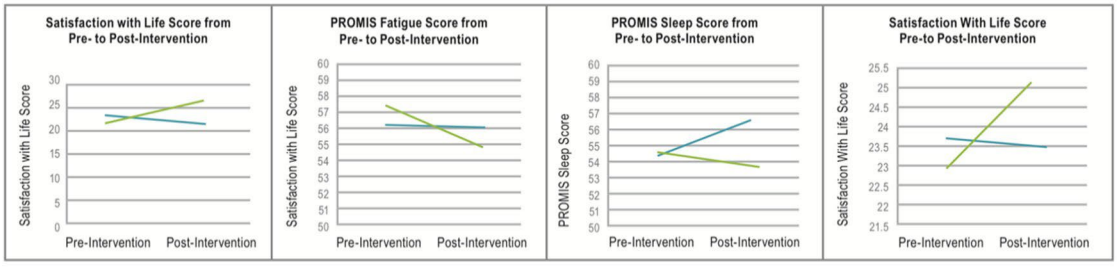


Figure 1. Positive Activity Interventions

We have two ongoing studies on the Positive Piggy Bank. In Study 1, 18 control and 16 Positive Piggy Bank intervention participants, who are generally healthy and have mild or no symptoms of depression, completed 30-day post- intervention PROs (**Figure 1**). There was a significant difference in intervention participants' satisfaction with life (p=0.021), reflecting changes in cognitive well- being. Although not statistically significant, there were general trends toward greater decreases in fatigue and sleep problems in the Positive Piggy Bank arm compared with the control arm. In Study 2, chronic back pain patients undergoing an epidural steroid injection in an outpatient setting are randomized to receive the injection and Positive Piggy Bank or the injection and standard follow-up care. In a preliminary analysis of the first 52 patients, we observed significant improvement in satisfaction with life in the Positive Piggy Bank arm (**Figure 1**, far right). In addition, 77% of participants completed slips on at least 28 of 30 days, reflecting excellent adherence.

Scientific Premise. Family caregiving is an *urgent public health issue.*[75] Advances in technology with consumer-grade platforms and sensors, high performance computing with data science, and economic trends toward family-centered medicine that reduces health care costs make this an opportune time to develop the proposed approaches. Our strong preliminary data, coupled with the need to deliver an effective intervention in one of the most vulnerable caregiver populations, form the scientific premise (**Figure 2**). Based on the literature and our team's prior work, it is logical to expand BMT Roadmap and test its efficacy in a randomized controlled trial. *Our central hypothesis is that a multi-component technology-mediated intervention with focus on the positive aspects of caregiving will improve caregiver HRQOL*.

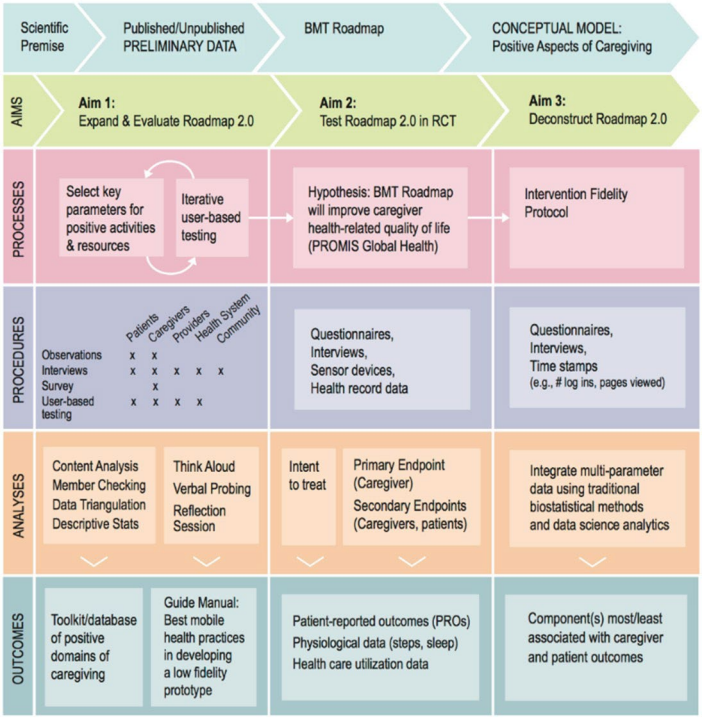


Figure 2. Scientific Premise and Study Schema

2. STUDY DESIGN

2.1 Study Overview

This study will use a two-arm randomized study design. Each of the caregiver-patient dyadic participants will be randomized to an active "treatment" arm (mobile platform + Roadmap 2.0) or to a control arm (mobile platform + usual care). The random allocation of participants to the treatment arm or control arm establishes the basis for testing the statistical significance or difference between the groups in the measured outcome (caregiver health-related quality of life, assessed by the PROMIS Global Health scale). Caregiver age, gender, and other prognostic baseline characteristics that could potentially confound an observed association, including those that are unknown or unmeasured, will be distributed equally, except through chance alone, through random assignment. Thus, this design is well-suited to our goal of assessing the efficacy of a mobile health intervention, Roadmap 2.0, on participants.

2.2 Primary Hypothesis

The primary hypothesis is that a multi-component technology-mediated intervention (Roadmap 2.0) with focus on the positive aspects of caregiving will improve caregiver HRQOL.

2.3 Study Objectives

2.3.1 Primary Objective

The primary objective is to test the statistical significance or difference between the “treatment” (Roadmap 2.0) arm and the control (usual care) arm in the measured outcome of caregiver HRQOL, assessed by the PROMIS Global Health scale, at day 120 post-HCT.

2.3.2 Exploratory Objectives

2.3.2.1 Caregiver and patient HRQOL, as assessed by the following PROMIS measures: Global Health, Profile 29+2 and 25, Companionship, Self-Efficacy for Managing Symptoms, Self-Efficacy for Managing Daily Activities, Positive Affect and Well-Being, and Emotional Support.

2.3.2.2 Caregiver and patient HRQOL, as assessed by the Perceived Stress Scale.

2.3.2.3 Caregiver and patient HRQOL, as assessed by the Resilience, Optimism and Gratitude scales

2.3.2.4 Patient (ages 8-17 years) and parent proxy for pediatric patients (ages 5-17 years) HRQOL, as assessed by measures of PROMIS sleep disturbance and Profile 25.

2.3.2.5 Caregiver and patient negative and positive dyadic interaction, as assessed by measures of the Dyadic Relationship Scale.

2.3.2.6 Caregiver and patient physical activity through physiological data capture using the wearable sensors.

2.3.2.7 Caregiver and patient health care utilization data (e.g., total count of hospital days, readmissions, and ambulatory care clinic visits).

2.3.2.8 Overall patient survival during first 120 days' post-HCT.

2.3.2.9 Obtain user experience of the Roadmap 2.0 app through the Mobile Application Rating Scale (MARS) and qualitative interviews.

2.4 Participant Eligibility

Subjects must meet all of the eligibility criteria to be enrolled to the study. Study intervention may not begin until a subject is enrolled.

2.4.1 Inclusion Criteria

2.4.1.1 The caregiver must have an eligible patient (defined in 2.4.1.5 – 2.4.1.9).

2.4.1.2 The caregiver must be of age ≥18 years.

2.4.1.3 The caregiver should be comfortable in reading and speaking English and signing informed consents.

2.4.1.4 The caregiver should provide at least 50% of care needs.

2.4.1.5 An eligible patient is one who identifies the eligible caregiver as their primary caregiver (i.e., provides at least 50% of care needs).

2.4.1.6 An eligible patient is age ≥ 5 years.

2.4.1.7 An eligible patient is scheduled to undergo HCT or recently had an HCT.

2.4.1.8 An eligible patient is able to sign informed consent/assent form or has an appropriate parent/guardian to sign on their behalf.

2.4.1.9 Patients and caregivers agree to provide informed consent that is in regulatory compliance and IRBMED-approved and also in accordance to institutional guidelines.

2.4.1.10 The caregiver and patient must have his/her own smartphone to participate.

2.4.2 Exclusion Criteria

2.4.2.1 Patient does not meet eligibility criteria to undergo HCT at any participating site.

2.5 Intervention Plan

2.5.1 How will the intervention work?

Participants (caregiver-patient dyads) who are consented, enrolled, and randomized will be scheduled for a one-hour training session with the Research Coordinator(s) prior to or during admission to undergo the HCT. Based on our experience, these training sessions will be coordinated with other clinic appointments at the hospital in efforts to minimize burden on the caregiver and patient or remotely via institutionally approved virtual meeting platform. Once the intervention has begun, the Research Coordinator(s) will meet with the participants (caregiver-patient dyad) weekly to review any questions or concerns, to perform data download (wearable sensor device), and to ensure adherence to the protocol. HCT patients are typically inpatient for approximately four weeks. During this period, the Research Coordinator(s) will be available by pager and will schedule weekly visits with the participants or virtual visits. Once discharged, HCT patients return to clinic on a weekly visit in the ambulatory care setting. The Research Coordinator will meet with participants during those routine appointments. Roadmap 2.0 software will be maintained in collaboration with Arbormoon Software, Inc.

2.5.2 Intervention arm (Roadmap 2.0)

Participants (caregiver-patient dyads) randomized to the intervention arm will be instructed on how to download the wearable sensor app on their mobile phones or tablet (iOS, Android) and how to operate the wearable sensor. Each individual (caregiver, patient) will create her/his own password. The caregiver and patient will each receive a wearable sensor device (Fitbit).

University of Michigan inpatient only: Caregivers will be instructed on how to use the Roadmap 1.0 iPad. The Roadmap 1.0 iPad includes all of the features of Roadmap 1.0 components (see Table 1 of Section 1.8). After many rounds of discussion with HITS Compliance, it was deemed safest to maintain the previous components of Roadmap 1.0 in the inpatient setting (within the firewalls of Michigan Medicine due to privacy and security of patient-related data).

Caregivers will download the Roadmap 2.0 app onto their mobile phone or tablet (iOS, Android) to use it freely throughout inpatient and outpatient (intervention) period. Roadmap 2.0 contains no patient-related information. Timestamps will be recorded of each caregiver's use of Roadmap 1.0 and 2.0 (i.e., number of log-ins and pages viewed: when and how long and in what order). Please see **Appendix A** to view the components of Roadmap 1.0 and 2.0, and see **Appendix B** to view specifications of the wrist-worn sensor.

2.5.3 Control arm

Participants randomized to the control arm will be instructed on how to download the Roadmap 2.0 (without Positive Activities) and wearable sensor app on their mobile phones or tablet (iOS, Android), and how to operate the wearable sensor. Each individual (caregiver, patient) will create her/his own password.

2.5.4 Wearable Sensor Device (Fitbit)

Each participant (caregiver, patient) will be given a wearable sensor to wear throughout the treatment period, except while in water or when charging. The goal is to collect objective, continuous, multi-parameter physiological data (e.g., total hours of sleep, sleep quality, total number of steps) on caregivers and patients throughout the treatment period to correlate with their subjective, snapshot caregiver- and patient-reported outcomes collected at three time points throughout the Intervention Period (baseline, and days 30 and 120 post-BMT). Participants will receive an instruction manual on how to charge and conveniently download data from the device. The data will be backed up to a HIPPA-secure data repository. For troubleshooting, detailed instructions will be provided for all participants, and customer support will be available 8AM – 5PM CST. Our team is available by pager after hours, if needed. Participants may use any Fitbit they may already have if they do not want to use the study provided Fitbit. Our study team will not be replacing any lost or broken Fitbit once a participant has reached Day 120 on study.

2.5.5 Social Rhythms App

Each participant will download the Social Rhythms app and upload their data at baseline (+/- 14 days), day 30 (+/- 14 days), and day 120 (+/- 30 days). At baseline, Social Rhythms will collect data starting 1 week prior to consenting. If a subject misses a Social Rhythms data upload, it will not be considered a study deviation. The Social Rhythms app is a tool developed by U-M investigators (Danny Forger PhD) that provides information regarding one's circadian rhythm based on physiological data, which could inform how they organize their schedules. The Social Rhythms app collects data in a de-identified manner, we would be able to link our participants through a Fitbit identification number that is accounted for the Roadmap 2.0 app. We first debuted the Social Rhythms app in our study in University of Michigan students and COVID (HUM00185391). See **Appendix C** for details.

2.5.6 Qualitative Interviews

Qualitative interviews may occur at day discharge (+/- 7 days), Day +30 (+/- 14 days), Day +60 (+/-14 days), Day +90 (+/- 14 days), and/or Day +120 (+/-30 days). Qualitative interviews will occur based on study team and participant choice and may include all, some, or none of the interviews for a participant.

Not obtaining qualitative interviews will not be considered a deviation. Study subjects may be asked to participate in a 20 min interview, permission will be asked to audio-record the qualitative interviews. These may be conducted in person, through video conferencing platforms (such as Zoom), or by phone. Participants will opt-in or out of being audio recorded on the informed consent document.

3.0 STUDY ENDPOINTS

3.1 Primary Endpoint

The primary endpoint is caregiver HRQOL, as assessed by the PROMIS Global Health scale, at day 120 post-HCT. To be evaluable for caregiver HRQOL, the caregiver must complete this scale at day 120 post-HCT. Caregivers of patients who relapse or die before this endpoint will not be evaluable for this endpoint; both caregiver and patient will be censored on the date the patient was last examined. See **Appendix D** for a copy of all PROMIS PROs.

3.2 Exploratory Endpoints

3.2.1 Caregiver HRQOL will be assessed by the PROMIS Global Health and Profile 29+2 scales at baseline (pre-intervention) and days 30 post-HCT.

3.2.2 Caregiver and patient HRQOL will be assessed by the PROMIS Companionship scale at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.3 Caregiver and patient HRQOL will be assessed by the PROMIS Self-Efficacy for Managing Symptoms and Self-Efficacy for Managing Daily Activities scales at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.4 Caregiver and patient HRQOL will be assessed by the PROMIS Positive Affect and Well-Being scale at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.5 Caregiver and patient HRQOL will be assessed by the PROMIS Emotional Support at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.6 Caregiver and patient HRQOL will be assessed by the Perceived Stress Scale at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.7 Caregiver and patient HRQOL will be assessed by the Resilience, Optimism and Gratitude scales at baseline (pre-intervention), and days 30 and day 120 post-HCT.

3.2.8 Patient HRQOL will be assessed by the PROMIS Sleep Disturbance scale at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.9 Caregiver and patient negative and positive dyadic interaction will be assessed by measures of the Dyadic Relationship Scale at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.10 Caregiver HRQOL will be assessed by the TBI-CareQOL (PROMIS affiliate) Caregiver Anxiety at baseline (pre-intervention), and days 30 and 120 post-HCT.

3.2.11 Caregiver HRQOL will be assessed by the TBI-CareQOL (PROMIS affiliate) Caregiver Strain scale.

3.2.12 Activity data. Caregiver and patient activity (steps) and sleep will be measured continuously from the start to the end of the intervention (day 120 post-HCT) through wearable sensors.

3.2.13 Health care utilization data. Patient health care utilization data (e.g., total count of hospital days, emergency department visits, readmissions, and ambulatory care clinic visits) will be captured through the electronic health record as well as self-report (i.e., if the patient is re-admitted at an outside hospital other than a participating site). Caregiver health care utilization data (e.g., hospital admissions, emergency department visits, and ambulatory care clinic visits) will be collected through self-report at the day 30 (+/-14) and day 120 (+/- 30) post-HCT PRO assessment period. The study team may access the electronic medical records for 1 year from the date of study enrollment.

3.2.14 Mobile Application Rating Scale (MARS) was added to the day 120 questionnaire to obtain user experience of the Roadmap 2.0 app.

3.2.15 Social Rhythms Application. We are interested in looking at how circadian rhythm may affect the participant's overall health. Participants may upload retroactive data from the Fitbit and will receive a personalized report about their circadian rhythm. Participant will be encouraged to upload their data at baseline (+/- 14 days), day 30 (+/- 14 days), and day 120 (+/- 30 days).

4.0 PATIENT ENROLLMENT AND EVALUATION

4.1 Participant Recruitment

The Adult and Pediatric BMT Programs at the participating sites have regularly scheduled New Patient Evaluation meetings where patients being considered for BMT are presented and discussed. Investigators and study coordinators attend the meetings and will identify potential study subjects who meet eligibility for the non-invasive, wearable activity monitoring device. Study team members will recruit subjects to the study around the time of patient admission to undergo allogeneic or autologous BMT in the inpatient Adult or Pediatric BMT Units. Permission to approach will be obtained from subjects' primary BMT physician prior to attempting to recruit them to the study.

4.2 Participant Enrollment and Evaluation

Participants (caregiver-patient dyads) will be approached for this study after the decision to proceed with transplantation is made by the patient. Caregivers will be identified by the patient as the primary caregiver providing at least 50% of the caregiving needs. Multiple caregivers are not allowed by study design. Eligibility criteria will be verified by the Study Team. Ineligible participants will proceed off study and no further follow-up will be obtained.

4.3 Informed Consent Process

Patient and Caregivers will be told about the study in detail, and will be given a copy of the consent to look through. If the patients and caregivers decide that they want to move forward with participation, the caregiver (who will always be an adult) will be provided with an access code and instructions on how to download the Roadmap 2.0 application on their phone or tablet (iPhone or Android). The application cannot be used without an access code. Once the access code is entered and confirmed, the caregiver will be presented with an electronic copy of the consent on the phone, and will have to click the button to confirm their willingness to proceed. After the caregiver has completed the consent on their phone or tablet, they will be provided with another access code for the patient, who might be an adult or a minor. The patient will then use this access code to open the app on their own device and go through their own electronic consent/assent process. Once the patient has completed the consent/assent, the pair will be officially enrolled in the trial. The database will store the access codes and the timestamps of when the electronic form was completed. The link between the access codes and the patient identifiers will be stored by the study team in a separate location from the application server so that the identity of the participants will never be stored within the application or the supporting application server, thus protecting privacy.

The consent process relies on a waiver of documentation, meaning that

participants will not use their actual signature to denote consent since the act of consenting is done by checking boxes within the app. The app will know which site's consent/assent to present to a subject based on the center ID, study ID, and access code.

4.4 Transplant Protocol Registration

Before randomization occurs, the Research Coordinator must state through the OnCore Clinical Trials Management System the baseline caregiver biological characteristics (e.g., age, gender, race/ethnicity). This will avoid potential biases that preferential use of gender, for example, on one arm could confer to the study. At this stage, the Research Coordinator will also verify that the patient is still a candidate for transplantation, and both caregiver and patient are eligible for this clinical trial.

4.5 Randomization

Once the caregiver-patient dyad is deemed eligible and has provided written informed consent, the Research Coordinator will confirm eligibility. The study statistician, Thomas Braun (Co-I), will create a randomization list before the study begins enrollment using the statistical package R. Dr. Braun will then forward the list to the Data Manager/Research Coordinator, who will be responsible for enrolling patients and assigning them to the correct study arm. Caregiver-patient dyads will not be randomized more than 21 days from the planned initiation of conditioning. All patient treatments related to the transplant should be scheduled PRIOR to randomization. This includes planning an admission date and ensuring that donors can be used in a coordinated fashion with the planned transplant.

4.6 Pre-transplant Caregiver Evaluations

Based on prior work, our Study Team has experience obtaining Caregiver Demographics on a user-friendly electronic format via Qualtrics directly through the Roadmap 2.0 app. The following data will be collected (i.e., caregiver self-report) within 30 days of randomization, including demographic, caregiving, and personal health variables, such as marital status, alcohol/tobacco use, education, employment, annual household income, use of technology, relationship to the patient, number of household members, health insurance status, number of years and number of hours per week (of caregiving), health comorbidities. Caregivers may also be asked in the onboarding session about their own health and any medications that they may be taking.

4.7 Pre-Intervention Evaluation

PROMIS Patient-Reported Outcomes (PROs) – Well-being or HRQOL assessments will be obtained at baseline, pre-intervention. The surveys will be

obtained through Qualtrics which will be linked directly to the Roadmap 2.0 app on mobile phones. Based on prior work, our Study Team has experience administering PROMIS PROs on mobile devices.

4.8 Post-Intervention Evaluation

PROMIS Patient-Reported Outcomes (PROs) Well-being or HRQOL assessments will be obtained at days 30 (+/- 14) and 120 (+/- 30) post-HCT, during and at the end of the intervention period, respectively. The surveys will be obtained through Qualtrics, which will be linked directly to the Roadmap 2.0 app on the mobile phone. Based on prior work, our Study Team has experience administering PROMIS PROs on mobile devices. If a participant relapses, our team will continue to collect clinical data post-transplant. In the event of a relapse, the patient will be censored, and we will not collect any further surveys from the patient or caregiver.

Missing surveys will not be considered a protocol deviation.

4.9 Participant Withdrawal

At any time, a participant may request that her or his data no longer be collected, that her/his data be removed from the study database, that their physiologic data no longer be collected or used for research now or in the future. The participant may make this request to the Research Coordinator or to any member of the Study Team or the BMT clinical team. The participant's research information will be deleted from the study database (with a comment that the participant withdrew consent for collection). Upon withdrawal, the participant may keep all physiological monitoring devices used in the study. A note will be made in the study record documenting the reason the patient withdrew from the study.

4.10 Study Regulations

The trial will be performed in accordance with all applicable regulatory requirements and laws. All investigators, research administrators, and other personnel who are involved in the studies will at a minimum be required to complete an online tutorial on the protection of human research subjects (this may be site-specific or through a multi-institutional platform like CITI). All sites will send their training certificates to the University of Michigan.

All patient subjects will receive care either inpatient or outpatient through one of the participating sites by trained medical personnel skilled in the care of BMT recipients who will be responsible for ensuring necessary medical or professional intervention in the event of adverse events to subject.

4.11 Risks

4.11.1 Wearable Sensor Device (Fitbit): Patient Subjects who agree to wear a device (s) for data collection may experience mild skin irritation, which will be monitored by the care team. The subject can decline to wear the device(s) or request to try a different device(s) that may be more comfortable. They will be instructed to remove the device before any scans or radiation therapy.

4.11.2 Confidentiality: There is a possible risk of loss of confidentiality. However, every effort will be made to keep your medical information confidential. We will code data by assigning a number to each individual patient and then store the data by that number. No mention of patient subject identities is made in analyses of the data or in any publications, which result from such research.

4.12 Adverse Event Reporting Requirements

No adverse events related to this intervention are expected, as the focus of this intervention (if randomized to Roadmap 2.0) is on informational resources as well as positive activity exercises. If the PI or study team judges that an adverse event is related to the subject's participation in this clinical trial, it will be reported to IRBMED per institutional guidelines. The coordinating site will meet with other sites at least once a month to review any potential adverse events. The University of Michigan site will report any adverse events for all the performance sites.

Participants will be considered on study for approximately 120-days post-HCT and are likely to have adverse events completely unrelated to the intervention but related to their underlying disease and/or allogeneic/autologous HCT. One example of a study-related adverse event that would be reported could include loss of confidentiality of data. Examples of events that would not be reported would include any complications from any procedures (specifically, transplant-related), surgeries, treatments (e.g., GVHD, chemotherapy, radiation therapy), or death unless due to the study.

4.13 Participant Data Security and Compliance

The wearable sensor device monitoring system data will be downloaded to a secure, password-protected University of Michigan core imaged computer and stored with subject codes in Dr. Sung Won Choi's Laboratory (MPB) following rules for secure data storage (e.g., M+Box, Dropbox, RedCAP). Research devices will not interface with MiChart. All study personnel will complete training related to Human Subjects Research Protections and HIPAA. All study information will be stored in a password-protected encrypted files and identified by case number. The technologies proposed in this proposal have all been carefully reviewed and approved by the governing bodies at Michigan Medicine. All regulatory and security requirements have been met and have been fully documented in accordance with the policies and best practices that govern the use of technology

for patient care and research at Michigan Medicine. The MiChart web services were built and are supported by HITS, and their use for this project has been approved by HITS. All standard procedures and protocols for security and data integrity that apply to this project are being followed. All PHI will be stored in the HITS Oracle Database. Each study participant's contact information will be securely stored in RedCap for use during the study. Each site will keep a master list of their site's participant names and matching participant IDs. The coordinating center will have access to this information, though participating sites will not see subjects enrolled at other sites. Site personnel will keep subject information in password-protected files on a secure server or in a secure environment (e.g., locked cabinet, restricted access). No one other than the study team at the study site will have access to their site's master list (except when needed for study monitoring). At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and managed by the University of Michigan. Individual participants and their research data will be identified by a unique study identification number, where possible. The study data entry and study management systems (e.g., Roadmap app, REDCap, Qualtrics, M-Box, Dropbox, Fitbit®, etc.) used by clinical sites and by University of Michigan research staff are secured and password protected. Data will also be entered into Oncore/Velos as requested by the Rogel Cancer Center. At the end of the study, all study databases will be coded using subject IDs and archived at the University of Michigan.

4.14 Data and Safety Monitoring Plan

This study will be monitored in accordance with the NCI approved University of Michigan Rogel Cancer Center Data and Safety Monitoring Plan, with oversight by the Rogel Cancer Center Data and Safety Monitoring Committee (DSMC).

The Study Principal Investigator will provide ongoing monitoring of data and patient safety in this trial and conduct regular data review with participating sites.

The Study Principal Investigator and/or the Study Coordinator/Delegate will review data and patient safety issues with participating sites per a defined bi-annual meeting cadence. Depending on the protocol activity, the meeting cadence may be more frequent. This data review meeting may be achieved via a teleconference or another similar mechanism to discuss matters related to:

- Enrollment rate relative to expectations, characteristics of participants
- Safety of study participants (SAE reporting, unanticipated problems)
- Adherence to protocol (protocol deviations)
- Completeness, validity and integrity of study data

- Retention of study participants

The Study Coordinator/Delegate is responsible for collating the data from all participating sites and completing the Protocol Specific Data and Safety Monitoring Report (DSMR) form to document the data review meeting discussion.

The DSMR will be signed by the Study Principal Investigator or designated Co-Investigator and submitted to the DSMC on a bi-annual basis for independent review.

4.15 Quality Assurance and Audits

The Data and Safety Monitoring Committee can request a 'for cause' quality assurance audit of the trial if the committee identifies a need for a more rigorous evaluation of study-related issues.

A regulatory authority (e.g. FDA) may also wish to conduct an inspection of the study, during its conduct or even after its completion. If an inspection has been requested by a regulatory authority, the site investigator must immediately inform University of Michigan Rogel Cancer Center that such a request has been made. Audits will be performed by the University of Michigan Rogel Cancer Quality Assurance Review Core (QARC), per institutional guidelines.

During an audit access to relevant documentation, including patient records, must be given by the site investigator to the University of Michigan Rogel Cancer Center representative conducting the audit to verify consistency of data collected with the original source data.

The University of Michigan Rogel Cancer Center expects the relevant investigational staff to be available to facilitate the conduct of the visit, that source documents are available at the time of the visit, and that a suitable environment will be provided for review of study-related documents. Issues identified during these visits will be communicated to the site and are expected to be resolved by the site in a timely manner.

4.16 Clinical Monitoring Procedures

Clinical studies coordinated by The University of Michigan Rogel Cancer Center must be conducted in accordance with the ethical principles that are consistent with Good Clinical Practices (GCP) and in compliance with other applicable regulatory requirements.

Prior to subject recruitment, a participating site will undergo site initiation meeting to be conducted by the Study PI/Delegate. This will be done as an actual site visit; teleconference, videoconference, or web-based meeting. The site's principal investigator and study staff should make every effort in attending the

site initiation meeting. Study-related questions or issues identified during the site initiation meeting will be followed-up by the appropriate personnel until they have been answered and resolved. Monitoring of this study will include centralized surveillance of study specific data at a defined cadence.

Participating sites will also undergo a site close-out upon completion, termination, or cancellation of a study to ensure fulfillment of study obligations during the conduct of the study, and that the site Investigator is aware of his/her ongoing responsibilities. In general, the site close-out can occur without a site visit.

5.0 STATISTICAL CONSIDERATIONS

5.1 Study Design

This study will use a two-arm randomized design. Each caregiver-patient dyad will be randomized to an active "treatment" arm (mobile platform + Roadmap 2.0) or to a control arm (Mobile platform + usual care). The random allocation of participants to the treatment arm or control arm establishes the basis for testing the statistical significance or difference between the groups in the measured outcome (caregiver health-related quality of life, assessed by the PROMIS Global Health scale). Caregiver age, gender, and other prognostic baseline characteristics that could potentially confound an observed association, including those that are unknown or unmeasured, will be distributed equally, except through chance alone, through random assignment. Thus, this design is well-suited to our goal of assessing the efficacy of a mobile health intervention, Roadmap 2.0, on caregivers.

5.2 Accrual

It is estimated that 5 yearswill be necessary to enroll the targeted sample size. Accrual will be reported by race, ethnicity, gender, and age.

5.3 Study Duration

Participants will be followed on intervention for 120-days post-transplant for primary, secondary, and exploratory endpoints. Subjects will remain in follow-up for 1-year post-HCT. The study team will have access to the electronic medical records for 1-year post-HCT.

5.4 Randomization

Blocked randomization will be used to limit bias and achieve an equal distribution of participants to the treatment and control arms. This approach will recruit participants in small blocks to ensure that half of the participants within each block will be allocated to the treatment and the other half to the control. The size of the blocks will be permuted to limit selection bias, and within each block, the

order of patients will be random. Randomization will be stratified by type of transplant (adult allo, adult auto, pediatric), so that three separate randomization lists will be created. The study statistician, Thomas Braun (Co-I), will create the randomization lists before the study begins enrollment using the statistical package R. Assignments will be allocated in list order, and an assignment will not be reused with future patients if a patient later declines to participate after being randomized. Adequate training will be given to the Project Manager and Research Coordinator, including enrollment of participants, allocation of treatment arm, and training the participants.

5.5 Blinding

Study arm assignments cannot be blinded to the investigators nor the subjects, because it will be known whether participants have the positive activity components of Roadmap 2.0 on their mobile device or not (due to technical purposes). Treatment assignments will not be blinded to the statistician/data scientists (Tom Braun, Co-I, and his research staff) or other Study Team members who will be ascertaining and adjudicating the outcomes (Noelle Carolozzi, Co-I, and her research staff). In addition, Research Assistants who collect the outcomes data (e.g., participant reported outcome measures, interviews) will be different from the Research Coordinator who will provide study training and ensuring weekly adherence to the study protocol (e.g., fidelity).

5.6 Primary Endpoint

The primary endpoint of this trial is the self-report outcome measure of caregiver HRQOL. The primary objective of this clinical trial is to test Roadmap 2.0/Positive Activities in caregiver-patient dyads undergoing HCT and determining the statistical significance or difference between the treatment arm and control arm in caregiver HRQOL. We will use a hypothesis testing framework to assess the potential efficacy of a mobile health intervention (Roadmap 2.0) to improve caregiver HRQOL.

5.7 Sample Size Considerations

The power calculation was completed by Dr. Braun using simulations in the statistical package R. Our primary endpoint (i.e., caregiver health-related quality of life from the PROMIS® Global Health scale) is focused solely on this outcome in caregivers, while our secondary endpoints are based on outcomes for both caregivers and patients. Given this, we determined our sample size based solely on caregivers. The age- and sex-adjusted norm for the Global Health scale is 50 points, with a standard deviation of 10 points. These statistics have been shown to be generalizable to the allogeneic BMT population. Our study will have power of 0.80, assuming a two-sided Type I error rate of 0.05, to detect an effect size of 0.5 between the intervention and control arms if 67 caregivers are enrolled in each arm. A mean difference of one-half a standard deviation is biologically meaningful

and is considered a medium effect size for clinical trials. We will accrue a total of 83 caregivers in each arm to account for dropout, assuming a 5% failure to undergo BMT, 8% death before day 120, and 10% missing day 120 PRO from participants. These percentages are inflated but based on adjustments of published BMT data.

Because our main goal is to assess the primary objective in adult allo dyads, we plan accrue approximately 260 dyads with adult patients, as that is the expected number of total adult dyads needed to enroll at least 166 allo dyads. We also plan to enroll approximately 40 dyads with pediatric patients in the time it takes to enroll the 260 adult dyads.

PROMIS® measures use Item Response Theory (IRT), a family of statistical models that link individual questions to a presumed underlying trait or concept of global health represented by all items in the scale. PROMIS® instruments are scored using item-level calibrations. The most accurate way to score a PROMIS® instrument is to use the HealthMeasures Scoring Service, which our Study Team has experience with (Noelle Carlozzi, Co-I and Tom Braun, Co-I). This method of scoring uses "response pattern scoring," which uses responses to each item for each participant. Response pattern scoring is especially useful when there is missing data (i.e., a respondent skipped an item), or different groups of participants responded to different items).

There are four key features of the score for PROMIS® Global Health:

1. Reliability: The degree to which a measure is free of error. It can be estimated by the internal consistency of the responses to the measure, or by correlating total scores on the measure from two time points when there has been no true change in what is being measured (for z-scores, reliability = $1 - SE^2$).
2. Precision: The consistency of the estimated score (reciprocal of error variance).
3. Information: The precision of an item or multiple items at different levels of the underlying continuum (for z-scores, information = $1/SE^2$).
4. Standard Error (SE): The possible range of the actual final score based upon the scaled T-score. For example, with a T-score of 52 and a SE of 2, the 95% confidence interval around the actual final score ranges from 48.1 to 55.9 (T-score ± (1.96*SE) = 52 ± (1.96*2) = 48.1 to 55.9)

The final score is represented by the T-score, a standardized score with a mean of 50 and a standard deviation of 10 points.

5.8 Interim Analysis

There will be no interim analyses for efficacy or futility for this trial.

5.9 Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized for all participants. Caregiver characteristics to be examined may include, age, gender, race/ethnicity, spirituality, employment, education (years), co-morbidities, caregiving (years), household members. Patient characteristics to be examined may include: age, gender, race/ethnicity, Karnofsky performance status, HCT-Comorbidity Index, primary disease, disease risk group, number of treatments received before transplant, conditioning regimen, donor type, donor source, degree of match.

5.10 Analysis Populations and General Analysis Guidelines

5.10.1 Primary Analysis Population

All participants enrolled, consented, and completing at least the baseline outcome measures will be included in the primary analysis population. Analyses for the primary and secondary endpoints will use the primary analysis population: Caregivers of adult patients [age ≥18 years] will be analyzed separately from caregivers of pediatric patients [age 5-17 years]). The primary analysis will occur once all patients have been followed for 120-days post-transplant, data adjudication completed, and data are locked.

5.10.2 General Analysis Guidelines

Primary analyses for the primary, secondary, and exploratory endpoints will use the primary analysis population. Analyses of each endpoint in each population will follow the analysis plans, as described below. We expect minimal missing data (<5%) for the primary endpoint and secondary endpoints based on past experience with Roadmap 1.0 studies.

5.11 Analysis of Primary Endpoint

Analysis will be an intent-to-treat analysis that includes all caregivers. Mean Global Health scores for each arm at day 120 will be compared using a two-sample *t*-test (or Wilcoxon Rank Sum test if non-normality is apparent) with a significance level of 0.05. Linear regression models will be performed to complement the results of the *t*-test and adjust for specific baseline caregiver characteristics (e.g., demographic, social, environmental) to increase the precision of our inference. We plan to do analyses separately for allo dyads, auto dyads, and pediatric dyads, although we have only powered the study for the analysis in the allo dyads. There is a possibility that patient characteristics will be unbalanced since our randomization scheme will be applied to caregivers. Thus, our models also will assess potential moderating or mediating effects, described below.[76]

5.12 Analysis of Secondary Endpoint

Mean Profile 29+2 scores for each arm at day 120 will be compared using a two-sample *t*-test (or Wilcoxon Rank Sum test if non-normality is apparent) with a significance level of 0.05. Linear regression models will be performed to

complement the results of the *t*-test and adjust for specific baseline caregiver characteristics (e.g., demographic, social, environmental) to increase the precision of our inference. There is a possibility that patient characteristics will be unbalanced since our randomization scheme will be applied to caregivers. Thus, our models also will assess potential moderating or mediating effects, described below.[76]

5.13 Analysis of Exploratory Endpoints

5.13.1 Caregiver and patient demographics and baseline characteristics

Caregivers in each arm (treatment vs. control) will be compared descriptively according to Consolidated Standards of Reporting Trials Guidelines.[77] Continuous measures will be described using means and standard deviations (or medians and ranges if non-normality is apparent), while categorical measures will be summarized with frequencies and percentages. Formal comparisons will be made between the arms, although no significant differences are expected due to the randomization of the arm assignments. Similar summaries will be done for patient characteristics.

5.13.2 Caregiver and patient PROs (see Appendix C)

All questionnaires will be scored according to coding manuals. The resulting scores will be compared between arms at baseline and days 30 and 120 using the Wilcoxon Rank Sum test. Outcome measures will be compared between arms using linear regression modeling of day 30 and day 120 outcomes after adjusting for baseline scores. We also will model the outcomes from all three time points simultaneously using a linear mixed model to account for within-subject correlation, as well as adjust for possible moderating or mediating characteristics of the caregiver or patient.[76]

5.13.3 Caregiver and patient overall survival

Death from any cause will be calculated from randomization to death or loss to follow-up. Participants alive at last follow-up will be censored. Survival curves will be calculated for each arm using the methods of Kaplan and Meier[78] and will be compared between arms using the log-rank test.

5.13.4 Mediation and moderation

Our assessment for potential mediation will follow the Baron and Kenny approach.[83] Specifically, we will first fit models examining the effect of the intervention on our dependent variables. We will refer to the treatment effect estimates from these models as Estimates A. We will then fit each of our models again, but with all potential mediators included as covariates. We will refer to the parameter estimates for these covariates as Estimates B. We will then apply the Baron and Kenny

approach to Estimates A and B to determine the direct and indirect effects of the intervention on each of the dependent variables, with corresponding standard error estimates determined using bootstrap methods, as described by Whittle, et al.[84] These models will be adjusted for any confounders that are discovered, although we expect the randomization to account for most confounding. Moderation will be assessed by including main effects of potential moderators and interaction terms of each potential moderator with the intervention.

5.13.5 Caregiver and patient activity

The accelerometer data of each subject will be transformed into a low-dimensional representation using motif discovery algorithms.[79] Such techniques are completely data-driven, and search for motifs (i.e., patterns) in the data that occur more often than chance. A signal can then be represented by the number of times a particular motif occurs. Others have successfully used such techniques for representing a variety of waveform data, including accelerometer and continuous glucose data.[80-82] The accelerometer data will be processed to derive estimates of total sleep duration (i.e., hours per night), wake after sleep onset, and sleep efficiency (i.e., ratio of sleep to wake). The variables will be compared between arms.

5.13.6 Caregiver and patient health care utilization

The total count of hospital days, ED visits, readmissions, and ambulatory care clinic visits within the first 120 days post-BMT, with adjustment for follow-up, will be compared between arms using a Poisson regression model, with adjustment for potential mediating or moderating effects of patient or caregiver characteristics, if needed. The data will be captured at the time of PRO assessments. Subjects will remain in follow-up for 1-year post-HCT. The study team will have access to the electronic medical record for 1-year post-HCT.

APPENDICES
APPENDIX A: FITBIT CHARGE 3

The Fitbit Charge 3 is a smart watch capable of measuring heart rate, exercise amount, and sleep levels. There is a retail version available, and that is the model we will be using for our study. The data collected by the Fitbit Charge 3 is transferred from the smart watch to the Fitbit application installed on the patient's phone via Bluetooth Low Energy (BLE), a form of Bluetooth specifically designed to lower power consumption without compromising range. The app then transmits the data to Fitbit's information management system securely and without identifiable information. The smart watch can be worn on either wrist to give accurate measurements. The Charge 3 is made of safe-to-use aluminum and flexible, non-elastic elastomer material common in fitness watches.

Patient Fitbits will be managed through Fitbit's proprietary management system. Each Fitbit will be connected to an account that is registered to a study coordinator. Using that account, the study coordinator will create Fitbit accounts for each unique user using a study gmail account. A Fitbit will then be synced to the subject account. The subject's account will be given the study ID assigned to the patient and an individual password to protect confidentiality.

The subject will wear the Charge 3 as often as they like. This will begin the collection of the subject's data. The smart watch will upload the data to the patient's phone every 15 minutes via BLE. The data is then sent to the Fitbit, where it is housed in secure Microsoft Azure servers, compliant with ISO/IEC 27001:2006 industry standards of encryption. Data sent from the phone includes the subject ID, all of the individual measurements taken by the Charge 3. This data can only be accessed by the study team.

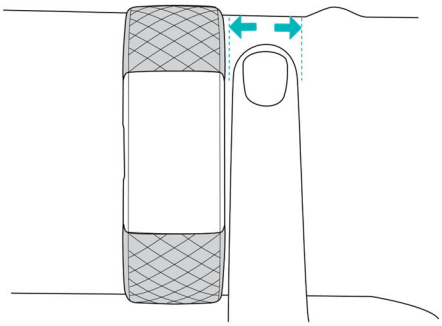
Additional details of this device are provided below.

Wear Charge 3

Place Charge 3 around your wrist.

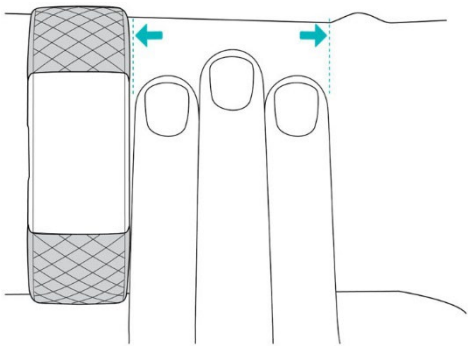
Placement for all-day wear vs exercise

When you're not exercising, wear Charge 3 a finger's width below your wrist bone.



For optimized heart-rate tracking while exercising:

- Try wearing Charge 3 higher on your wrist during exercise for an improved fit and more accurate heart-rate reading. Many exercises, such as bike riding or weight lifting, cause you to bend your wrist frequently, which can interfere with the heart-rate signal if the tracker is lower on your wrist.



- Make sure the tracker is in contact with your skin.
- Don't wear your tracker too tight; a tight band restricts blood flow, potentially affecting the heart-rate signal. However, the tracker should be slightly tighter (snug but not constricting) during exercise than during all-day wear.
- With high-intensity interval training or other activities where your wrist is moving vigorously and non-rhythmically, the movement may limit the sensor's ability to provide a heart-rate reading. If your tracker doesn't show a heart-rate reading, try relaxing your wrist and staying still briefly.

Activity and Sleep

Charge 3 continuously tracks a variety of stats whenever you wear it. The information is transferred to the Fitbit app every time you sync your tracker.

See your stats

From the clock face, swipe up to see your daily stats, including:

- Core stats: steps taken today, calories burned, distance covered, floors climbed, and active minutes
- Hourly activity: steps taken this hour and the number of hours you met your hourly activity goal
- Heart rate: current heart rate and heart-rate zone
- Female health tracking: information on the current stage of your menstrual cycle (if you don't use the female health feature in the Fitbit app, this tile won't appear)

Find your complete history and other information automatically detected by your tracker, such as sleep data, in the Fitbit app.

Track a daily activity goal

Charge 3 tracks your progress towards a daily activity goal of your choice. When you reach your goal, the tracker vibrates and shows a celebration.

Choose a goal

Set a goal to help you get started on your health and fitness journey. To begin, your goal is to take 10,000 steps per day. Choose to change the number of steps taken, or to make your goal distance traveled, calories burned, or active minutes instead.

For instructions on how to change your goal, see help.fitbit.com.

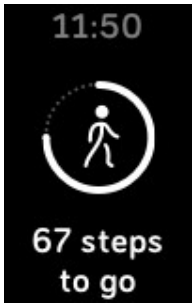
See goal progress

For information on how to see detailed progress toward your goal, see "See your stats" on the previous page.

Track your hourly activity

Charge 3 helps you stay active throughout the day by keeping track of when you're stationary and reminding you to move.

Reminders nudge you to walk at least 250 steps each hour. You'll feel a vibration and see a reminder on your screen at 10 minutes before the hour if you haven't walked 250 steps. When you meet the 250-step goal after receiving the reminder, you'll feel a second vibration and see a congratulatory message.



For more information on hourly activity, including how to customize the hours you receive reminders, see help.fitbit.com.

Track your sleep

Wear Charge 3 to bed to automatically track your time asleep and sleep stages (time spent in REM, light sleep, and deep sleep). To see your sleep stats, sync your tracker when you wake up and check the app.

For more information about sleep tracking, see help.fitbit.com.

Set a sleep goal

By default, you have a sleep goal of 8 hours of sleep per night. Customize this goal to meet your needs.

For more information about your sleep goal, including how to change it, see help.fitbit.com.

Set a bedtime reminder

The Fitbit app can recommend consistent bedtimes and wake times to help you improve the consistency of your sleep cycle. You can choose to be reminded nightly when it's time to start getting ready for bed.

For more information about how to set bedtime reminders, see help.fitbit.com.

Learn about your sleep habits

Charge 3 tracks several sleep metrics including when you go to bed, how long you're asleep, and your time spent in each sleep stage. Track your sleep with Charge 3 and check the Fitbit app to understand how your sleep patterns compare to your peers.

For more information about sleep stages, see help.fitbit.com.

See your heart rate

Charge 3 tracks your heart rate throughout the day. Swipe up from the clock screen to see your real-time heart rate and heart-rate zone. For more information on the stats on your tracker, see "See your stats" on page 30.

During a workout, Charge 3 shows your heart-rate zone to help you target the training intensity of your choice.

For more information about heart-rate zones on Charge 3, see "Check your heart rate" on page 40.

Adjust your heart-rate setting

Track your heart rate day and night with Charge 3. To preserve battery life, turn off heart-rate tracking in the Settings app > **Heart Rate**.

Note that the green LED on the back of Charge 3 continues to flash even if you turn off heart-rate tracking.

For more information about adjusting the heart-rate tracker, see help.fitbit.com.

Practice guided breathing

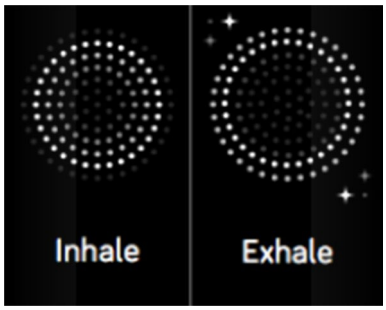
The Relax app on Charge 3 provides personalized guided breathing sessions to help you find moments of calm throughout the day. You can choose between 2-minute and 5-minute sessions.

To begin a session:

On Charge 3, open the Relax app.

The 2-minute session is the first option. Swipe left to choose the 5-minute session.

Tap the play icon to start the session and follow the on-screen instructions.



After the exercise, you'll see a summary that shows your alignment (how closely you followed the breathing prompt), your heart rate at the start and end of the session, and how many days you completed a guided breathing session this week.

All notifications are automatically disabled during the session.

For more information about guided breathing sessions, including the benefits of practicing deep breathing and safety information, see help.fitbit.com.

Fitness and Exercise

Track activity with the Exercise app and set exercise goals based on distance, time, or calories, or choose to automatically track exercise.

Sync Charge 3 with the Fitbit app and share your activity with friends and family, see how your overall fitness level compares to your peers, and more.

Track your exercise automatically

Charge 3 automatically recognizes and records high-movement activities at least 15 minutes long—including run, elliptical, and swim. Sync your device to see basic stats about your activity in your exercise history.

For greater precision or to see real-time stats and a workout summary on your tracker, manually start and stop an exercise with the Exercise app. For more information, see "Track and analyze exercise with the Exercise app" below.

For more information about tracking activity, see help.fitbit.com.

Track and analyze exercise with the Exercise app

Track specific exercises—such as run, bike, swim, or weights—with the Exercise app on Charge 3 to see real-time stats, including heart-rate data, calories burned, and elapsed time, and a post-

workout summary on your wrist. For complete workout stats, and route and pace information if you used GPS, review your exercise history in the Fitbit app.

Note: The connected GPS feature on Charge 3 works with the GPS sensors on your nearby phone.

GPS requirements

To use connected GPS:

1. Turn on Bluetooth and GPS on your phone.
2. Make sure the Fitbit app has permission to use GPS or location services.
3. Check that connected GPS is turned on for the exercise.
    a. Open the Exercise app and swipe to find the exercise you want to track.
    b. Swipe up and make sure **Use Phone GPS** is set to **On**.
4. Keep your phone with you while you exercise.

Track an exercise

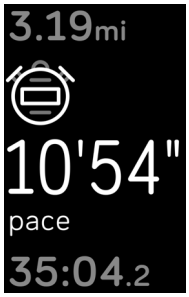
To track an exercise:

1. On your tracker, open the Exercise app.
2. Swipe to find an exercise.
3. Tap the exercise to select it.
4. Tap **Start** to begin the exercise, or tap **Set Goal** to choose a time, distance, or calorie goal depending on the activity.

Note: If the exercise uses GPS, you'll see an icon in the top left as your tracker connects to your phone's GPS sensors. When the screen says "connected" and Charge 3 vibrates, GPS is connected.

1. Tap the play icon to begin tracking your exercise. Charge 3 shows several real- time stats including heart rate, calories burned, and

elapsed time. Tap the middle stat to see additional stats.



2. When you're done with your workout or want to pause, press the button. Note that if you set an exercise goal, your tracker vibrates when you reach the goal.
3. Press the button again and tap **Finish** to end the workout.
4. Swipe up to see your workout summary.
5. Press the button to close the summary screen.

Customize your exercise settings and shortcuts

Customize settings for various exercise types and change or reorder exercise shortcuts in the Fitbit app. For example, turn connected GPS and cues on or off or add a yoga shortcut to Charge 3.

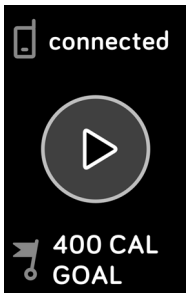
To customize an exercise setting:

1. From the Fitbit app dashboard, tap the Account icon ( ) > Charge 3 tile > **Exercise Shortcuts**.
2. Tap the exercise you want to customize.
3. Choose the settings you want to customize, then sync your device.

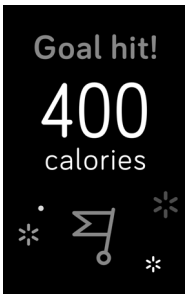
For more information about changing or reordering exercise shortcuts, see help.fitbit.com.

Check your workout summary

After you complete a workout, Charge 3 shows a summary of your stats.



4. Charge 3 vibrates when you reach your goal.



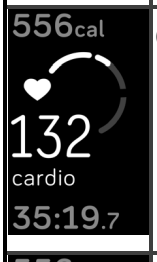
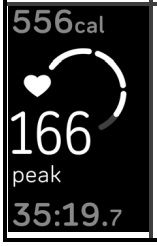
Check your heart rate

Heart-rate zones help you target the training intensity of your choice. Charge 3 shows your current zone and progress toward your maximum heart rate next to your heart-rate reading. In the Fitbit app, you can see your time spent in zones during a particular day or exercise. Three zones based on American Heart Association recommendations are available by default, or you can create a custom zone if you have a specific heart rate you're targeting.

Default heart-rate zones

Default heart-rate zones are calculated using your estimated maximum heart rate. Fitbit calculates your maximum heart rate with the common formula of 220 minus your age.

Icon	Zone	Calculation	Description
	Out of Zone	Below 50% of your maximum heart rate	Your heart rate may be elevated, but not enough to be considered exercise.

	Fat Burn	Between 50% and 69% of your maximum heart rate	This is a low-to-medium intensity exercise zone. This zone may be a good place to start for those new to exercise. It's called the Fat Burn zone because a higher percentage of calories are burned from fat, but the total calorie burn rate is lower.
	Cardio	Between 70% and 84% of your maximum heart rate	This is a medium-to-high intensity exercise zone. In this zone you're pushing yourself but not straining. For most people this is the exercise zone to target.
	Peak	Greater than 85% of your maximum heart rate	This is a high-intensity exercise zone. This zone is for short intense sessions that improve performance and speed.

Custom heart-rate zones

Configure a custom heart-rate zone or a custom max heart rate in the Fitbit app if you have a specific target in mind. For example, elite athletes might have a target that differs from the American Heart Association's recommendations for most people.

For more information, including links to relevant American Heart Rate Association information, see help.fitbit.com.

General Info and Specifications

Sensors

Fitbit Charge 3 contains the following sensors and motors:

A MEMS 3-axisaccelerometer, which tracks motion patterns

- An altimeter, which tracks altitude changes
- An optical heart-rate tracker

Materials

The housing and buckle on Charge 3 are made of anodized aluminum. While anodized aluminum can contain traces of nickel, which can cause an allergic reaction

in someone with nickel sensitivity, the amount of nickel in all Fitbit products meets the European Union's stringent Nickel Directive.

The Fitbit Charge 3 classic band is made of a flexible, durable elastomer material similar to that used in many sports watches.

Wireless technology

Charge 3 contains a Bluetooth 4.0 radio transceiver and Fitbit-Pay enabled trackers contain an NFC chip.

Haptic feedback

Charge 3 contains a vibration motor for alarms, goals, notifications, and reminders.

Battery

Charge 3 contains a rechargeable lithium-polymer battery.

Memory

Charge 3 stores your data, including daily stats, sleep information, and exercise history, for 7 days. For best results, sync your tracker daily.

Display

Charge 3 has an OLED display.

Wristband size

Wristband sizes are shown below. Note that accessory wristbands sold separately may vary slightly.

Small wristband	Fits a wrist between 5.5 - 7.1 inches (140 - 180 mm) in circumference
Large wristband	Fits a wrist between 7.1 - 8.7 inches (180 - 220 mm) in circumference

Environmental conditions

Operating Temperature	14° to 113° F (-10° to 45° C)
Non-operating Temperature	-4° to 14° F (-20° to -10° C) 113° to 140°F (45° to 60° C)
Maximum Operating Altitude	30,000 feet (9,144 m)

Learn more

To learn more about your tracker and dashboard, visit help.fitbit.com.

Regulatory & Safety Notices

Notice to the User: Regulatory content for certain regions can also be viewed on your device. To view the content:

Settings > About > Regulatory Info

USA: Federal Communications Commission (FCC) statement
Model FB409

FCC ID: XRAFB409

Model FB410:

FCC ID: XRAFB410

Notice to the User: The FCC ID can also be viewed on your device. To view the content:

Settings > About > Regulatory Info

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
This device may not cause harmful interference and
This device must accept any interference, including interference that may cause undesired operation of the device.
FCC Warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the

receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device meets the FCC and IC requirements for RF exposure in public or uncontrolled environments.

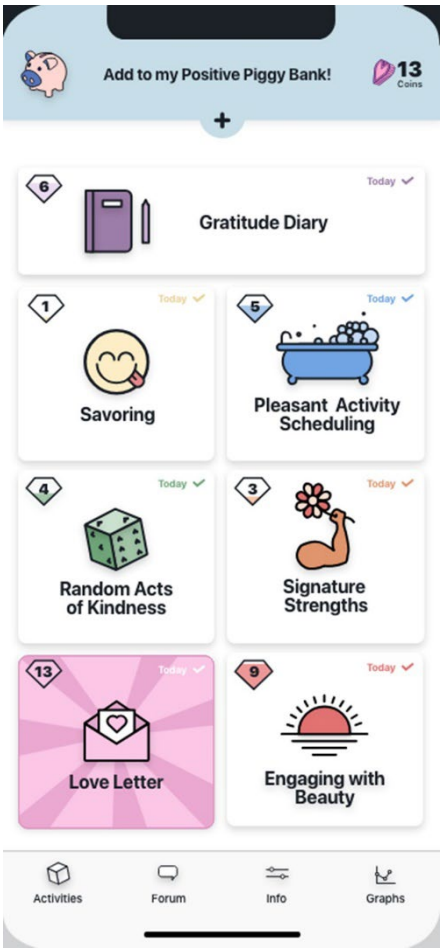
APPENDIX B: ROAMDAP 2.0 COMPONENTS

For study participants randomized to the Treatment Arm (Positive Activity Exercises), they will have access to components A – D outlined below.

Study participants randomized to the Control or Usual Care Arm (defined as all informational or educational resources provided through verbal communication or written hand-out materials) will only have access to component D, outlined below.

All study participants will respond to survey questionnaires on their mobile devices.

A. Positive Activity Exercises (Sample Landing Screen page):
    1. Positive Piggy Bank
    2. Gratitude Diary
    3. Savoring
    4. Pleasant Activity Scheduling
    5. Random Acts of Kindness
    6. Signature Strengths
    7. Love Letter
    8. Engaging with Beauty



Sample text with instructions provided to the caregiver:

1. Positive Piggy Bank:

As human beings, we tend to focus on negative things, people and events. This focus on the negative can undermine our happiness. Keeping a Positive Piggy Bank can help us focus on all the good things in our world, too.

Step 1: When you observe something that makes you happy, take a moment as savor it. Think about what makes this so special to you.

Step 2: Make a note to capture this thing or moment with enough detail that you can immediately recall what happened later.

Step 3: Now, tap the coin and it will drop into your positive piggy bank.

Step 4: You can make as many of these happy memory "deposits" as you like. The best part is that when you need a little pick-me-up, you may "break" open your piggy bank and read all of these happy notes.

Examples:

My best friend called to cheer me up. It worked!

Peach pie with homemade whipped cream, yummy.

My husband paid me the kindest compliment today.

I love the feel of grass under my feet.

2. Gratitude Diary:

Feeling grateful is a powerful way to ward off depression and inspire feelings of optimism. It is perhaps the easiest positive emotion to tap in to when things are difficult. For that reason, we encourage you to keep a gratitude diary. You can do that right here! This is how to go about it:

Step 1: Every day, note at least 2 things for which you are grateful. It can be anything – your friends and family, your pets, feeling the sunshine on your face, happy that a friend phoned, receiving a present, being able to take a walk, chocolate cupcakes … anything. Evenings, right before you go to sleep, usually works best.

Step 2: Make a commitment to yourself that you will note at least 2 things every day, but here is a twist - the things you list MUST be DIFFERENT. Try never to repeat anything.

Step 3: Smile as you write these things down. This will help you to feel even more grateful.

There are examples within the instructions above, but here are some if more are needed:

Bigger things: *My family*
My health
Having enough food to eat
My dear friend, Terry

Smaller things: *Children laughing*
The beach
Peanut butter
Puppies!

3. Savoring:

Savoring involves recognizing special moments and taking efforts to make them last and be more memorable. You can savor food, experiences, moments with loved ones, anything that brings you pleasure.

Step 1: Consider a typical weekday. Review your morning routine, your daily activities, and your evening rituals, and consider how much time you spend noticing and enjoying the pleasures of the day, both small and large.

Step 2: Every day for the next week, be sure to savor at least two experiences (for example, your morning coffee, or the sun on your face as you walk to your car). Spend at least 2-3 minutes savoring each experience.

Step 3: Log these savoring experiences here so you can revisit them later.

Here are some more things you could savor:

Sunsets
Fresh baked cookies
Time with your best friend
Visiting a new place
Playing your favorite game
A walk on a lovely day

4. Pleasant Activity Scheduling:

Providing care for loved ones can be incredibly time consuming. You might have already noticed that you have stopped doing many of the fun things you used to do. Yet, these pleasant activities are incredibly important and can help you better cope with stress. By scheduling and taking part in pleasant activities, you may find that you feel happier and have more energy.

Step 1: Identify activities that you find to be pleasant. These activities do not have to be expensive or time consuming – they just need to be things you enjoy. Activities could include taking a walk in the park, listening to music, working on your hobby, seeing a movie with a friend or reading a great book.

Step 2: Set aside time in the next week to do at least two of these activities. Put them on your calendar like an appointment and treat them with the same importance as you would a doctor's appointment.

Step 3: Log what you did for your pleasant activity. Have fun, it's good for you!

5. Random Acts of Kindness:

Although we do kind things daily, we often do not set out to intentionally do something nice for somebody else. Kindness is something always available for us to both give and receive.

Step 1: For this activity, one day this week, do five kind acts all in one day. Take a little time to plan what you are going to do. For the first ***four*** acts, do these for other people. These people can be complete strangers or friends and family members. These can be small acts of kindness such as holding a door open, sharing a genuine compliment or giving somebody a hug.

Step 2: You must also do ***one*** kind thing for you. People who take care of others tend to put them first and forget to be kind to themselves. It's important to take care of yourself, too! Perhaps, you could take a long bubble bath, go for a walk in the park, enjoy a Popsicle or sleep an extra 20 minutes.

Step 3: Smile as you do these kind acts. You are putting good into the world!

Here are some more ideas about kind acts you could do:

Leave inspiring message sticky notes to be found.
Give a friend a small gift for no particular reason.
Call a family member out of the blue and tell them how much they mean to you.

6. Signature Strengths:

Character strengths are connected with resilience and buffer people from vulnerabilities that can lead to depression and anxiety. Your unique set of character strengths make you, you. Using these strengths more regularly and in different ways can help you lead a more successful and rewarding life.

Step 1: Based on the Brief Strengths Test, note your top seven strengths.

Step 2: Every day for the next week, use one of these strengths in a way that you have not used it before.

Step 3: Each night, note how you used one of your strengths that day, including what strength you used, how you felt before, during, and after the activity, and whether you plan to repeat it in the future.

Examples:

If "creativity" is one of your strengths and you usually use creativity for arts and crafts, try using creativity to solve a difficult problem at work.

If "zest" is a strength of yours and you focus this on your hobby of cooking, try using zest to improve the quality of your friendships.

If "hope" is a strength of your and you tend to use hope to strengthen your faith, perhaps you could use hope in your exercise regime to envision the positive strides you can make.

7. Love Letter:

Finding ways to express warmth, care, deep positive regard, and authentic appreciation to those we love is important to us (the giver) to express, and for the receiver to hear and experience.

Step 1: Think about the love you have for the person for whom you are providing care.

Step 2: Write a brief love letter to this person. In the letter, tell your loved one about your love for him or her, offering your thoughts, feelings and specific examples. Also, consider linking your love to something that happened today or recently.

Step 3: Share your letter with the person you care for.

8. Engaging with Beauty:

Beauty in nature can inspire the emotion of 'awe,' beauty in art and skill can inspire admiration, and the witnessing of beauty in positive acts of human behavior can inspire more positive acts echoing like a ripple in a pond.

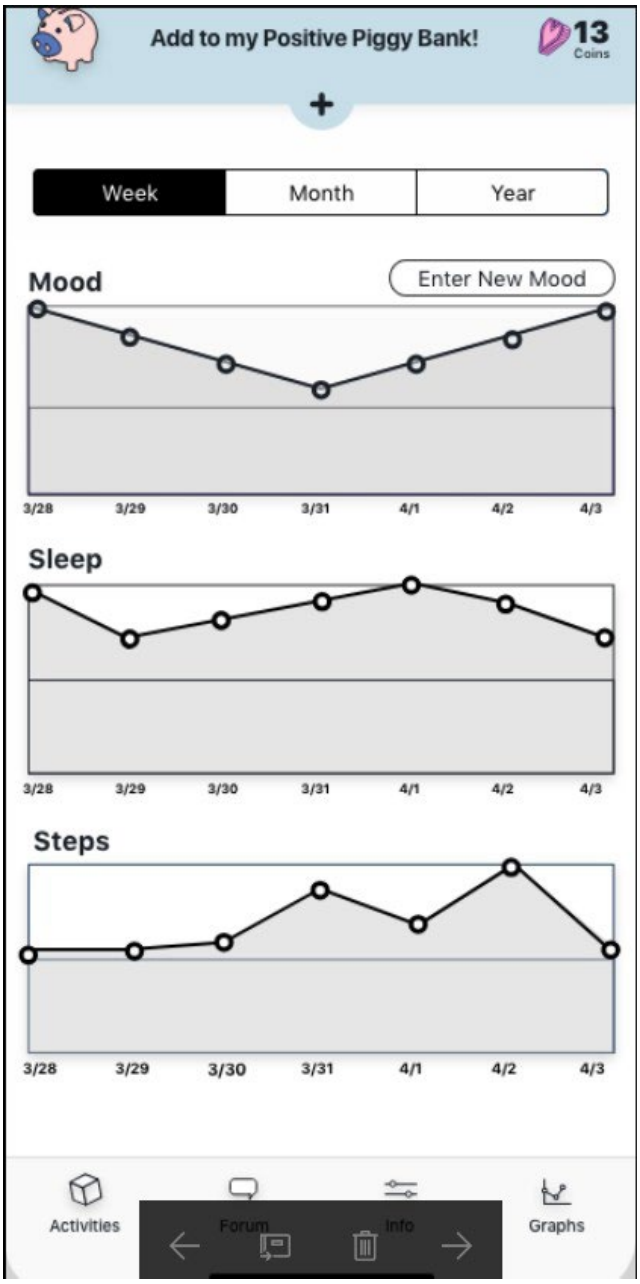
Step 1: Create a Beauty Log where you will add your observations about three different types of beauty: beauty in nature, beauty that is man-made (e.g., art, music, dance, architecture) or beautiful human behavior (e.g., kind acts, brave acts).

Step 2: Look for beauty as you go through the day. When you observe something that is beautiful, add it to your log in text or photo form.

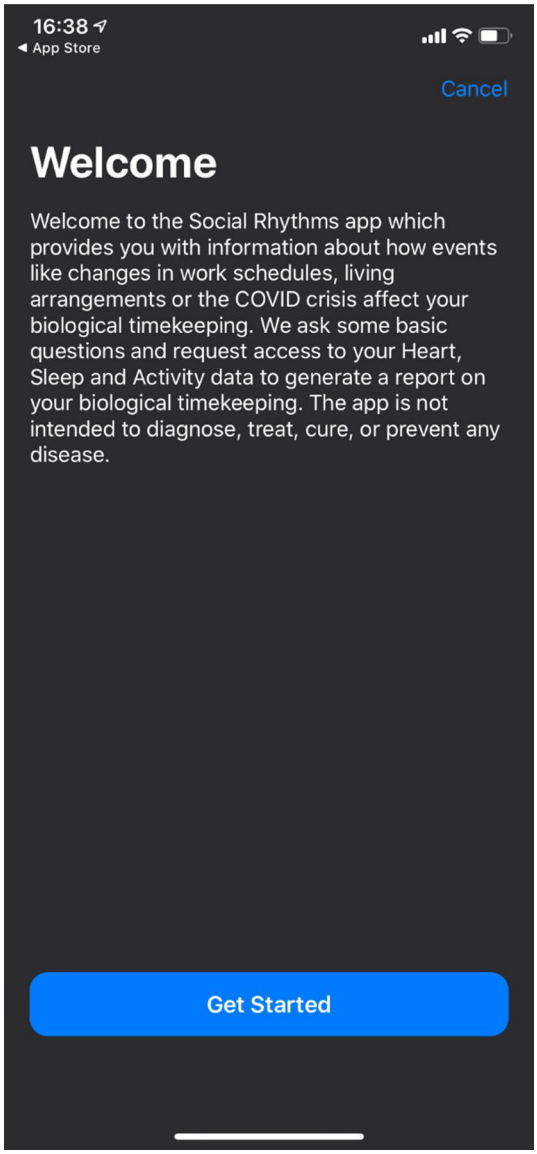
B. Forum for Caregivers to post positive comments based on Positive Activity exercises that are shared with other Caregiver participants:
   1. Gratitude Room
   2. Acts of Kindness Room
   3. Observed Beauty Room
   4. Strengths Room
   5. Love Letter Room

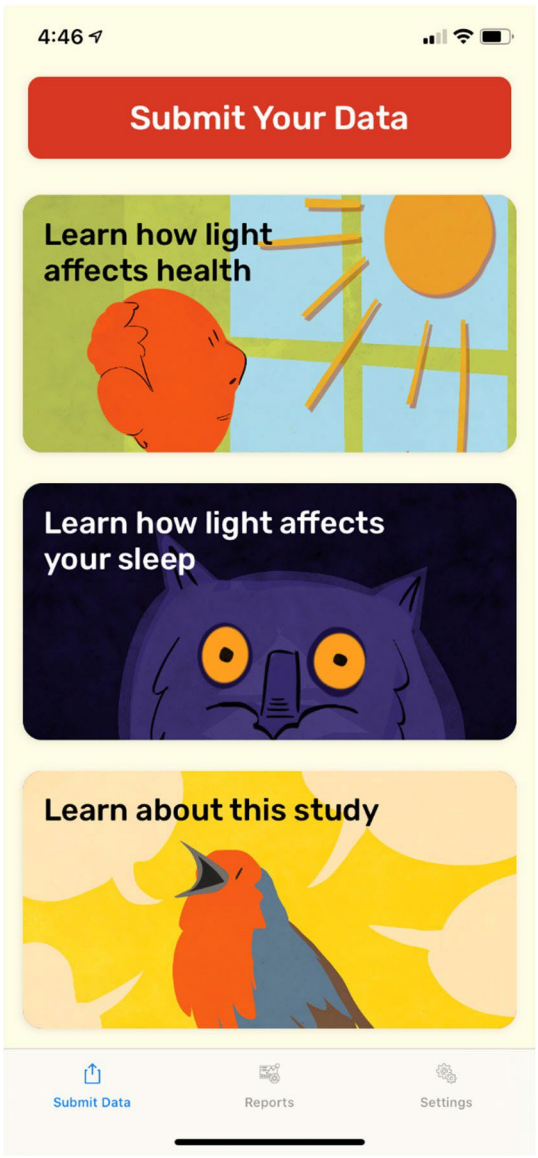
C. Caregiver-Specific Resources (Guides)
   1. Healthy Nutrition, Physical Activity, and Sleep Tips
   2. Ann Arbor Guide and Caregiver Resource Links
   3. Caregiver's Guide to Patient's Symptom Management Tips
   4. Navigating through Hematopoietic Cell Transplantation (HCT): A Guide for Pediatric HCT

D. Mood, Sleep, and Steps
   1. Patients and caregivers will be provided graphs of daily mood, sleep, and steps data (sample data plot shown on next page), depending on whether the participants respond to the daily mood questionnaire – scale between 1-10, anchored to "worst possible" and "best possible," respectively – and wear the Fitbit Charge 3.


Add to my Positive Piggy Bank!
13
Coins
Week
Month
Year
Mood
Enter New Mood
3/28
3/29
3/30
3/31
4/1
4/2
4/3
Sleep
3/28
3/29
3/30
3/31
4/1
4/2
4/3
Steps
3/28
3/29
3/30
3/31
4/1
4/2
4/3
Activities
Forum
Info
Graphs

APPENDIX C: SOCIAL RHYTHMS APP INTERFACE





Social rhythms is an app that collects data from either HealthKit on the app or Fitbit (health, sleep, and activity data). It uses this data to generate a report to the user about their circadian rhythm and supplies this report after a few days. The user can submit their data and obtain a report as frequently or little as they would like.

The report gives information on;

a. Activity pattern: How your body's time clock has shifted due to the pandemic
b. Regularity: Has your schedule become more or less regular during COVID
c. Shift: Has your internal clock shifted to become earlier or later
d. Sleep time: What time does your body start preparing for sleep
e. Avoid light: What time should you begin to avoid bright light to avoid delaying your clock
f. Light exposure: What time being exposed to light help you stay on track

APPENDIX D: CAREGIVER- AND PATIENT-REPORTED OUTCOME MEASURES

NIH PROMIS Tools

	SELF-REPORT			
	Adult Patient (age ≥ 18 years)	Pediatric Patient (ages 8-17 years)	Adult Caregiver (≥ 18 years)	Parent Proxy for Pediatric Patients (ages 5-17 years)
Baseline Caregiver Assessment			44	
Global Health	10	9	10	9
Companionship	4		4	
Self-Efficacy for Managing Symptoms	4		4	
Self-Efficacy for Managing Daily Activities	4		4	
Positive Affect and Well-Being	9	10 (ages 13-17 years)	9	
Emotional Support	8	7	8	
Sleep Disturbance		4		4
Caregiver Anxiety			6	
Caregiver Strain			6	
Perceived Stress Scale	10		10	
Profile 25* and 29+2†	29	25	29	25

*A collection of 4-item short forms assessing anxiety, depressive symptoms, fatigue, pain interference, physical function-mobile, and peer relationships as well as a single pain intensity item.

†A collection of 4-item short forms assessing anxiety, depression, fatigue, pain interference, physical function, sleep disturbance, and ability to participate in social roles and activities as well as a single pain intensity item.

CAREGIVER PARTICIPANT DEMOGRAPHICS

ABOUT YOU

1. What is your age? _____

2. What is the age fo the patient you care for?
    a. 5-17 years old
    b. 18 years old or older

3. What is your zip code? _____

4. What is your gender?
    a. Female
    b. Male
    c. Not listed (Please specify_____)

5. Are you of Spanish, Hispanic or Latino origin or descent?
    a. No
    b. Yes

6. What is your race? (choose all that apply)
    a. White
    b. Black or African American
    c. Asian
    d. Native Hawaiian or other Pacific Islander
    e. American Indian or Alaska Native
    f. Other (please specify) _____

7. What is your marital status?
    a. Single, never married
    b. Married or in domestic partnership
    c. Widowed
    d. Divorced
    e. Separated

8. What is the highest grade or level of schooling that you have completed?
    a. Elementary school
    b. 8th grade or less
    c. Some high school, did not graduate
    d. High school graduate or GED
    e. Some college or 2-year degree
    f. 4-year college graduate
    g. More than 4-year college degree
    h. Not applicable

9. Including yourself, how many adults 18 years or older currently live in your household?
   Write in number of adult(s): _____

10. How many children under 18 years old currently live in your household?
    Write in number of children: _____

11. What is your current occupation, or if not currently working, what was your last job for pay?
    Please specify occupation: _____

12. What is your current employment status?
    a. Employed full-time (40 or more hours per week)
    b. Employed part time (up to 39 hours per week)
    c. Self-employed
    d. Student
    e. Retired
    f. Homemaker
    g. Unemployed and currently looking for work
    h. Unemployed and not currently looking for work
    i. Unable to work (i.e. due to caregiving)

13. What was your job for pay during the week of your transplant?
    Please specify occupation: _____

14. What is your <u>monthly income</u> from employment at this time?
    ☐ Less than $1,000
    ☐ $1,000 to $2,999
    ☐ $3,000 to $4,999
    ☐ $5,000 to $6,999
    ☐ $7,000 or more

15. How supportive has your employer been about your loved one's (the patient) illness and need to undergo transplant?

Unsupportive				Completely Supportive	Not Applicable
1	2	3	4	5	NA

16. Have you been able to use family and medical leave (FMLA) provided through your employer?
    ☐ Yes
    ☐ No, not offered by employer
    ☐ No, did not need it
    ☐ No, self-employed or not employed

17. Have you used any of the following to help care for your loved one? Please mark yes or no for each.

Vacation time..... ☐ Yes ☐ No

Employer paid sick days or paid medical leave.....	☐ Yes	☐ No
Personally purchased or employer-sponsored disability insurance	☐ Yes	☐ No
Unpaid time off.....	☐ Yes	☐ No

18. Since your loved one's transplant, about how much total time have you taken off from work?

Write in number of weeks: _____

19. How much of the time you took off was paid time off?

☐ None
☐ Less than half
☐ About half
☐ More than half
☐ All

CURRENT HOUSEHOLD FINANCES

20. In general, how satisfied are you with your family's present financial situation? Please circle one.

Not satisfied at all				Completely satisfied
1	2	3	4	5

21. How difficult is it for you/your family to meet monthly payments on your bills? Please circle one.

Not difficult at all				Extremely difficult
1	2	3	4	5

22. How do your family's finances usually work out at the end of the month?

☐ Some money left over
☐ Just enough money
☐ Not enough money

23. Compared to before your loved one's transplant, how has your monthly household income changed?

☐ It has decreased
☐ It is about the same
☐ It has increased

24. The following questions ask about things people do when money is tight. Since your loved one's transplant, how often did you or your family have to do any of the following? Please circle one.

	Never	Rarely	Sometimes	Often
Reduce spending on essential household expenses (food, clothing, rent/mortgage)?.....	1	2	3	4

Withdraw from retirement or savings accounts?...	1	2	3	4
Borrow money to help pay for bills?.....	1	2	3	4
Reduce leisure activities?.....	1	2	3	4
Cut back on prescribed medications?.....	1	2	3	4

25. Related to your loved one's transplant, have you received any of the following resources to help cover expenses? Please check all that apply.

- ☐ Social Security Disability Insurance or Social Security Insurance
- ☐ Government assistance programs (food stamps, fuel or cash assistance)
- ☐ Institutional financial assistance from the hospital or university(discount hotel rooms, gas, food gift cards)
- ☐ Local or national charities (churches/synagogues)
- ☐ None of the above

26. What is your annual household income?

a. Less than $10,000
b. $10,000 - $14,999
c. $15,000 - $24,999
d. $25,000 - $34,999
e. $35,000 - $49,999
f. $50,000 - $74,999
g. $75,000 - $99,999
h. $100,000 - $200,000
i. More than $200,000
j. Prefer not to answer

HEALTH INSURANCE AND MEDICAL COSTS

27. Are you currently covered by any of the following types of health insurance or health coverage plans? Please check all that apply.

- ☐ Insurance through a current or former employer or union (of you or another family member)
- ☐ Insurance purchased directly from an insurance company (of you or another family member)
- ☐ Medicare, for people 65 and older, or people with certain disabilities
- ☐ Medicaid
- ☐ VA or TRICARE or other military health care

28. How satisfied are you with your current insurance coverage? Please circle one.

Not satisfied at All Completely satisfied

1 2 3 4 5

29. About how much of your <u>own money</u> did you spend <u>last year</u> for your medical care (including prescriptions, co-payments, deductibles, and premiums)?

    $_____dollars per month

30. The next questions are about costs associated with your loved one's transplant that are not direct medical costs. Since your loved one's transplant, how difficult has it been for you to pay for the following costs? Please circle one

number or "N/A" if you did not have the type of cost after your transplant.

	Not at all difficult				Extremely difficult	Not Applicable
Paying to temporarily relocate closer to transplant center.....	1	2	3	4	5	N/A
Paying for transportation to and from your appointments (gas, parking).....	1	2	3	4	5	N/A
Paying for transplant-related changes at home (cleaning, special foods).....	1	2	3	4	5	N/A
Paying for care services for children or parents usually in my care.....	1	2	3	4	5	N/A

31. How difficult is it for you to pay your medical bills (including prescriptions, co-payments, premiums, and deductibles)? Please circle one.

Not difficult at all				Extremely difficult
1	2	3	4	5

32. The following questions ask about things that may make your life more difficult or stressful.
During the last year, how much have each of the following added stress in your life?

	Not at all			A lot
Worry about being a burden on your family…	1	2	3	4
Worry about not having money for necessities like food, utilities, and housing…….	1	2	3	4
Worry about losing or not having health insurance……..	1	2	3	4
Worry about cost of your health insurance.....	1	2	3	4
Worry about paying medical bills…….	1	2	3	4

33. Thinking back to before your loved one's transplant, how informed do you feel you are about post-transplant related costs?

☐ Not at all informed

☐ Somewhat informed

☐ Extremely informed

34. Who gave you information about post-transplant related costs? (Check all that apply)

- ☐ Doctor
- ☐ Nurse
- ☐ Social worker
- ☐ Resource specialist
- ☐ Someone else → Who? _____
- ☐ No one

35. What is your relationship to the person you are caring for who will receive a transplant? I am the patient's:

a. Mother
b. Father
c. Daughter/Son
d. Daughter/Son
e. Wife
f. Husband
g. Grandmother
h. Grandfather
i. Sister
j. Brother
k. Aunt
l. Uncle
m. Cousin
n. Neighbor
o. Friend
p. Other (please specify _____)

YOUR CURRENT HEALTH AND WELL-BEING

36. For the following questions please circle the number between 1 and 7 that best applies to you.

How would you rate your <u>overall health</u> during the past year?

Very Poor						Excellent
1	2	3	4	5	6	7

How would you rate your <u>overall quality of life</u> during the past year?

Very Poor						Excellent
1	2	3	4	5	6	7

YOUR CAREGIVING EXPERIENCES

37. At the time of transplant, how many hours of caregiving did you provide per week for (NAME)? By caregiving, we mean help with meals, dressing, bathing, errands, cooking and cleaning, as well as medical care. Please do not include time that you would usually spend caring for young children.
    a. Less than 5 hours
    b. 5 – 10 hours
    c. Between 10 – 20 hours
    d. Between 20 – 30 hours
    e. Between 30 – 40 hours
    f. More than 40 hours

38. What is the proximity of the patient's primary residence to your primary residence?
    a. Lived with me
    b. Same state
    c. In a different state
    d. In a different country
    e. Other (please specify) _____

39. [IF Q2=b,c, or e] How far do you live from the patient?
    a. Less than 30 minutes by car
    b. 30 minutes -1 hour by car[TS1]
    c. 1 – 2 hours by car
    d. 2 – 5 hours by car
    e. More than 5 hours by car
    f. Other (please specify) _____

40. While caring for your loved one during the upcoming transplant, who else are you supporting with medical care? (Please mark all that apply)?
    a. Child(ren)
    b. Spouse
    c. Parent
    d. Sibling
    e. Other (please specify) _____
    f. No one else

41. Did you receive financial support for providing medical care for the patient?
    a. Yes
    b. No
    c. I'm not sure

YOUR USE OF MOBILE DEVICES/TECHNOLOGY

We would like to learn about how caregivers use mobile technology. We refer to mobile technology as devices such as cell phones (smartphones), tablets (iPads), laptop computers, and wearable devices (e.g., Fitbit, Apple Watch).

41. What is your primary type of cell phone?
    a. Apple iPhone
    b. Android smartphone (e.g., Samsung, Google)
    c. Microsoft windows smartphone (e.g., Microsoft, HP Elite)
    d. Cell phone that is not a smartphone
    e. Other (please specify) _____
    f. I do not own a cell phone

42. Do you own a mobile tablet device? (selectall that apply)
    a. Apple iPad
    b. Android tablet (e.g., Samsung, Kindle)
    c. Microsoft windows tablet (e.g., Microsoft Surface, Dell Venue)
    d. Other (please specify) _____
    e. I do not own a tablet

43. Do you own a fitness or smart watch? (select all that apply)
    a. Apple iWatch
    b. Fitbit Fitness Watch
    c. Garmin Fitness Watch
    d. Other (please specify) _____
    e. I do not own a fitness or smart watch

42. How many different mobile applications or "apps" do you have on your cell or tablet phone?
    a. 5 or less applications
    b. 6 – 10 applications
    c. 11 – 20 applications
    d. 21 – 50 applications
    e. More than 50 applications

    f. How many different apps do you use at least once a day on your cell phone or tablet?5 or less applications
    g. 6 – 10 applications
    h. 11 – 20 applications
    i. 21 – 50 applications
    j. More than 50 applications

43. Which of the following health or wellness-related apps do you use on your smartphone or tablet? (Select all that apply)
    a. Fitness workouts
    b. Counting steps
    c. Nutrition (e.g., tracking calories, recording diet)
    d. Meditation or stress management
    e. Sleep
    f. Other (please specify) _____
    g. None, or I do not own a smartphone or tablet

44. Do you have any of the following health conditions? (Selectall that apply)
    a. High blood pressure
    b. High cholesterol

c. Heart disease
d. Stroke
e. Arthritis
f. Diabetes
g. Kidney disease
h. Migraine headaches
i. Seasonal allergies
j. Anxiety
k. Depression
l. Post-traumatic stress disorder
m. Other mental health disorder
n. COPD
o. Alzheimer's disease
p. Cancer
q. Asthma
r. Multiple sclerosis (MS)
s. Parkinson's disease
t. Brain injury
u. Spinal cord injury
v. None
w. Other (please specify) _____

Do you use any apps to help you manage any specific health conditions for yourself? (please check all that apply)

	YES	NO
a. Diabetes		
b. Heart conditions		
c. Mental health (e.g., depression, anxiety)		
d. Cognitive behavioral therapy		
e. Allergies		
f. Migraine headaches		
g. Other (please specify) _____		

Other than your calendar, do you use any apps to help you manage your health?

	YES	NO
x. Medication management		
y. Appointment reminders		
z. Menstruation or fertility planning		
aa. Food intake or diet		
bb. Weight management		
cc. Other (please specify) _____		

45. Overall, how satisfied are you with these applications to self-manage your health?
a. Satisfied
b. Neutral
c. Dissatisfied

46. In the space below, please feel free to add any comments about the survey, the study or how the transplant has made an impact on your financial situation.

Thank you for completing this survey!

Patient PARTICIPANT DEMOGRAPHICS

ABOUT YOU

47. What is your age? _____

48. What best describes you?
    a. 18 and older
    b. 16-17
    c. 13-15
    d. 10-12
    e. 8-9
    f. 5-7

49. What is your gender?
    a. Female
    b. Male
    c. Not listed (Please specify_____)

50. Are you of Spanish, Hispanic or Latino origin or descent?
    a. No
    b. Yes

51. What is your race? (choose all that apply)
    a. White
    b. Black or African American
    c. Asian
    d. Native Hawaiian or other Pacific Islander
    e. American Indian or Alaska Native
    f. Other (please specify) _____

52. What is your marital status?
    a. Single, never married
    b. Married or in domestic partnership
    c. Widowed
    d. Divorced
    e. Separated

53. What is the highest grade or level of schooling that you have completed?
    a. Elementary school
    b. 8th grade or less
    c. Some high school, did not graduate
    d. High school graduate or GED
    e. Some college or 2-year degree
    f. 4-year college graduate
    g. More than 4-year college degree

h. Not applicable

54. Including yourself, how many adults 18 years or older currently live in your household?

_____

55. How many children under 18 years old currently live in your household?

_____

The following questions are only for participants that are at least 18 years old

56. What is your current occupation, or if not currently working, what was your last job for pay?

_____

57. What is your current employment status?

a. Employed full-time (40 or more hours per week)
b. Employed part time (up to 39 hours per week)
c. Self-employed
d. Student
e. Retired
f. Homemaker
g. Unemployed and currently looking for work
h. Unemployed and not currently looking for work
i. Unable to work (i.e. due to caregiving)

58. What is your <u>monthly income</u> from employment at this time?

☐ Less than $1,000

☐ $1,000 to $2,999

☐ $3,000 to $4,999

☐ $5,000 to $6,999

☐ $7,000 or more

59. How supportive has your employer been about your illness and need to undergo transplant? Please circle one.

Completely Unsupportive	Unsupportive	Neutral	Supportive	Completely Supportive	Not Applicable
1	2	3	4	5	NA

60. Have you been able to use family and medical leave (FMLA) provided through your employer?

☐ Yes
☐ No, not offered by employer
☐ No, did not need it

CURRENT HOUSEHOLD FINANCES (Only displayed if the patient is at least 18 years old)

61. In general, how satisfied are you with you/your family's present financial situation?

a. Extremely satisfied
b. Somewhat satisfied
c. Neither satisfied nor dissatisfied
d. Somewhat dissatisfied
e. Extremely dissatisfied

62. How difficult is it for you/your family to meet monthly payments on your bills?

a. Extremely easy
b. Somewhat easy
c. Neither easy nor difficult
d. Somewhat difficult
e. Extremely difficult

63. How do your family's finances usually work out at the end of the month?

☐ Some money left over

☐ Just enough money

☐ Not enough money

64. Compared to before your transplant, how has your monthly household income changed?

☐ It has decreased
☐ It is about the same
☐ It has increased

65. The following questions ask about things people do when money is tight. Since your transplant, how often did you or your family have to do any of the following? Please circle one.

	Never	Rarely	Sometimes	Often
Reduce spending on essential household expenses (food, clothing, rent/mortgage)?	1	2	3	4
Withdraw from retirement or savings accounts?	1	2	3	4
Borrow money to help pay for bills?	1	2	3	4
Reduce leisure activities?	1	2	3	4
Cut back on prescribed medications?.....	1	2	3	4

66. Related to your transplant, have you received any of the following resources to help cover expenses? Please check all that apply.

☐ Social Security Disability Insurance or Social Security Insurance
☐ Government assistance programs (food stamps, fuel or cash assistance)
☐ University of Michigan financial assistance (discount hotel rooms, gas, food gift cards)
☐ Local or national charities (churches/synagogues)
☐ None of the above

67. What is your annual household income?

a. Less than $10,000

b. $10,000 - $14,999
c. $15,000 - $24,999
d. $25,000 - $34,999
e. $35,000 - $49,999
f. $50,000 - $74,999
g. $75,000 - $99,999
h. $100,000 - $200,000
i. More than $200,000
j. Prefer not to answer

HEALTH INSURANCE AND MEDICAL COSTS (Only displayed if the patient is at least 18 years old)

68. Are you currently covered by any of the following types of health insurance or health coverage plans? Please check all that apply.

☐ Insurance through a current or former employer or union (of you or another family member)
☐ Insurance purchased directly from an insurance company (of you or another family member)
☐ Medicare, for people 65 and older, or people with certain disabilities
☐ Medicaid
☐ VA or TRICARE or other military health care

69. How satisfied are you with your current insurance coverage?

a. Extremely satisfied
b. Somewhat satisfied
c. Neither satisfied nor dissatisfied
d. Somewhat dissatisfied
e. Extremely dissatisfied

70. About how much of your <u>own money</u> did you spend <u>last year</u> for your medical care (including prescriptions, co-payments, deductibles, and premiums)?

$_____dollars per month

71. How difficult is it for you to pay your medical bills (including prescriptions, co-payments, premiums, and deductibles)?

a. Extremely easy
b. Somewhat easy
c. Neither easy nor difficult
d. Somewhat difficult
e. Extremely difficult
f. Not applicable

72. The next questions are about costs associated with your loved one's transplant that are not direct medical costs. Related to your transplant, how difficult has it been for you to pay for the following costs? Please circle one number or "N/A" if you did not have the type of cost after your transplant.

73. The	Not at all difficult		As difficult as usual		Extremely difficult	Not Applicable
Paying to temporarily relocate closer to transplant center	1	2	3	4	5	N/A
Paying for transportation to and from your appointments (gas, parking, bus fares, etc)	1	2	3	4	5	N/A
Paying for transplant-related changes at home (cleaning, special foods)	1	2	3	4	5	N/A
Paying for care services for children or parents usually in my care	1	2	3	4	5	N/A

following questions ask about things that may make your life more difficult or stressful.

During the last year, how much have each of the following added stress in your life?

	Not at all			A lot
Worry about being a burden on your family	1	2	3	4
Worry about not having money for necessities like food, utilities, and housing	1	2	3	4
Worry about losing or not having health insurance	1	2	3	4
Worry about cost of your health insurance	1	2	3	4
Worry about paying medical bills	1	2	3	4

74. Thinking back to before your transplant, how informed do you feel you are about post-transplant related costs?

- ☐ Not at all informed
- ☐ Somewhat informed
- ☐ Extremely informed

75. Who gave you information about post-transplant related costs? (Check all that apply)

- ☐ Doctor
- ☐ Nurse
- ☐ Social worker
- ☐ Resource specialist
- ☐ Someone else → Who? _____
- ☐ No one

YOUR USE OF MOBILE DEVICES/TECHNOLOGY

We would like to learn about how caregivers use mobile technology. We refer to mobile technology as devices such as cell phones (smartphones), tablets (iPads), laptop computers, and wearable devices (e.g., Fitbit, Apple Watch).

44. What is your primary type of cell phone?
    a. Apple iPhone
    b. Android smartphone (e.g., Samsung, Google)
    c. Microsoft windows smartphone (e.g., Microsoft, HP Elite)
    d. Cell phone that is not a smartphone
    e. Other (please specify) _____
    f. I do not own a cell phone

45. Do you own a mobile tablet device? (slecetall that apply)
    a. Apple iPad
    b. Android tablet (e.g., Samsung, Kindle)
    c. Microsoft windows tablet (e.g., Microsoft Surface, Dell Venue)
    d. Other (please specify) _____
    e. I do not own a tablet

46. Do you own a fitness or smart watch? (select all that apply)
    a. Apple iWatch
    b. Fitbit Fitness Watch
    c. Garmin Fitness Watch
    d. Other (please specify) _____
    e. I do not own a fitness or smart watch

47. How many different mobile applications or "apps" do you have on your cell or tablet phone?
    a. 5 or less applications
    b. 6 – 10 applications
    c. 11 – 20 applications
    d. 21 – 50 applications
    e. More than 50 applications

48. How many different apps do you use at least once a day on your cell phone or tablet?
    a. 5 or less applications
    b. 6 – 10 applications
    c. 11 – 20 applications
    d. 21 – 50 applications
    e. More than 50 applications

49. Which of the following health or wellness-related apps do you use on your smartphone or tablet? (select all that apply)
    a. Fitness workouts
    b. Counting steps
    c. Nutrition (e.g., tracking calories, recording diet)
    d. Meditation or stress management
    e. Sleep
    f. Other (please specify) _____

g. None, or I do not own a smartphone or tablet

50. Do you have any of the following health conditions? (select all that apply)

a. High blood pressure
b. High cholesterol
c. Heart disease
d. Stroke
e. Arthritis
f. Diabetes
g. Kidney disease
h. Migraine headaches
i. Seasonal allergies
j. Anxiety
k. Depression
l. Post-traumatic stress disorder
m. Other mental health disorder
n. COPD
o. Alzheimer's disease
p. Cancer
q. Asthma
r. Multiple sclerosis (MS)
s. Parkinson's disease
t. Brain injury
u. Spinal cord injury
v. None
w. Other (please specify) _____

If none is not selected above: If any, for which of the following of your illnesses do you use an app to help manage? (please check all that apply)

	YES	NO
High blood pressure		
High cholesterol		
Heart disease		
Stroke		
Arthritis		
Diabetes		
Kidney disease		
Migraine headaches		
Seasonal allergies		
Anxiety		
Depression		
Post-traumatic stress disorder		
Other mental health disorder		
COPD		
Alzheimer's disease		
Cancer		
Asthma		
Multiple sclerosis (MS)		

Parkinson's disease		
Brain injury		
Spinal cord injury		
None		
Other (please specify) _____		

Other than your calendar, do you use any apps to help you manage your health?

	YES	NO
x. Medication management		
y. Appointment reminders		
z. Menstruation or fertility planning		
aa. Food intake or diet		
bb. Weight management		
cc. Other (please specify) _____		

51. Overall, how satisfied are you with these applications to self-manage your health?
    a. Satisfied
    b. Neutral
    c. Dissatisfied

Feasibility and Acceptability (Provided for caregivers and patients that are older than 12)

Regarding the Fitbit watch;

The instructions for the Fitbit® set up were easy to understand.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Fitbit® was easy to set up.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Fitbit® was easy to use.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Fitbit® was comfortable to wear.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Fitbit® data was easy to sync with my phone.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

I was confident using the Fitbit®.
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

Regarding the Roadmap 2.0 App;

The instructions for the Roadmap app set up were easy to understand
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Roadmap 2.0 app was easy to download and set up
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The Roadmap 2.0 app was easy to use
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

I am confident using the Roadmap 2.0 app
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

Regarding the questionnaires

The survey questions were easy to understand
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

The survey questions were easy to answer
1 = Totally disagree, 2 = Disagree, 3 = Sometimes agree/disagree, 4 = Agree, 5 = Totally agree

Regarding the overall experience

What is your overall rating of the design of the screens on the app, including the colors and the layout?
1 = Poor, 2 = Fair, 3 = Good, 4 = Very Good, 5 = Excellent

Please comment any thoughts or suggestions to make the app more user-friendly, enjoyable, or helpful?

How likely would you be to engage in a similar study that lasted 6 months?
1. Extremely unlikely
2. Unlikely
3. Neutral

4. Likely
5. Extremely likely

How likely would you be to engage in a similar study that lasted 1 year?

1. Extremely unlikely
2. Unlikely
3. Neutral
4. Likely
5. Extremely likely

Compared to what you expected, how would you rate your experience in participating in this research study?

1. A lot worse than expected
2. A little worse than expected
3. About the same as expected
4. A little better than expected
5. A lot better than expected

Global Health: Adult Patient and Caregiver will complete

PROMIS® Scale v1.2 – Global Health

Global Health

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

13 April 2018

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		None	**Mild**	**Moderate**	**Severe**	**Very severe**
Global08r	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Global07r	How would you rate your pain on average?	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain imaginable**

Global Health: Pediatric Patient (age 8-17 years) will complete

PROMIS Pediatric Scale v1.0 – Global Health 7+2

Pediatric Global Health 7+2

Please respond to each question or statement by marking one box per row.

		Excellent	Very Good	Good	Fair	Poor
Global01R1	In general, would you say your health is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02R1	In general, would you say your quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03R1	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04R1	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Never	**Rarely**	**Sometimes**	**Often**	**Always**
PedGlobal2R1	How often do you feel really sad?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Always	**Often**	**Sometimes**	**Rarely**	**Never**
PedGlobal5R1	How often do you have fun with friends?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PedGlobal6R1	How often do your parents listen to your ideas?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…					
		Never	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
2876R1r	I got tired easily	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3793R1r	I had trouble sleeping when I had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Global Health: Parent Proxy for Pediatric Patients (age 5-17 years) will complete

PROMIS Parent Proxy Scale v1.0 – Global Health 7+2

Parent Proxy Global Health 7+2

Please respond to each question or statement by marking one box per row.

		Excellent	Very Good	Good	Fair	Poor
Global01_PXR1	In general, would you say your child's health is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02_PXR1	In general, would you say your child's quality of life is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03_PXR1	In general, how would you rate your child's physical health?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04_PXR1	In general, how would you rate your child's mental health, including mood and ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Never	**Rarely**	**Sometimes**	**Often**	**Always**
PedGlobal2_PXR1	How often does your child feel really sad?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Always	**Often**	**Sometimes**	**Rarely**	**Never**
PedGlobal5_PXR1	How often does your child have fun with friends?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PedGlobal6_PXR1	How often does your child feel that you listen to his or her ideas?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…					
		Never	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf4fatigue3r	My child got tired easily.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2pain5r	My child had trouble sleeping when he/she had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Companionship: Adult Patient and Caregiver will complete

Companionship – Short Form 4a

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
FSE31057x2	Do you have someone with whom to have fun?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31061x2	Do you have someone with whom to relax?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FSE31068x	Do you have someone with whom you can do something enjoyable?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
UCLA15x2	Can you find companionship when you want it?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

23 June 2016

Self-Efficacy for Managing Symptoms: Adult Patient and Caregiver will complete

Self-Efficacy for Managing Symptoms – Short Form 4a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSX010	I can manage my symptoms during my daily activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX014	I can keep my symptoms from interfering with relationships with friends and family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX009	I can manage my symptoms in a public place	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX011	I can work with my doctor to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last Updated: 5 August 2016

Self-Efficacy for Managing Daily Activities: Adult Patient and Caregiver will complete

Self-Efficacy for Managing Daily Activities – Short Form 4a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMDA021	I can perform my household chores	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMDA018	I can go shopping and run errands	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMDA010	I can walk around inside my house	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMDA030	I can maintain a regular exercise program	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last Updated: 5 August 2016

Positive Affect and Well-Being: Adult Patient and Caregiver will complete

Positive Affect and Well-Being - Short Form

Please respond to each question or statement by marking one box per row.

	Lately…	Never	Rarely	Sometimes	Often	Always
NQPPF14	I had a sense of well-being……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF12	I felt hopeful……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF15	My life was satisfying……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF20	My life had purpose……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF17	My life had meaning……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF22	I felt cheerful……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF19	My life was worth living……	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF16	I had a sense of balance in my life…….	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
NQPPF07	Many areas of my life were interesting to me……...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Positive Affect: Pediatric Patients (age 13-17 years) will complete

Positive Affect (Ages 13-17) – Fixed Form

Please respond to each question or statement by marking one box per row.

In the past 7 days:

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PA001	I felt cheerful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA002	I felt attentive	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA006	I felt delighted	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA014	I felt joyful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA018	I felt at ease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA019	I felt enthusiastic	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA021	I felt interested	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA030	I felt peaceful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA037	I felt good-natured	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PA044	I felt content	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Support (Ages 18+) – Fixed Form

Please respond to each question or statement by marking one box per row.

In the past month, please describe how often…		**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
SOC200	I have someone who understands my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC203	I have someone who will listen to me when I need to talk.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC204	I feel there are people I can talk to if I am upset.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC205	I have someone to talk with when I have a bad day.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC206	I have someone I trust to talk with about my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC207	I have someone I trust to talk with about my feelings.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC222	I can get helpful advice from others when dealing with a problem	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

SOC229	I have someone to turn to for suggestions about how to deal with a problem.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Emotional Support (Ages 8-17) – Fixed Form

Please respond to each question or statement by marking one box per row.

	In the past month, please describe how often…	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
SOC200	I have someone who understands my problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC203	I have someone who will listen to me when I need to talk	☐ 1	☐ 1	☐ 2	☐ 3	☐ 4
SOC205	I have someone to talk with when I have a bad day	☐ 1	☐ 1	☐ 2	☐ 3	☐ 4
SOC216	There is someone around to help me if I need it	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC222	I can get helpful advice from others when dealing with a problem.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC225	I get useful advice about important things in my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SOC226	I have someone to talk with about school problems	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance: Pediatric Patients (age 8-17 years) will complete

Pediatric Sleep Disturbance – Short Form 4a

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Never	Almost never	Sometimes	Almost always	Always
sq005c	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
sq020c_r	I slept through the night	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
sq041c_r	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
sq042c	I had trouble sleeping	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance: Parent Proxy for Pediatric Patients (age 5-17 years) will complete

Parent Proxy Sleep Disturbance – Short Form 4a

Please respond to each question or statement by marking one box per row.

	In the past 7 days…	Never	Almost never	Sometimes	Almost always	Always
sq005p	My child had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
sq020p_r	My child slept through the night	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
sq041p_r	My child had a problem with his/her sleep.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
sq042p	My child had trouble sleeping	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Caregiver Anxiety: Adult caregiver will complete

TBI-CareQOL SF v1.0- Caregiver-Specific Anxiety

Caregiver-Specific Anxiety- Short Form

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
TBICQ_CW11r	I worry that something small will irritate the person I care for.	☐	☐	☐	☐	☐
TBICQ_CW67r	I feel like I have to choose my words carefully around the person I care	☐	☐	☐	☐	☐
TBICQ_CW28r	I feel drained because of the person with the injury's unpredictable	☐	☐	☐	☐	☐
TBICQ_CW8r	I cannot enjoy myself because I am worried about the person I care	☐	☐	☐	☐	☐
TBICQ_CW24r	I cannot focus on other activities because of my worry for the person I care for.	☐	☐	☐	☐	☐
TBICQ_CW79r	I feel frightened that the person I care for might behave	☐	☐	☐	☐	☐

Caregiver Strain: Adult caregiver will complete

TBI-CareQOL SF v1.0- Caregiver Strain

Caregiver Strain- Short Form

Please respond to each item by marking one box per row.

		Never	Rarely	Sometimes	Usually	Always
TBICQ_S46r	I feel that there are not enough hours in the day to get everything done.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
TBICQ_S27r	I feel stressed when it comes to providing care for the person with the	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
TBICQ_S43r	I feel that stress makes it difficult to start anything new.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
TBICQ_S32r	I feel drained by my responsibilities as a caregiver.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
TBICQ_S24r	I cannot handle any more responsibility when it comes to providing care for the	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
TBICQ_S62r	I feel burdened with the responsibility of caring for the person with the injury.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

Name_____Date_____

Age_____Gender (*Circle*): **M F** Other _____

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last month, how often have you been upset because of something that happened unexpectedly?.....	**0**	**1**	**2**	**3**	**4**
2. In the last month, how often have you felt that you were unable to control the important things in your life?.....	**0**	**1**	**2**	**3**	**4**
3. In the last month, how often have you felt nervous and "stressed"?	**0**	**1**	**2**	**3**	**4**
4. In the last month, how often have you felt confident about your ability to handle your personal problems?.....	**0**	**1**	**2**	**3**	**4**
5. In the last month, how often have you felt that things were going your way?.....	**0**	**1**	**2**	**3**	**4**
6. In the last month, how often have you found that you could not cope with all the things that you had to do?	**0**	**1**	**2**	**3**	**4**
7. In the last month, how often have you been able to control irritations in your life?.....	**0**	**1**	**2**	**3**	**4**
8. In the last month, how often have you felt that you were on top of things?.....	**0**	**1**	**2**	**3**	**4**
9. In the last month, how often have you been angered because of things that were outside of your control?	**0**	**1**	**2**	**3**	**4**
10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?.....	**0**	**1**	**2**	**3**	**4**

Please feel free to use the *Perceived Stress Scale* for your research. The PSS Manual is in the process of development, please let us know if you are interested in contributing.

Mind Garden, Inc.
1690 Woodside Road, Suite #202 Redwood
City, CA 94061 USA
Phone: (650) 261-3500 Fax: (650) 261-3505
e-mail: mindgarden@msn.com
www.mindgarden.com**References**

The PSS Scale is reprinted with permission of the American Sociological Association, from Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24,* 386-396

Cohen, S and Williamson, G. Perceived Stress in a probability sample of the United States. Spacapan, S. and Oskamp, S. (eds.) The Social Psychology of Health. Newbury Park, CA: Sage, 1988

Profile 25: Pediatric Patient (age 8-17 years) will complete

PROMIS Pediatric Profile v2.0 – Profile-25

Pediatric Profile-25

Please respond to each question or statement by marking one box per row.

	Physical Function Mobility **In the past 7 days…**	**With no trouble**	**With a little trouble**	**With some trouble**	**With a lot of trouble**	**Not able to do**
235R1r	I could do sports and exercise that other kids my age could do.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4124R1r	I could get up from the floor	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2707R2r	I could walk up stairs without holding on to anything.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
5023R1r	I have been physically able to do the activities I enjoy most	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
2220R2r	I felt like something awful might happen..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
713R1r	I felt nervous.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5044R1r	I felt worried.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3459bR1r	I worried when I was at home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depressive Symptoms **In the past 7 days...**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
5041R1r	I felt everything in my life went wrong.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
711R1r	I felt lonely	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
228R1r	I felt sad.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3952aR2r	It was hard for me to have fun.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
4239aR2r	Being tired made it hard for me to keep up with my schoolwork.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2876R1r	I got tired easily.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last update: 20 July 2016

	Fatigue **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
4241R2r	I was too tired to do sports or exercise.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4196R1r	I was too tired to enjoy the things I like to do.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Peer Relationships **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
5018R1r	I felt accepted by other kids my age.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5059R1r	I was able to count on my friends	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5055R1r	My friends and I helped each other out.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
233R2r	Other kids wanted to be my friend.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Interference **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
3793R1r	I had trouble sleeping when I had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9004r	It was hard for me to pay attention when I had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2045R1r	It was hard for me to run when I had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2049R1r	It was hard for me to walk one block when I had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Pain Intensity **In the past 7 days…**											
9033R1r	How bad was your pain on average?...	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain you can think of**

Profile 25: Parent Proxy for Pediatric Patients (age 5-17 years) will complete

PROMIS Parent Proxy Profile v2.0 – Profile-25

Parent Proxy Profile – 25

Please respond to each question or statement by marking one box per row.

	Physical Function Mobility **In the past 7 days…**	**With no trouble**	**With a little trouble**	**With some trouble**	**With a lot of trouble**	**Not able to do**
Pf1mobil3r	My child could do sports and exercise that other kids his/her age could do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Pf3mobil9r	My child could get up from the floor	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Pf2mobil4r	My child could walk up stairs without holding on to anything	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Pf1mobil1r	My child has been physically able to do the activities he/she enjoys most	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf2anxiety1r	My child felt like something awful might happen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf1anxiety9r	My child felt nervous	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2anxiety9r	My child felt worried	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2anxiety5r	My child worried when he/she was at home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depressive Symptoms **In the past 7 days...**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf1depr7r	My child felt everything in his/her life went wrong	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2depr10r	My child felt lonely	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2depr3r	My child felt sad	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2depr6r	It was hard for my child to have fun	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf2fatigue8r	Being tired made it hard for my child to keep up with schoolwork	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf4fatigue3r	My child got tired easily	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Last Update: 26 July 2016

PROMIS Parent Proxy Profile v2.0 – Profile-25

	Fatigue **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf3fatigue8r	My child was too tired to do sports or exercise.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf4fatigue4r	My child was too tired to enjoy the things he/she likes to do.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Peer Relationships **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf3socabil9r	My child felt accepted by other kids his/her age	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf4socabil12r	My child was able to count on his/her friends.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2socrole4r	My child and his/her friends helped each other out	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf1socabil2r	Other kids wanted to be my child's friend..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Interference **In the past 7 days…**	**Never**	**Almost Never**	**Sometimes**	**Often**	**Almost Always**
Pf2pain5r	My child had trouble sleeping when he/she had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf3pain2r	It was hard for my child to pay attention when he/she had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf2pain4r	It was hard for my child to run when he/she had pain.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pf1pain4r	It was hard for my child to walk one block when he/she had pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Pain Intensity

In the past 7 days…

prx9033R1	How bad was your child's pain on average?.....	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain you can think of**

Last Update: 26 July 2016

Profile 29+2: Adult Patient and Caregiver will complete

PROMIS® 29+2 Profile v2.1 (PROPr)

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA53	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDANX01	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX40	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX41	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression **In the past 7 days...**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
EDDEP04	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP06	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
HI7	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
AN3	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Fatigue **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
FATEXP41	How run-down did you feel on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATEXP40	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Sleep Disturbance **In the past 7 days…**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
Sleep109	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
Sleep116	My sleep was refreshing.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep20	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep44	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Ability to Participate in Social Roles and Activities	**Never**	**Rarely**	**Sometimes**	**Usually**	**Always**
SRPPER11 CaPS	I have trouble doing all of my regular leisure activities with others	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER18 CaPS	I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER23 _CaPS	I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
SRPPER46 CaPS	I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PAININ9	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ22	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ31	How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PAININ34	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Cognitive Function - Abilities **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
PC6r	I have been able to concentrate	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PC27r	I have been able to remember to do things, like take medicine or buy something I needed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Intensity **In the past 7 days…**					
Global07	How would you rate your pain on average?	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain imaginable**

Mobile Application Rating Scale (MARS)- Caregiver/Patients Day 120 (Ages 10 or older)

App Quality Ratings

The Rating scale assesses app quality on four dimensions. All items are rated on a 5-point scale from "1.Inadequate" to "5.Excellent". Circle the number that most accurately represents the quality of the app component you are rating. Please use the descriptors provided for each response category.

SECTION A

Engagement – fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience

1. Entertainment: Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?

1 Dull, not fun or entertaining at all
2 Mostly boring
3 OK, fun enough to entertain user for a brief time (< 5 minutes)
4 Moderately fun and entertaining, would entertain user for some time (5-10 minutes total)
5 Highly entertaining and fun, would stimulate repeat use

2. Interest: Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?

1 Not interesting at all
2 Mostly uninteresting
3 OK, neither interesting nor uninteresting; would engage user for a brief time (< 5 minutes)
4 Moderately interesting; would engage user for some time (5-10 minutes total)
5 Very interesting, would engage user in repeat use

3. Customisation: Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?

1 Does not allow any customisation or requires setting to be input every time
2 Allows insufficient customisation limiting functions
3 Allows basic customisation to function adequately
4 Allows numerous options for customisation
5 Allows complete tailoring to the individual's characteristics/preferences, retains all settings

4. Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customisable and not overwhelming in order to be perfect.

1 No interactive features and/or no response to user interaction
2 Insufficient interactivity, or feedback, or user input options, limiting functions
3 Basic interactive features to function adequately
4 Offers a variety of interactive features/feedback/user input options
5 Very high level of responsiveness through interactive features/feedback/user input options

5. Target group: Is the app content (visual information, language, design) appropriate for your target audience?

1 Completely inappropriate/unclear/confusing
2 Mostly inappropriate/unclear/confusing
3 Acceptable but not targeted. May be inappropriate/unclear/confusing
4 Well-targeted, with negligible issues
5 Perfectly targeted, no issues found

SECTION B

Functionality – app functioning, easy to learn, navigation, flow logicand gestural design of app

6. Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?

1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
2 Some functions work, but lagging or contains major technical problems
3 App works overall. Some technical problems need fixing/Slow at times
4 Mostly functional with minor/negligible problems
5 Perfect/timely response; no technical bugs found/contains a 'loading time left' indicator

7. Ease of use: How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?

1 No/limited instructions; menu labels/icons are confusing; complicated
2 Useable after a lot of time/effort
3 Useable after some time/effort
4 Easy to learn how to use the app (or has clear instructions)
5 Able to use app immediately; intuitive; simple

8. Navigation: Is moving between screens logical/accurate/appropriate/ uninterrupted; are all necessary screen links present?

1 Different sections within the app seem logically disconnected and random/confusing/navigation is difficult
2 Usable after a lot of time/effort
3 Usable after some time/effort
4 Easy to use or missing a negligible link
5 Perfectly logical, easy, clear and intuitive screen flow throughout, or offers shortcuts

9. Gestural design: Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?

1 Completely inconsistent/confusing
2 Often inconsistent/confusing
3 OK with some inconsistencies/confusing elements
4 Mostly consistent/intuitive with negligible problems
5 Perfectly consistent and intuitive

SECTION C

Aesthetics – graphic design, overall visual appeal, colour scheme, and stylistic consistency

10. Layout: Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?

1 Very bad design, cluttered, some options impossible to select/locate/see/read device display not optimised
2 Bad design, random, unclear, some options difficult to select/locate/see/read
3 Satisfactory, few problems with selecting/locating/seeing/reading items or with minor screensize problems
4 Mostly clear, able to select/locate/see/read items
5 Professional, simple, clear, orderly, logically organised, device display optimised. Every design component has a purpose

11. Graphics: How high is the quality/resolution of graphics used for buttons/icons/menus/content?

1 Graphics appear amateur, very poor visual design - disproportionate, completely stylistically inconsistent
2 Low quality/low resolution graphics; low quality visual design – disproportionate, stylistically inconsistent
3 Moderate quality graphics and visual design (generally consistent in style)
4 High quality/resolution graphics and visual design – mostly proportionate, stylistically consistent
5 Very high quality/resolution graphics and visual design - proportionate, stylistically consistent throughout

12. Visual appeal: How good does the app look?

1 No visual appeal, unpleasant to look at, poorly designed, clashing/mismatched colours
2 Little visual appeal – poorly designed, bad use of colour, visually boring
3 Some visual appeal – average, neither pleasant, nor unpleasant
4 High level of visual appeal – seamless graphics – consistent and professionally designed
5 As above + very attractive, memorable, stands out; use of colour enhances app features/menus

SECTION D

Information – Contains high quality information (e.g. text, feedback, measures, references) from a credible source. Select N/A if the app component is irrelevant.

13. Accuracy of app description (in app store): Does app contain what is described?

1 Misleading. App does not contain the described components/functions. Or has no description
2 Inaccurate. App contains very few of the described components/functions
3 OK. App contains some of the described components/functions
4 Accurate. App contains most of the described components/functions

5 Highly accurate description of the app components/functions

14. Goals: Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)?

N/A Description does not list goals, or app goals are irrelevant to research goal (e.g. using a game for educational purposes)
1 App has no chance of achieving its stated goals
2 Description lists some goals, but app has very little chance of achieving them
3 OK. App has clear goals, which may be achievable.
4 App has clearly specified goals, which are measurable and achievable
5 App has specific and measurable goals, which are highly likely to be achieved

15. Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?

N/A There is no information within the app
1 Irrelevant/inappropriate/incoherent/incorrect
2 Poor. Barely relevant/appropriate/coherent/may be incorrect
3 Moderately relevant/appropriate/coherent/and appears correct
4 Relevant/appropriate/coherent/correct
5 Highly relevant, appropriate, coherent, and correct

16. Quantity of information: Is the extent coverage within the scope of the app; and comprehensive but concise?

N/A There is no information within the app
1 Minimal or overwhelming
2 Insufficient or possibly overwhelming
3 OK but not comprehensive or concise
4 Offers a broad range of information, has some gaps or unnecessary detail; or has no links to more information and resources
5 Comprehensive and concise; contains links to more information and resources

17. Visual information: Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?

N/A There is no visual information within the app (e.g. it only contains audio, or text)
1 Completely unclear/confusing/wrong or necessary but missing
2 Mostly unclear/confusing/wrong
3 OK but often unclear/confusing/wrong
4 Mostly clear/logical/correct with negligible issues
5 Perfectly clear/logical/correct

18. Credibility: Does the app come from a legitimate source (specified in app store description or within the app itself)?

1 Source identified but legitimacy/trustworthiness of source is questionable (e.g. commercial business with vested interest)
2 Appears to come from a legitimate source, but it cannot be verified (e.g. has no webpage)
3 Developed by small NGO/institution (hospital/centre, etc.) /specialised commercial business, funding body
4 Developed by government, university or as above but larger in scale
5 Developed using nationally competitive government or research funding (e.g. Australian Research Council, NHMRC)

19. Evidence base: Has the app been trialled/tested; must be verified by evidence (in published scientific literature)?

N/A The app has not been trialled/tested
1 The evidence suggests the app does not work
2 App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has partially positive outcomes in studies that are not randomised controlled trials (RCTs), or there is little or no contradictory evidence.
3 App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has positive outcomes in studies that are not RCTs, and there is no contradictory evidence.
4 App has been trialled and outcome tested in 1-2 RCTs indicating positive results
5 App has been trialled and outcome tested in > 3 high quality RCTs indicating positive results

App subjective quality

SECTION E

20. Would you recommend this app to people who might benefit from it?

1 **Not at all** I would not recommend this app to anyone
2 There are very few people I would recommend this app to
3 **Maybe** There are several people whom I would recommend it to
4 There are many people I would recommend this app to
5 **Definitely** I would recommend this app to everyone

21. How many times do you think you would use this app in the next 12 months if it was relevant to you?

1 **None**
2 1-2
3 3-10
4 10-50
5 >50

22. Would you pay for this app?

1 No
3 Maybe
5 Yes

23. What is your overall star rating of the app?

1 Star: One of the worst apps I've used

2 .Stars

3 .Stars: Average

4. Stars

5 .Stars: One of the best apps I've used

These added items can be adjusted and used to assess the perceived impact of the app on the user's knowledge, attitudes, intentions to change as well as the likelihood of actual change in the target health behavior.

SECTION F: On A Scale of 1-5

(1:Strongly disagree 5:Strong agree)

1. Awareness: This app is likely to increase awareness of the importance of addressing health related quality of life or well-being

2. Knowledge: This app is likely to increase knowledge/understanding of addressing health related quality of life or well-being

3. Attitudes: This app is likely to change attitudes toward improving addressing health related quality of life or well-being

4. Intention to change: This app is likely to increase intentions/motivation to address addressing health related quality of life or well-being

5.Help seeking: Use of this app is likely to encourage further help to enhance your health related quality of life or well-being

6. Behavior change: Use of this app is likely increase/decrease addressing health related quality of life or well-being

Qualitative Interviews: Discharge, Day 30, Day 60, Day 90, Day 120

General semi-structured interview questions (both caregiver and patient participants)

1) In your opinion, what information is most important for you to have post-transplant?

2) Would an app with this information be beneficial to you?

3) If you could design an app or additional intervention post-transplant, what would it involve?

4) Do you think this additional app or intervention would be helpful, burdensome, or neutral?

5) What information do you feel was missing during your stay? For days +30, +60, +90, and +120: What do you wish you had been told between discharge and now?

6) Do you have an interest in tracking some of your symptoms post-transplant? Which ones would you want to track?

7) Are you interested in tracking your sleep, heart rate, temperature, etc. post-transplant?

8) What has helped you cope post-transplant?

BMT Roadmap 2.0-directed questions (both caregiver and patient participants)

1) What do you think of BMT Roadmap 2.0, wearable sensor, and positive activities (if applicable)?

- What do you find most helpful?
- What do you find least helpful?

2) Would you change anything about any of the above (add, change, take away)?

Social Rhythms App Questionnaire:
The social rhythms app has a few baseline questions for the user upon entry into the app.

1. What is your age, in years?

2. Please select your gender?

3. If they select "Prefer to self-describe" then they also get a question: "Please enter your gender" with a text box.

4. What is your race?

5. Did you social distance for COVID-19, or are you currently doing so?

6. When did you begin social distancing for COVID-19?

7. Have you ended Social distancing for COVID-19

8. When did you end social distancing for COVID-19?9. What type of Urban or Rural environment do you live in?

Revised Life Orientation Test (LOT-R)

Instructions:

Please answer the following questions about yourself by indicating the extent of your agreement using the following scale:

I 0 I = strongly disagree
I I I = disagree
I 2 I = neutral
I 3 I = agree
I 4 I = strongly agree

Be as honest as you can throughout, and try not to let your responses to one question influence your response to other questions. There are no right or wrong answers

_____ 1. In uncertain times, I usually expect the best.
_____ 2. It's easy for me to relax.
_____ 3. If something can go wrong for me, it will.
_____ 4. I'm always optimistic about my future.
5. I enjoy my friends a lot.
_____ 6. It's important for me to keep busy.
_____ 7. I hardly ever expect things to go my way.
_____ 8. I don't get upset too easily.
9. I rarely count on good things happening to me.
_____ 10 Overall, I expect more good things to happen to me than bad.
_____

Scoring:

1. Reverse code items 3, 7, and 9 prior to scoring (0=4) (1=3) (2=2) (3±1) (4=0).

2. Sum items l, 3, 4, 7, 9, and 10 to obtain an overall score.

Note Items 2, 5, 6, and 8 are filler items only. They are not scored as part of the revised scale.

Conner-Davidson Resilience Scale 10 (CD-RISC-10)

Initials ID# date / / visit age

Please indicate how much you agree with the following statements as they apply to you over the last **month**. If a particular situation has not occurred recently, answer according to how you think you would have felt.

	not true at all (0)	rarely true (1)	sometimes true (2)	often true (3)	true nearly all the time (4)
1. I was able to adapt when change occur.		<	<	<	<
2. I can deal with whatever comes my way.		<	<	<	<
3. I try to see the humous side of things when I am faced with problems.	<	<	<	<	<
4. Having to cope with stress can make me stronger.	<	<	<	<	<
5. I tend to bounce back after illness, injury or other hardships.	<	<	<	<	<
6. I believe I can achieve my goals, even if there are obstacles.	<	<	<	<	<
7. Under pressure, I stay focused and think clearly.	<	<	<	<	<
8. I am not easily discouraged by failure.	<	<	<	<	<
9. I think of myself as a strong person when dealing with life's challenges and difficulties.	<	<	<	<	<
	<	<	<	<	<
10. I am able to handle unpleasant or painful feelings like sadness, fear, and anger.	<	<	<	<	<

The Gratitude Questionnaire-Six Item Form (GQ-6)

By Michael E. McCullough, Ph.D., Robert A. Emmons, Ph.D., Jo-Ann Tsang, Ph.D.

Using the scale below as a guide, write a number beside each statement to indicate how much you agree with it.

1 = strongly disagree
2 = disagree
3 = slightly disagree
4 = neutral
5 = slightly agree
6 = agree
7 = strongly agree

____1. I have so much in life to be thankful for.

____2. If I had to list everything that I felt grateful for, it would be a very long list.

____3. When I look at the world, I don't see much to be grateful for.*

____4. I am grateful to a wide variety of people.

____5. As I get older I find myself more able to appreciate the people, events, and situations that have been part of my life history.

____6. Long amounts of time can go by before I feel grateful to something or someone.*

* Items 3 and 6 are reverse-scored.

Dyadic Relationship Scale

Dyadic Relationship Scale (Caregiver)

This series of questions address some of the difficulties that people face as they care for a relative. I'd like to talk about how helping your [REL] has affected your relationship with her/him during the past month. [HAND CG CARD]. Please refer to this card for your responses. How much do agree or disagree with the following statements?

Because of helping my [REL]:	Strongly Agree	Agree	Disagree	Strongly Disagree
a. I felt closer to her/him than I have in awhile	0	1	2	3
b. I have learned some good things about my [REL]	0	1	2	3
c. I felt angry toward her/him	3	2	1	0
d. I felt depressed because of my relationship with her/him	3	2	1	0
e. I felt resentful toward her/him	3	2	1	0
f. I have had more patience than I have had in the past	0	1	2	3
g. I have learned some good things about myself	0	1	2	3
h. I felt that my relationship with her/him was strained	3	2	1	0
i. I have learned some nice things about other people in my life	0	1	2	3
j. Communication between my [REL] and me has improved	0	1	2	3
k. I felt that s/hhe madee requests over and above what s/he needed	3	2	1	0

Dyadic Relationship Scale (Care Recipient)

I'd like to talk about how your memory problems have affected your relationship with your [CG] over the past month? **[HAND RESP CARD]**. Please refer to this card for your responses and again, we are talking about the past month. How much do you agree or disagree with the following statements?

[For Care Recipients who are unabe to distinguish between the four response categories, use only the **"Yes"** and **"No"** response options and the reverse of RESP CARD which has the appropriate "Yes" "No" responses for the **entire** scale]

Because of helping my [REL]:	Strongly Agree	Agree	Disagree	Strongly Disagree
a. I felt closer to her/him than I have in awhile	0	1	2	3
b. I have learned some good things about myself	0	1	2	3
c. I felt angry toward [CG]	3	2	1	0
d. I felt depressed because of my relationship	3	2	1	0
e. I felt resentful toward my [CG]	3	2	1	0
f. I have had more patience than I have had in the past	0	1	2	3
g. I have learned some good things about my [CG]	0	1	2	3
h. I felt that my relationship with my [CG] was strained	3	2	1	0
i. I have learned some nice things about other people in my life	0	1	2	3
j. Communication between my [REL] and me has improved	0	1	2	3

COVID-19 Patient Questions

Please indicate if you have experienced any of the following during the COVID-19 pandemic:

a. You have contracted COVID
b. A member of your household contracted COVID-19
c. You or your partner where considered essential personnel
d. Loss or involuntary reduction of your employment income
e. Loss or involuntary reduction of your partner's employment income
f. Loss of childcare or school closure
g. You worked primarily from home
h. You voluntarily reduced your work hours
i. You are considering reducing your work hours
j. Your partner worked primarily from home
k. Your partner voluntarily reduced their work hours
l. Your partner is considering reducing their work hours
m. You or your partner has health insurance benefits reduced or lost

To what extent did you find that COVID19 made it more difficult to get essential supplies including food, medicine, hygiene products, and healthcare?

a. Significantly more difficult than prior to COVID
b. A little more difficult than prior to COVID
c. About the same as prior to COVID
d. A little easier than prior to COVID
e. Significantly easier than prior to COVID

Did a family member or close friend…

a. Have symptoms of COVID-19
    a. Fever
    b. Chills
    c. Shortness of breath
    d. New or worsening cough
    e. Sore throat
    f. Body aches
    g. Vomiting
    h. Diarrhea
    i. Loss of smell
    j. Loss of taste
    k. Other
b. Have a confirmed COVID-19 diagnosis
c. Have a hospitalization for COVID
d. Die from COVID

What was your relation to that family member or close friend?

a. A brother or sister

b. Your parents
c. Your child
d. A cousin
e. An aunt/uncle
f. A close friend

Did you…

a. Have any of the following symptoms of COVID-19
    a. Fever
    b. Chills
    c. Shortness of breath
    d. New or worsening cough
    e. Sore throat
    f. Body aches
    g. Vomiting
    h. Diarrhea
    i. Loss of smell
    j. Loss of taste
    k. Other
b. Have a confirmed COVID diagnosis
c. Have a hospitalization for COVID
d. Have an ICU visit as a result of COVID

If “Have a confirmed COVID diagnosis”, “hospitalization”, or “ICU visit” is selected:

How many times did you get COVID?

Did you receive any treatments for COVID? (Yes/No)

If yes, please select the type of treatment(s) you received (check all that apply):

Oral medication at home

Infusion at a hospital or an infusion center

Other (please describe)

Have you had a confirmed diagnosis of Long COVID?

Yes

No, but I suspect I have/had Long COVID

No, never had Long COVID

If “yes” or “suspected” to confirmed diagnosis of Long COVID:

- Please select the following symptoms of Long COVID that you experienced:
    - Fatigue
    - Shortness of breath or difficulty breathing
    - Cough

- Joint or muscle pain
- Chest pain
- Stomach pain
- Difficulty thinking or concentrating (“brain fog”)
- Sleep problems
- Headache
- Fast or pounding heartbeat (heart palpitations)
- Loss of smell or taste
- Depression or anxiety
- Fever
- Dizziness when you stand
- Pins-and-needles feelings
- Diarrhea
- Rash
- Changes in menstrual cycles
- Worsened symptoms after physical or mental activities (“post-exertional malaise”)

Have you been vaccinated against COVID? (Y/N)

If yes:

How many doses?

Which brand(s) of the COVID vaccine did you receive? Select all that apply

- Pfizer
- Moderna
- Johnson & Johnson/Jassen
- Other (please specify)

Was your treatment changed or delay as a result of COVID? Yes/No

If yes, please select all that apply

a. Treatment delayed including chemotherapy or radiation
b. Imaging or scans delay
c. Initial consult appointment delayed

If yes, please select

a. I or my family wanted to reschedule
b. Provider recommendation to reschedule
c. Other; please specify _____

If yes, do you feel the delay has or will negatively change the outcome of your disease?

a. Yes
b. No
c. Not sure
d. Other; please explain _____

Overall, what was the effect of COVID on your physical well-being?

a. Made it a lot better
b. Made it a little better
c. About the same
d. Made it a little worse
e. Made it a lot worse

Overall, what was the effect of COVID on your emotional well-being?

a. Made it a lot better
b. Made it a little better
c. About the same
d. Made it a little worse
e. Made it a lot worse

Overall, how much distress have you experienced related to COVID?

1 2 3 4 5 6 7

No Distress Extreme Distress

COVID-19 Caregiver Questions

Please indicate if you have experienced any of the following during the COVID-19 pandemic:

a. You provided direct care to a family member with known or suspected COVID-19
b. You have contracted COVID
c. A member of your household contracted COVID-19
d. You or your partner where considered essential personnel
e. Your household living arrangements changed to protect others in your household from COVID-19 (caregiver)
f. Loss or involuntary reduction of your employment income
g. Loss or involuntary reduction of your partner's employment income
h. Loss of childcare or school closure
i. You worked primarily from home
j. You voluntarily reduced your work hours
k. You are considering reducing your work hours
l. Your partner worked primarily from home
m. Your partner voluntarily reduced their work hours
n. Your partner is considering reducing their work hours

[*BRANCH: If "yes" to child care/school closure, both questions below*]

Who is/was primarily responsible for providing childcare or schooling during this period?

- You
- Your spouse or partner
- A sibling
- Other family (e.g. grandparents, aunts/uncles)
- A paid in-home child care provider (e.g. nanny)
- A child care facility located outside your home
- Other_____

Who in your family is/was responsible for performing day-to-day (non-childcare) household tasks during this period (such as cleaning, cooking, laundry, etc.)?

- I performed most or all of the household tasks
- I performed slightly more household tasks than my significant other
- My significant other and I shared the responsibility for performing household tasks evenly
- My significant other performed slightly more household tasks than I do
- My significant other performed most or all of the household tasks
- Other family performed most household tasks
- We employed outside help to aid with most household tasks

To what extent did you find that COVID19 made it more difficult to get essential supplies including food, medicine, hygiene products, and healthcare?

f. Significantly more difficult than prior to COVID
g. A little more difficult than prior to COVID
h. About the same as prior to COVID
i. A little easier than prior to COVID
j. Significantly easier than prior to COVID

Did a family member or close friend…

e. Have symptoms of COVID-19
    a. Fever
    b. Chills
    c. Shortness of breath
    d. New or worsening cough
    e. Sore throat
    f. Body aches
    g. Vomiting
    h. Diarrhea
    i. Loss of smell
    j. Loss of taste
    k. Other
f. Have a confirmed COVID-19 diagnosis
g. Have a hospitalization for COVID
h. Die from COVID

If yes, what was the family member(s) and/or friend(s) relation?

What was your relation to that family member or close friend?

g. A brother or sister
h. Your parents
i. Your child
j. A cousin
k. An aunt/uncle
l. A close friend

Did you…

e. Have any of the following symptoms of COVID-19
    a. Fever
    b. Chills
    c. Shortness of breath
    d. New or worsening cough
    e. Sore throat
    f. Body aches
    g. Vomiting
    h. Diarrhea
    i. Loss of smell
    j. Loss of taste
    k. Other

f. Have a confirmed COVID diagnosis
g. Have a hospitalization for COVID
h. Have an ICU visit as a result of COVID

If “Have a confirmed COVID diagnosis”, “hospitalization”, or “ICU visit” is selected:

How many times did you get COVID?

Did you receive any treatments for COVID? (Yes/No)

If yes, please select the type of treatment(s) you received (check all that apply):

Oral medication at home

Infusion at a hospital or infusion center

Other (please describe)

Have you had a confirmed diagnosis of Long COVID?

Yes

No, but I suspect I have/had Long COVID

No, never had Long COVID

If “yes” or “suspected” to confirmed diagnosis of Long COVID:

- Please select the following symptoms of Long COVID that you experienced:
  - Fatigue
  - Shortness of breath or difficulty breathing
  - Cough
  - Joint or muscle pain
  - Chest pain
  - Stomach pain
  - Difficulty thinking or concentrating (“brain fog”)
  - Sleep problems
  - Headache
  - Fast or pounding heartbeat (heart palpitations)
  - Loss of smell or taste
  - Depression or anxiety
  - Fever
  - Dizziness when you stand
  - Pins-and-needles feelings
  - Diarrhea
  - Rash
  - Changes in menstrual cycles
  - Worsened symptoms after physical or mental activities (“post-exertional malaise”)

Have you been vaccinated against COVID? (Y/N)

If yes:

How many doses?

Which brand(s) of the COVID vaccine did you receive? Select all that apply

- Pfizer
- Moderna
- Johnson & Johnson/Jassen
- Other (please specify)

Was your loved one's (patient's) treatment changed or delay as a result of COVID? Yes/No

If yes, please select all that apply

d. Treatment delayed including chemotherapy, or radiation
e. Imaging or scans delay
f. Initial consult appointment delayed

If yes, please select

d. Patient/family wanted to reschedule
e. Provider recommendation to reschedule
f. Other; please specify _____

If yes, do you feel the delay has or will negatively change the outcome of your loved one's (patient's) disease?

e. Yes
f. No
g. Not sure
h. Other; please explain _____

Overall, what was the effect of COVID on your physical well-being?

f. Made it a lot better
g. Made it a little better
h. About the same
i. Made it a little worse
j. Made it a lot worse

Overall, what was the effect of COVID on your emotional well-being?

f. Made it a lot better
g. Made it a little better
h. About the same
i. Made it a little worse
j. Made it a lot worse

Overall, how much distress have you experienced related to COVID?

1 2 3 4 5 6 7

No Distress Extreme Distress

APPENDIX E: REFERENCES

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