



A pilot intervention of using a mobile health app (ONC Roadmap) to enhance health-related quality of life in family caregivers of pediatric patients with cancer

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Background: The Roadmap mobile health (mHealth) app was developed to provide health-related quality of life (HRQOL) support for family caregivers of patients with cancer.

Methods: Eligibility included: family caregivers (age ≥ 18 years) who self-reported as the primary caregiver of their pediatric patient with cancer; patients (age ≥ 5 years) who were receiving cancer care at the University of Michigan. Feasibility was calculated as the percentage of caregivers who logged into *ONC Roadmap* and engaged with it at least twice weekly for at least 50% of the 120-day study duration. Feasibility and acceptability was also assessed through a Feasibility and Acceptability questionnaire and the Mobile App Rating Scale to specifically assess app-quality. Exploratory analyses were also conducted to assess HRQOL self- or parent proxy assessments and physiological data capture.

Results: Between September 2020–September 2021, 100 participants (or 50 caregiver-patient dyads) consented and enrolled in the *ONC Roadmap* study for 120-days. Feasibility of the study was met, wherein the majority of caregivers ($N=32$; 65%) logged into *ONC Roadmap* and engaged with it at least twice weekly for at least 50% of the study duration (defined *a priori* in the Protocol). The Feasibility and Acceptability questionnaire responses indicated that the study was feasible and acceptable with the majority (>50%) reporting *Agree* or *Strongly Agree* with positive *Net Favorability* [(*Agree* + *Strongly Agree*) – (*Disagree* + *Totally Disagree*)] in each of the domains (e.g., Fitbit use, *ONC Roadmap* use, completing longitudinal assessments,

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engaging in similar future study, study expectations). Improvements were seen across the majority of the mental HRQOL domains across all groups; even though underpowered, there were significant improvements in caregiver-specific aspects of HRQOL and anxiety and in depression and fatigue for children (ages 8–17 years), and a trend toward improvement in depression for children ages 8–17 years and in fatigue for adult patients.

Conclusions: This study supports that mHealth technology may be a promising platform to provide HRQOL support for caregivers of pediatric patients with cancer. Importantly, the findings suggest that the study protocol was feasible, and participants were favorable to participate in future studies of this intervention alongside routine cancer care delivery.

Keywords: Mobile health (mHealth); wearable sensors; pediatric oncology

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Introduction

Over the past decade, our interdisciplinary team developed a positive psychology-based mHealth app (Roadmap) (1). We created this app, because when a child is diagnosed with cancer, the entire family is impacted (2,3). Invariably, cancer alters the health-related quality of life (HRQOL) of family members and their care recipients (patients) (4). Family caregivers face a myriad of challenges navigating the demands of paid jobs with unpaid caregiving tasks (5). Unsurprisingly, caregivers who assume significant caregiving responsibilities

at home face higher physical and emotional stressors, impeding their ability to provide care of loved ones, make decisions, and manage self-care (6-9). These chronic stressors can lead to adverse psychological and physiological effects on their daily lives that can adversely impact the patient (10,11).

The Roadmap mHealth app was developed to provide HRQOL support for family caregivers of patients with cancer (12,13). Applying Carbonneau's conceptual framework on the positive aspects of caregiving (14), iterative cycles of user-centered design were utilized (15). This framework included three central positive aspects of caregiving: (I) quality of caregiver and patient daily relationship; ii) caregiver feeling of accomplishment; and (III) meaning of the caregiver role in daily life. These domains were considered interdependent and working together to reinforce positive outcomes (e.g., caregiver well-being) and protect caregiver HRQOL. Caregiver self-efficacy and caregiver enrichment events in daily life influenced the enhancement of positive aspects of caregiving (14).

Guided by this framework (14), the Roadmap mHealth app was studied in a pilot intervention to support the HRQOL of family caregivers of pediatric patients with cancer. Herein, this Roadmap app was leveraged to: (I) assess the feasibility and acceptability of the Roadmap mHealth app (*henceforth*, ONC Roadmap, abbreviated for "oncology") in caregivers of pediatric patients with cancer; (II) characterize self-reported outcomes of physical, mental, and social HRQOL domains; and (III) evaluate the wearable sensor data outputs in both caregivers and patients. This work is important because it may inform future mHealth design

Highlight box

Key findings

- ONC Roadmap was shown to be feasible to use by caregivers of pediatric patients with cancer. This mHealth intervention may provide health-related quality of life (HRQOL) support in this population.

What is known and what is new?

- Cancer care delivery has focused primarily on involving the patient, and to an even lesser extent involving caregivers (in isolation). However, cancer experiences are shared by both members, which invariably influences each member of the dyad individually (through *independent effects*) as well as bidirectionally (through *interdependent effects*).

What is the implication and what should change now?

- Despite clear advantages of mHealth technology with regards to convenience and reach, designing dyadic interventions has been limited. Thus, in cancer care settings where family support is critical, including a dyadic mHealth approach has the potential to enhance HRQOL for both members.

and intervention considerations for families of children with cancer. We present the following article in accordance with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) reporting checklist (16) (available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-24/rc>).

Methods

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the University of Michigan Medical School (IRBMED HUM#01176584) and was registered on ClinicalTrials.gov (NCT04480541). IRBMED-approved informed consent/assent was taken from all the study participants.

Study site

The study was conducted at the University of Michigan, Ann Arbor, MI (U-M). All study activities were conducted remotely with no in-person contact, and all study materials were mailed to participants' residences. The design and development of ONC Roadmap have been previously published, including graphical images of the app (<https://www.roadmap.study>) (1).

Recruitment and enrollment

Inclusion Criteria: Eligibility for study participation of caregivers included: age ≥ 18 years and self-reported as the primary caregiver of their pediatric patient with cancer. Patients were required to be at least age ≥ 5 years and receiving cancer care at the data coordinating site. The study team has other IRB-approved studies in this patient population (age ≥ 5 years) where technology and wearable sensors are being examined. Patients in this age group have been participants in similar studies (17). While the intervention specifically targeted the caregiver, both members of the dyad (i.e., caregiver and patient) had to agree to participate. Additional eligibility requirements included *both* members having access to necessary resources for participating in an mHealth technology-based intervention (i.e., smartphone/tablet and internet access), and being willing to use personal equipment/internet for the study. All participants provided informed consents/

assents within the ONC Roadmap app. Of note, children (age 10–14 years) signed the IRB-approved Assent Form document and adolescents (age 15–17 years) signed the IRB-approved Consent Form document; children (age 5–9 years) did not sign any Assent Form documents.

Recruitment occurred between September 2020–September 2021. IRBMED-approved paper flyers and postings were distributed throughout the outpatient Pediatric Hematology/Oncology (PHO) waiting rooms, clinic rooms, and infusion center. Interested participants who contacted the study team by phone or email received additional study information (e.g., overview of study procedures). All recruitment and participant onboarding were conducted remotely due to the COVID-19 pandemic. The target sample was 50 dyads (see *Figure 1: TREND (16) Diagram of Participant Flow*).

The intervention: study procedures

The study procedures of the intervention are outlined in *Figure S1*.

Self-reported assessments

All self-reported HRQOL data were collected using ONC Roadmap, which utilized Qualtrics (Qualtrics, Provo, UT), an online research tool that enables researchers to create study-specific websites for administering study surveys and storing participant data. Participants were prompted by app alert to complete assessments at baseline (pre-study period (T0) and days 30 and 120 (post-baseline assessments at T1 and T2) using ONC Roadmap. Caregiver socio-demographic data (e.g., age, gender, race, ethnicity, education, occupation), household finances, caregiving experiences, and use of mobile devices/technology were obtained at T0, based on our National Caregiver Health Survey (18-20). A list of the HRQOL PROMIS[®] measures assessed at T0, T1, and T2 by self-report or parent proxy are provided in *Table S1* (21,22). The reference population for PROMIS[®] measures is the U.S. general population (23), whereas the reference population of the affiliate PROMIS[®] measures (the Neuro-QoL TBI-CareQoL measures) is other caregivers (24). PROMIS[®] Measure-Specific Scoring Guides available online through the PROMIS[®] Assessment Center were used to score the measures and calculate T-scores (25). A higher PROMIS[®] T-score represents more of the concept being measured. For example, an individual with T-score of 60 for the Global Mental or Physical Health scale is one standard deviation *better* (i.e., *healthier*) than

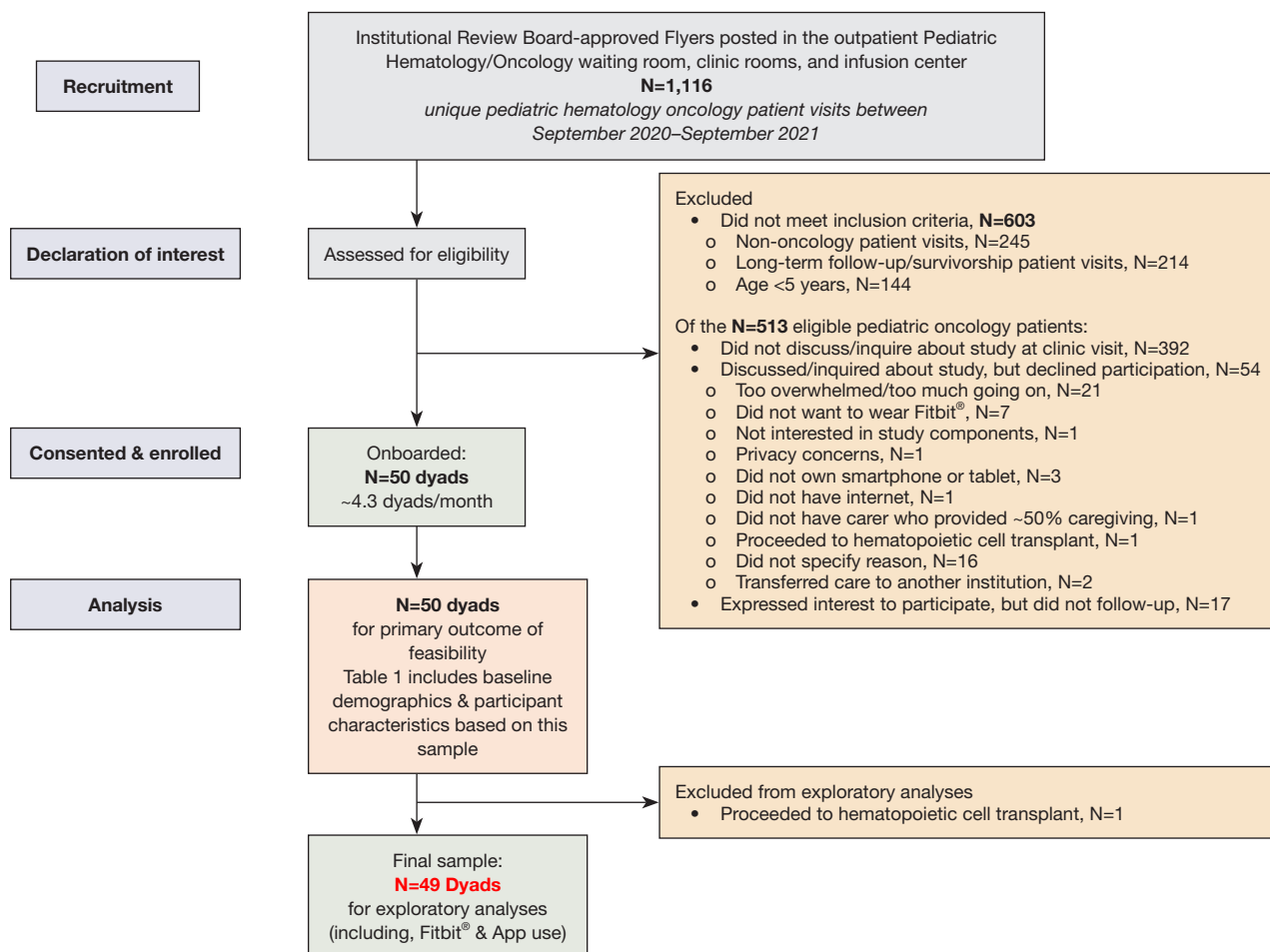


Figure 1 Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) diagram of participant flow.

the U.S. general population. While patients (age ≥ 8 years) and family caregivers (age ≥ 18 years) completed self-assessments, parent proxy assessments were also completed by family caregivers for patients (age 5–17 years only).

Roadmap and Fitbit® Apps

Participants (caregivers and patients) were instructed to download ONC Roadmap and Fitbit® apps on their smartphone or other mobile device (both free of charge and publicly available via Apple and Google app stores). As previously described (1), caregivers received the full-version of ONC Roadmap, which included positive activities, chat forums, resources, and graphs (mood, sleep, and steps). Graphs only were visible to patients (i.e., they did not have access to positive activities, chat forums, or resources).

Wearable sensor

Fitbits® were mailed to the participants' homes. They were instructed to wear it continuously, except while charging, to measure their physical activity, heart rate, and sleep during the 120-day monitoring period.

Feasibility and acceptability

Feasibility of the study, defined *a priori* in the Protocol, was calculated as the percentage of caregivers who logged into ONC Roadmap and engaged with it at least twice weekly for at least 50% of the 120-day study duration. These data were based on data use logs (i.e., timestamps) of: (I) positive activity completed; (II) chat/reply to chat posted or viewed in the forum, (III) and mood score reported (1).

Caregivers completed a Feasibility and Acceptability questionnaire, which was informed by existing measures of feasibility and acceptability (26,27), and the Mobile App Rating Scale (MARS) (28) at the end of study (i.e., day 120) to specifically assess app-quality. Our *a priori* hypothesis was that more than 50% of respondents would *Agree* or *Strongly Agree* with the feasibility and acceptability of ONC Roadmap. The MARS is a simple, objective, and reliable tool for assessing the quality of mHealth apps and has demonstrated internal consistency ($\alpha = 0.90$) and interrater reliability intraclass correlation coefficient (ICC = 0.79) (28). The MARS was scored by calculating the mean scores of *engagement*, *functionality*, *aesthetics*, and *information quality* objective subscales, and an overall mean app quality total score. Each MARS item used a 5-point scale (1-Inadequate, 2-Poor, 3-Acceptable, 4-Good, 5-Excellent). Higher total and subscale scores indicate better app-quality.

Statistical analyses

For the descriptive statistics, continuous measures were described using means/medians (M) and standard deviation (SD)/interquartile range (IQR), while categorical measures were summarized using frequencies and proportions. These data were analyzed using R (version 4.1.1).

Fitbit[®] automatically generated accelerometer-based summary data (per proprietary algorithms) based on “activity counts” collected over the course of the day. We assessed participant compliance in wearing the Fitbit[®] by identifying when heart rate data were present through the Roadmap platform using the Fitbit application programming interface (API) (29). As previously reported, we measured daily wear time using heart rate data with a minutes-level resolution. Compliance was expressed both in hours (0–24 h) and in percentages (i.e., by dividing the hours spent wearing the device by 24 h) (30,31). Using this assessment of compliance, we calculated the average daily step count for participants who wore the Fitbit[®] more than 6 h between 8 AM and 8 PM. We chose a cut-off of 6 h because the distribution of average daily step count did not change significantly for higher cut-offs. No compliance cut-off was applied for the calculation of asleep hours because the daily average changed by only about 0.05 h between a cut-off of 0 h and a cut-off of 11 h between 8 PM and 8 AM.

Although this pilot study was not powered to examine efficacy, exploratory analyses were conducted to assess for changes in HRQOL scores across time (i.e., T0, T1, T2). Baseline *vs.* day 30 and baseline *vs.* day 120 HRQOL mean

T-scores with SD were compared using two-tailed T tests with probability level of 0.05.

Next, we used a longitudinal regression model with random effects to determine whether caregiver PROMIS[®] global health outcome changed over time. The model included age, gender, self-report of any mental health condition, and caregiving hours/week.

To examine the relationship between caregiver and patient, we treated data from care partners as a paired or dyadic longitudinal series where the pairing was modeled at each timepoint in the series. Because longitudinal, dyadic data present a special case of nested data whereby interdependence exists at two hierarchies in the data, we employed the Actor-Partner Interdependence Model (APIM) (32–35). An important feature of the APIM analyses was to create within- and between-member versions of the outcome variable (e.g., PROMIS[®] global mental health), separately for caregivers and patients. The APIM also included age, gender, baseline self-report of any mental health condition, and caregiving hours/week. We specifically examined whether baseline (T0) caregiver and patient HRQOL (anxiety, depression) domains influenced caregiver and patient global (mental) health at 120-day (T2).

Results

Socio-demographic characteristics

One hundred participants consented/assented and enrolled in this study (*Figure 1*) with 50 family caregivers and 50 pediatric patients with cancer. There was low study attrition (<5%; *Table 1*). Nearly half of the caregivers were unable to work (N=21; 42%) due to caregiving responsibilities or unemployed (N=2; 4%). Twenty-nine caregivers (58%) reported annual family income \leq \$99,999 and three (6%) <\$10,000 for a mean number of 4.5 persons in the household (range, 2–8). Only one caregiver did not own a smartphone and opted to use a mobile tablet for study participation.

Feasibility and acceptability

The majority of caregivers (N=32; 65%) logged into ONC Roadmap and engaged with it at least twice weekly for ~50% of the study duration. Eighty percent of caregivers (N=39) logged in at least once weekly. The four most common activities used were gratitude journal, pleasant activity scheduling, savoring, and engaging with beauty

Table 1 Participant demographics

Characteristic	Family caregiver, N=50	Care recipient (Patient), N=50
Age in years, mean [range]	41.2 [18–56]	11.9 [5–20]
Gender (Female), n [%]	42 [84]	24 [48]
Ethnicity (Non-Hispanic), n [%]	48 [96]	48 [96]
Race (White), n [%]	44 [88]	42 [84]
Marital status (Married), n [%]	37 [74]	–
Education (Some college or more), n [%]	35 [70]	–
Disease characteristics, n [%]		
Leukemias/Lymphomas*	–	21 [42]
Solid tumors†	–	29 [58]
Adults (≥18 years) in household, mean (standard deviation)	2.34 (0.82)	–
Children in household (<18 years), mean (standard deviation)	2.12 (1.30)	–
Employment status, n [%]		
Full-time or self-employed	22 [44]	–
Part-time	3 [6]	–
Retired	2 [4]	–
Unemployed	2 [4]	–
Unable to work	21 [42]	–
Annual household income [§] , n [%]		
<\$10,000	3 [6]	–
\$10,000–\$14,999	1 [2]	–
\$15,000–\$24,999	2 [4]	–
\$25,000–\$34,999	4 [8]	–
\$35,000–\$49,999	6 [12]	–
\$50,000–\$74,999	8 [16]	–
\$75,000–\$99,999	5 [10]	–
\$100,000–\$200,000	13 [26]	–
>\$200,000	2 [4]	–
Prefer not to answer	6 [12]	–
Overall health (1–7, very poor–excellent), n [%]		
1	0 [0]	–
2	1 [2]	–
3	7 [14]	–
4	16 [32]	–
5	18 [36]	–
6	3 [6]	–
7	5 [10]	–

Table 1 (continued)

Table 1 (continued)

Characteristic	Family caregiver, N=50	Care recipient (Patient), N=50
Most Common health conditions (more than one response allowed), n [%]		
Anxiety	17	–
Seasonal allergies	16	–
Depression	15	–
High blood pressure	12	–
Weekly caregiving hours, n [%]		
<5	9 [18]	–
5–9	11 [22]	–
10–19	6 [12]	–
20–29	2 [4]	–
30–39	5 [10]	–
>40	17 [34]	–
Patient proximity (same household)	47 [94]	–
Providing additional medical care to ^v		
Child(ren)	24	–
Spouse	11	–
Parent	4	–
Sibling	3	–
No one else	18	–
Technology owned/used by caregivers		
Primary type of cell phone, n [%]		
Apple iPhone	29 [58]	–
Android phone	20 [40]	–
Do not own cell phone	1 [2]	–
Type of tablet device (more than one response allowed), n		
Apple iPad	21	–
Android tablet	15	–
Microsoft Windows tablet	2	–
Kindle	1	–
Do not own tablet device	13	–
Type of Fitness or Smart Watch (more than one response allowed), n		
Apple	9	–
Fitbit	13	–
Garmin	2	–
Other	2	–
Do not own fitness/smart watch	25	–

Table 1 (continued)

Table 1 (continued)

Characteristic	Family caregiver, N=50	Care recipient (Patient), N=50
Number of apps downloaded on mobile device (cell or tablet), n [%]		
≤5	2 [4]	–
6–10	4 [8]	–
11–20	18 [36]	–
21–50	18 [36]	–
>50	8 [16]	–
Number of apps used at least once a day on mobile device (cell or tablet), n [%]		
≤5	19 [38]	–
6–10	26 [52]	–
11–20	5 [10]	–
Health or wellness-related apps used on mobile device (more than one response allowed), n		
Fitness	8	–
Counting steps	15	–
Nutrition (e.g., tracking calories, recording foods)	12	–
Meditation or stress management	5	–
Sleep	11	–
None	18	–

*, B-cell ALL: N=10; T-cell ALL N=5; Hodgkin lymphoma (HL) N=4; non-Hodgkin lymphoma N=2. †, Osseous sarcoma N=9; soft tissue sarcoma N=8; neuroblastoma N=5; brain tumor N=5; wilms tumor N=1; ovarian tumor N=1. §, When we transformed baseline family income into a percentage of FPL for the year the survey was completed (2021) and stratified into two levels (≤200%, >200%), between 32%–50% of the study population met the criteria of ≤200% FPL (depending on their salary range). This stratification of ≤200% FPL is consistent with published definitions of low-income families and identifies those eligible for government support. Of note, year-specific FPLs are based on the Department of Health and Human Services Poverty Guidelines, which is calculated as baseline family income divided by the year-specific poverty guideline for household size and multiplied by 100 to achieve the percentage of FPL. ¶, more than one category can be selected (i.e., can surpass 100%). ALL, acute lymphoblastic leukemia; FPL, federal poverty level.

(Table 2). Not surprisingly, caregiver app use declined over time from 18-days during the first 30-days compared with 12-days during the last 30-days (Figure 2). Nonetheless, the Feasibility and Acceptability questionnaire responses indicated that the Fitbit®, ONC Roadmap app, and longitudinal self-reported assessments were feasible and acceptable with the majority reporting *Agree* or *Strongly Agree* with positive Net Favorability in all the categories (Table S2).

The MARS was also utilized to provide a multidimensional measure of ONC Roadmap app quality indicators of *engagement*, *functionality*, *aesthetics*, and *information quality* (28). The ONC Roadmap app quality total mean score was 3.59 (SD =0.78) and overall star rating was 3.38 (SD =0.86). The sub-scales, functionality and aesthetic, had the highest

reported mean subscale scores of 4.01 (SD =0.66) and 3.88 (SD =0.74), respectively (Table 3), followed by *information* and *engagement* [mean subscale scores of 3.76 (SD =0.75) and 2.99 (SD =0.87), respectively].

Using ONC Roadmap to obtain HRQOL data

Completion rates for the HRQOL assessments by caregivers at T0, T1, and T2 were 100% (N=50/50), 88% (N=43/49), and 88% (N=38/49), respectively. Completion rates by patients (age 8 years and older) were also 100% (N=34/34) at T0 but were lower than caregivers at T1 and T2 [61% (N=20/33), and 45% (N=15/33), respectively]. The Parent Proxy (age 5–17 years) assessments were completed at similar rates to the caregiver self-assessments [100% (N=41/41),

Table 2 Caregiver engagement with positive activities

Activity name	Activity description	Completed number of activities	Unique number of caregivers
Gratitude journal	<p>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:</p> <p>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.</p> <p>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.</p> <p>Step 3: Smile as you write these things down. This will help you to feel even more grateful.</p>	108	19
Pleasant activity scheduling	<p>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.</p> <p>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.</p> <p>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.</p> <p>Step 3: Log what you did for your pleasant activity. Have fun, it's good for you!</p>	94	17
Savoring	<p>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.</p> <p>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.</p> <p>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.</p> <p>Step 3: Log these savoring experiences here so you can revisit them later.</p>	70	13
Engaging with beauty	<p>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.</p> <p>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).</p> <p>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.</p>	55	14
Signature strengths	<p>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.</p> <p>Step 1: Based on the Brief Strengths Test, note your top seven strengths.</p> <p>Step 2: Every day for the next week, use one of these strengths in a way that you have not used it before.</p> <p>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.</p>	35	6

Table 2 (continued)

Table 2 (continued)

Activity name	Activity description	Completed number of activities	Unique number of caregivers
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.	33	12
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!	15	8
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.	12	9

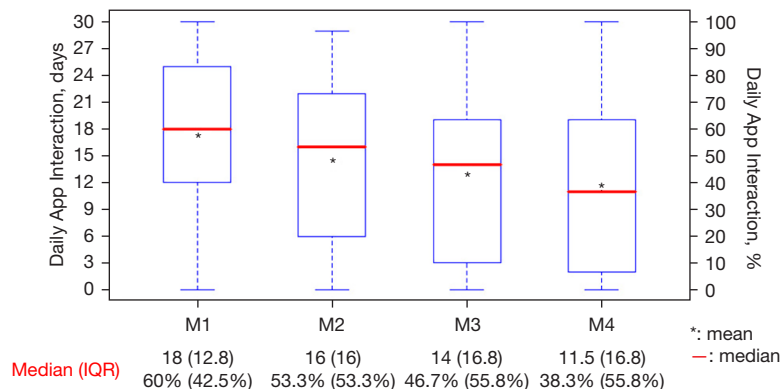


Figure 2 ONC Roadmap App use over time in family caregivers. Each boxplot represents the daily compliance averaged chronologically for each 30-day of the 120-day study period (N=49). M1 vs. M2, P=0.002; M1 vs. M3, P<0.001; M1 vs. M4, P<0.001. M, month; IQR, interquartile range.

Table 3 Mobile App rating scale of ONC Roadmap

Subscale/item	Mean	SD	Mean*	SD*
Section A: Engagement	2.99	0.87		
1 Entertainment	2.81	1.00	2.49	1.24
2 Interest	2.88	1.01	2.52	1.20
3 Customization	2.97	1.20	2.27	1.15
4 Interactivity	3.07	0.98	2.70	1.22
5 Target group	3.52	1.02	3.41	0.93
Section B: Functionality	4.01	0.66		
6 Performance	4.10	0.66	4.00	0.93
7 Ease of use	3.93	0.88	3.93	0.87
8 Navigation	3.87	1.11	4.00	0.94
9 Gestural design	4.18	0.67	4.10	0.79
Section C: Aesthetic	3.88	0.74		
10 Layout	4.03	0.72	3.91	0.87
11 Graphics	3.87	0.81	3.41	0.92
12 Visual appeal: How good does the app look?	3.74	0.89	3.14	0.91
Section D: Information	3.76	0.75		
13 Accuracy of app description	3.77	0.92	3.66	1.03
14 Goals	3.48	1.05	3.43	1.10
15 Quality of information	3.86	0.92	3.18	1.46
16 Quantity of information	3.97	1.00	2.87	1.54
17 Visual information	4.00	0.83	1.35	1.89
18 Credibility	3.72	1.07	2.79	0.95
19 Evidence base	3.50	0.95	–	–
Section E: Subjective quality	2.77	0.72		
20 Would you recommend this app?	3.50	1.14	2.31	1.17
21 How many times do you think you would use this apps?	3.00	1.05	2.46	1.12
22 Would you pay for this app?	1.27	0.69	1.31	0.60
23 What is your overall star rating of the app?	3.38	0.86	2.69	1.06
Section F: App specific	3.70	1.02		
24 Awareness	3.77	1.01		
25 Knowledge	3.73	1.08		
26 Attitudes	3.60	1.07		
27 Intention to change	3.66	1.04		
28 Help Seeking	3.73	1.08		
29 Behaviour to change	3.82	1.06		

*, The App Quality Total Mean Score for ONC Roadmap was 3.59 (SD =0.78); Stoyanov SR, Hides L, Kavanagh DJ, et al. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015;3:e27. SD, standard deviation.

85% (N=35/41), and 76% (N=31/41)], respectively.

In caregivers, the median wear time of sensors across the 120-day study period was: 17.8 h (of the 24 h day); 9.2 h during daytime (between 8 AM–8 PM), and 8.4 h during nighttime (between 8 PM–8 AM). In patients, the median wear time of sensors was: 6.3 h (of the 24 h day); 4.1 h during daytime (between 8 AM–8 PM), and 3.0 h during nighttime (between 8 PM–8 AM). Figure S2 shows the distribution of compliance (24 h) of Fitbit® wear across the study period. A decline in caregiver compliance was observed from a median of 19.3 h (first 30 days) to 15.8 h (last 30 days) of the study period (Figure S2A), while patient compliance declined from a median of 11.0 h (first 30 days) to 1.3 h (last 30 days, Figure S2B).

When we explored potential differences of steps, sleep, and self-reported mood, caregiver and patient mood were higher in the 5–11 years compared with 12–17 or 18+ years age-groups, $P=0.003$ or $P=0.022$ (caregiver) and $P<0.001$ or $P<0.001$ (patient), respectively (Table S3). Patient step count was also higher in those aged 5–11 compared with those aged 12–17 ($P=0.024$). There were no differences in sleep among caregiver and patient age-groups.

Exploratory analyses: Roadmap's preliminary efficacy on HRQOL outcomes

The change in mean pre- (T0) and post- (T1 and T2) HRQOL scores for participants are shown in Table S4. In general, although most analyses failed to meet conventional levels of statistical significance, there were improvements in almost all the different mental HRQOL domains across all of the groups over time. Specifically, at 30-day (T1), caregivers had higher levels of global mental health and lower levels of caregiver-specific anxiety. At 120-day (T2), caregiver-specific anxiety and strain and general anxiety were lower compared with baseline. Interestingly, caregiver-specific anxiety at T0 was negatively correlated with app use at T1 (i.e., higher baseline anxiety scores were associated with less app use over the next 30 days; Table S5).

In patients (8–17 years), there were lower levels of depression at T1, without reaching statistical significance at T2; patients 18+ years reported better global mental health at T1, without reaching statistical significance at T2. However, in parent proxy reports (8–17 years), depression and fatigue were both rated lower at T2. No significant changes were observed by parent proxy in patients 5–7 years; however, the means were in the anticipated direction.

To adjust for participant age, gender, number of

caregiving hours per week, and baseline self-report of any caregiver mental health condition, we then performed linear mixed models. While caregiver age >40 years and self-report of any mental health condition were negatively associated with global mental health of the caregiver, this outcome was improved at T1 compared with T0 (Table S6). Additionally, patient (8–17 years) depression was significantly lower over at T1 and T2 compared with T0. In our generalized linear APIM models, we found that “actor” (i.e., caregiver or patient) anxiety or depression at baseline influenced day 120 global mental health outcomes of the caregiver or patient, respectively. Interestingly, when we also assessed for “partner” effects (Table S7), caregiver depression at T0 was negatively associated with patient global mental health at T2.

Discussion

In this study, family caregivers of pediatric patients with cancer met our a priori defined measure for *Feasibility* for the study duration (120-day). Most family caregivers agreed that the ONC Roadmap app, Fitbit®, and study design were feasible and acceptable. They also indicated they were likely to engage in a similar future study lasting up to 6-month.

Our study also incorporated the MARS, which provided a multidimensional measure of *engagement*, *functionality*, *aesthetics*, and *information quality* (28). ONC Roadmap caregivers reported the sub-scale mean scores as well as overall mean app quality total score at least consistent with or higher than 50 apps that were previously selected for rating by the MARS (28). Caregivers generally *Agreed/Strongly Agreed* with the perceived impact of ONC Roadmap on users' knowledge and attitudes. Specific strengths of ONC Roadmap were *functionality*, *aesthetic*, and *information quality*. While overall a specific weakness was *engagement*, specific elements of *entertainment* and *interest* had mean scores higher than previously published studies on independent ratings of 50 mental health and well-being apps (20). This likely contributed to the decline in app use over the 120-day study period. Thus, we are considering strategies in future app refinements to enhance engagement by presenting content in interesting ways (e.g., alerts, messages, reminders, feedback) (36,37).

Nonetheless, caregivers were compliant with completing assessments, reporting mood scores, and wearing Fitbit®, consistent with what we observed in our recently completed college student study (30). However, we found patients to be more variable in completing the study-related procedures.

With the near ubiquitous use of technology in children, adolescents, and young adults (38), this was somewhat surprising. It is possible that caregivers experienced the benefit of having access to positive activities, chat forums, mood/steps/sleep graphs, and caregiving resources, whereas for patients, their only access to ONC Roadmap was limited to graphs. Alternatively, patients may have established their technology-related support and did not leverage ONC Roadmap to the extent that caregivers did. Semi-structured interviews with our dyads are ongoing to better understand these factors.

Not surprisingly, over one-third of the caregivers reported significant burden (i.e., providing more than 40 hours of unpaid caregiving) and up to one-half were unable to work due to caregiving responsibilities or unemployment. We also found that between 32–50% of our caregivers reported household incomes as less than or equal to 200% federal poverty level (\$55,500 for a family of 4 in 2022) (39). While these data were in line with reported rates of financial hardship in Michigan and U.S. families with children below 200% (~45%) (40), they highlight the potential implications of poverty, such as material hardship, when designing interventions to address the needs of families undergoing intensive medical management, such as cancer care. Indeed, psychosocial support that is low-burden and dyadic-focused are needed to integrate seamlessly with cancer care delivery (4,41).

Research across multiple disciplines is emerging on the importance of designing interventions that are *truly* dyadic in nature, integrating both caregiver and patient (42). Dyadic-level processes have been shown to influence the health and well-being of members within a dyad (43). For example, pediatric and adolescent and young adult patients' reports of subjective illness severity may indicate their own as well as their caregiver's mental health (44). Accordingly, while exploratory, herein we examined the influence of baseline HRQOL domains of the caregiver and patient on their mental health and found that baseline depression in caregiver influenced patient's global health 120-day later. Thus, with growing emphasis on interpersonal, dyadic-level processes likely contributing to the health, illness, recovery, treatment, and/or overall well-being of both members of the dyad (41,43), future studies should integrate both members of the dyad. Indeed, mHealth technologies offer scalable and flexible solutions for delivering family-based or dyadic-level interventions (45,46).

While this study was not powered to assess the efficacy of the ONC Roadmap in HRQOL outcomes, exploratory

analyses suggest preliminary efficacy on HRQOL outcomes. In general, we saw improvements in mental HRQOL over the 120-day study period for all groups, although this difference only met conventional levels of significance in a few instances, primarily for the caregiver group (where the intervention was intended for). Specifically, there were significant improvements in caregiver-specific strain, caregiver-specific anxiety, and general anxiety at day 120. Interestingly, higher baseline care-specific anxiety scores were associated with less app use; and higher baseline patient (8–17 years) depression scores were associated with less caregiver app use (data not shown). There was also evidence to suggest that patient fatigue improved with caregivers receiving the intervention. Accordingly, while the intervention's primary target was caregivers, it was unexpected that patients experienced reduced depression. Indeed, the "partner effects" observed in our APIM analyses suggest a potential interaction between both members of the dyad. Interestingly, while caregiver global mental health improved at day 30, this was not sustained at day 120, and physical function and positive affect declined at day 120.

It is possible that caregivers experienced increased physical burden while caring for other family members at home during the pandemic. We also speculate that with the PROMIS® positive affect's measure of "*In the past 7 days: I felt cheerful*," it may better reflect pleasurable engagement (e.g., ecstatic happiness) (47), separate from general well-being, as assessed by the PROMIS® global mental health (21). Lyubomirsky and Layous' positive activity model (48) suggests that the dosage and variety of positive activities coupled with motivation and effort of the individual (i.e., so called, *person-activity fit*) may influence the degree to which well-being is enhanced. Thus, this intersection between characteristics of the individual and the positive activities may be important considerations in how well those activities are able to enhance individual well-being. In the present research, we did not obtain information regarding psychological conditions/disorders or personality traits. These variables could have impacted the findings and will be considered in the design of our future studies. In our ongoing qualitative interviews, we are assessing these considerations in more detail.

Strengths of this study included the broad inclusion criteria of pediatric cancer diagnoses and phases of care, low-burden on participants, and a pre-registered study design plan. Our study also had limitations. Our findings are likely more generalizable to caregivers who were similar, mostly White, non-Hispanic, with at least some college education,

and who own mobile devices and routinely use apps. In the present study, patient compliance waned over time. The patient was not emphasized as the primary member of the study. It is possible their involvement was no longer considered novel or important over time. In future studies, we hope to incorporate the dyad as its primary target rather than one member of the dyad alone (e.g., caregiver). Additionally, we recognize the inherent biases afforded by single-arm, single-center study designs. Nonetheless, we are encouraged with the high proportion of caregivers who reported the intervention to be feasible and acceptable with no adverse events reported. While caregivers were compliant with completing assessments, reporting mood scores, and wearing Fitbit®, patients were more variable in completing the study-related procedures.

Conclusions

Our findings suggest that mHealth technology can be used to support the HRQOL of caregivers and their patients. We are currently exploring mechanisms of ONC Roadmap on HRQOL outcomes. We are also examining strategies to enhance engagement, such as just-in-time adaptive interventions (36) or digital coaching (49). Considering the growing populations of survivors and aging caregivers (50), developing and rigorously testing mHealth platforms that provide cancer supportive care for both members of the dyad are needed.

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Footnote

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Data Sharing Statement: Available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-24/dss>

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Institutional Review Board of the University of Michigan Medical School (IRBMED HUM# 01176584) and IRBMED-approved informed consent/assent was taken from all the study participants.

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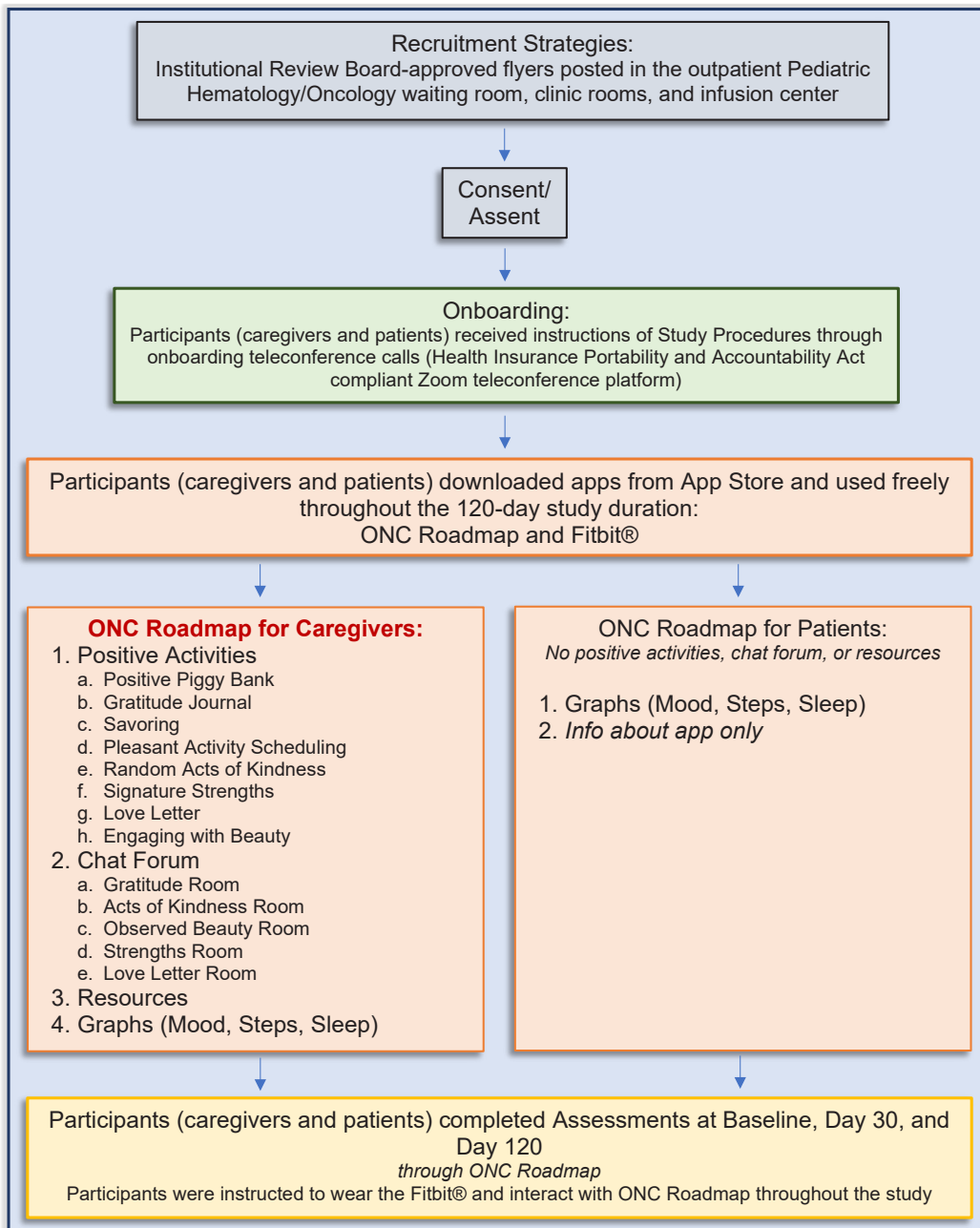


Figure S1 Study procedures.

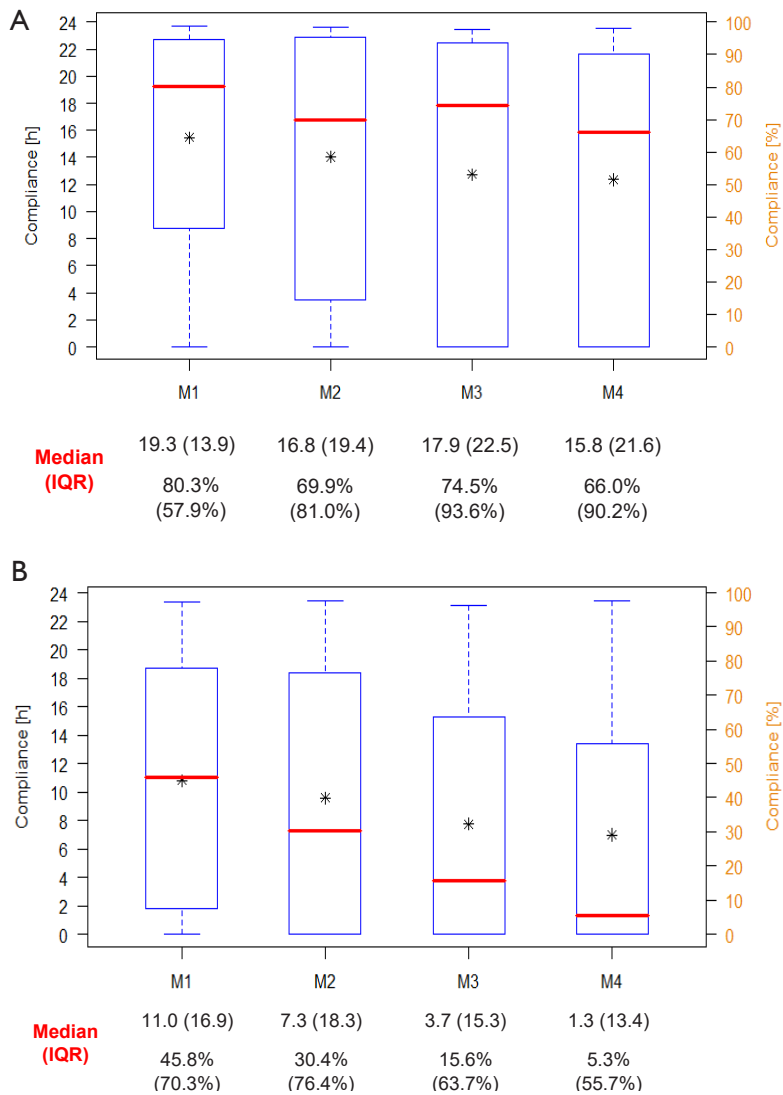


Figure S2 Fitbit® Compliance Over Time in Study Participants: Each boxplot represents the daily compliance averaged chronologically for each 30-day of the 120-day study period (N=49; mean: *; median: —). (A) represents Fitbit® Compliance Over Time in Family Caregivers: M1 vs. M2, $P < 0.001$; M1 vs. M3, $P = 0.004$; M1 vs. M4, $P = 0.051$. Figure 3B represents Fitbit® Compliance Over Time in Patients: Month 1 M1 vs. M2, $P < 0.001$; M1 vs. M3, $P = 0.001$; M1 vs. M4, $P = 0.008$.

Table S1 Self-Reported Assessments by Family Caregivers and Care Recipients (Patients) at Baseline, Day 30, Day 120

Measure	Description	Scoring
Age 18+ Years: Family Caregivers & Patients		
PROMIS® Global Health (Mental and Physical) v1.2	10-item Short Form represents Global Physical Health (overall physical health, physical function, pain, and fatigue) and Global Mental Health (quality of life, mental health, satisfaction with social activities and emotional problems)	T score (mean = 50; SD=10); Two summary scores: Physical Health, Mental Health, higher scores indicate better health.
PROMIS® Physical Function v2.1	4-item Short Form assesses physical function (e.g., errands/chores, up/downstairs, walk)	T score (mean = 50; SD=10); higher scores indicate better physical mobility.
PROMIS® Companionship v2.0	4-item Short Form assesses perceived availability of someone with whom to share enjoyable social activities.	T score with (mean = 50; SD=10); higher scores indicate better companionship to share activities.
Neuro-QoL (PROMIS® affiliate) Positive Affect and Well-Being v1.0	7-item Short Form assesses aspects of a person's life that relate to a sense of well-being, life satisfaction or an overall sense of purpose and meaning.	T score (mean = 50; SD=10); higher scores indicate better positive affect and well-being.
PROMIS® Self-Efficacy for Managing Symptoms v1.0	4-item Short Form assesses confidence to manage/control symptoms in different settings and to keep symptoms from interfering with work, sleep, relationships, or recreational activities.	T score with (mean = 50; SD=10); higher scores indicate better self-efficacy for managing symptoms.
PROMIS® Self-Efficacy for Managing Daily Activities v1.0	4-item Short Form assesses the confidence to perform various activities of daily living without assistance.	T score with (mean = 50; SD=10); higher scores indicate better self-efficacy for managing daily activities.
PROMIS® Ability to Participate in Social Roles and Activities v2.1	4-item Short Form assesses the ability to participate in social roles (friends, families, others) and activities (work, work at home).	T score with (mean = 50; SD=10); higher scores indicate better ability to participate in social roles and activities.
PROMIS® Emotional Support v2.0	4-item Short Form assesses the availability of others with whom to talk with and feel appreciated by others.	T score (mean = 50; SD=10); higher scores indicate better emotional support.
PROMIS® Sleep Disturbance v2.1	4-item Short Form assesses perceptions of sleep quality, sleep depth, and restoration associated with sleep.	T score (mean = 50; SD=10); higher scores indicate worse sleep disturbance.
PROMIS® Depression v2.1	4-item Short Form that assesses self-reported negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation).	T score (mean = 50; SD=10); higher scores indicate worse depression.
PROMIS® Anxiety v2.1	4-item Short Form that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal	T score (mean = 50; SD=10); higher scores indicate worse anxiety.
PROMIS® Fatigue v2.1	4-item Short Form that assesses fatigue	T score (mean = 50; SD=10); higher scores indicate worse fatigue.
PROMIS® Pain Interference v2.1	4-item Short Form that assesses pain interference.	T score (mean = 50; SD=10); higher scores indicate worse pain interference.
Age 18+ Years: Family Caregivers Only		
TBI-CareQOL (PROMIS® affiliate) Caregiver Anxiety v1.0	TBI-CareQOL (PROMIS® affiliate) Caregiver Anxiety v1.0	T score (mean = 50; SD=10); higher scores indicate worse caregiver anxiety.
TBI-CareQOL (PROMIS® affiliate) Caregiver Strain v1.0	TBI-CareQOL (PROMIS® affiliate) Caregiver Strain v1.0	T score (mean = 50; SD=10); higher scores indicate worse caregiver strain.

Table S1 (continued)

Table S1 (continued)

Measure	Description	Scoring
Age 18+ Years: Family Caregiver Only (Parent Proxy)		
PROMIS® Parent Proxy Physical Function v2.0	4-item Short Form assesses parent's overall evaluation of patient's physical function (e.g., errands/chores, up/downstairs, walk).	T score (mean = 50; SD=10); higher scores indicate better physical mobility.
PROMIS® Parent Proxy Depression v2.0	4-item Short Form that assesses parent's overall evaluation of patient's negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation).	T score (mean = 50; SD=10); higher scores indicate worse depression.
PROMIS® Parent Proxy Anxiety v2.0	4-item Short Form that assesses parent's overall evaluation of patient's fear, anxious misery, hyperarousal, and somatic symptoms related to arousal.	T score (mean = 50; SD=10); higher scores indicate worse anxiety.
PROMIS® Parent Proxy Fatigue v2.0	4-item Short Form that assesses parent's overall evaluation of patient's fatigue.	T score (mean = 50; SD=10); higher scores indicate worse fatigue.
PROMIS® Parent Proxy Pain Interference v2.0	4-item Short Form that assesses parent's overall evaluation of patient's pain interference.	T score (mean = 50; SD=10); higher scores indicate worse pain interference.
PROMIS® Parent Proxy Sleep Disturbance v1.0	4-item Short Form assesses parent's overall evaluation of patient's sleep quality, sleep depth, and restoration associated with sleep.	T score (mean = 50; SD=10); higher scores indicate worse sleep disturbance.
Age 8–17 Years: Patients Only		
PROMIS® Global Health 7 v1.0	The "7" scale includes the same global health score (overall evaluation of one's physical, mental, and social health, which is conceptually equivalent to its PROMIS adult counterpart).	T score (mean = 50; SD=10); One summary score: Higher scores indicate better overall health.
PROMIS® Physical Function v2.0	4-item Short Form assesses physical function (e.g., errands/chores, up/downstairs, walk)	T score (mean = 50; SD=10); higher scores indicate better physical mobility.
PROMIS® Depression v2.0	4-item Short Form that assesses self-reported negative mood (sadness, guilt), views of self (self-criticism, worthlessness), and social cognition (loneliness, interpersonal alienation).	T score (mean = 50; SD=10); higher scores indicate worse depression.
PROMIS® Anxiety v2.0	4-item Short Form that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal	T score (mean = 50; SD=10); higher scores indicate worse anxiety.
PROMIS® Peer Relationships v2.0	4-item Short Form that assesses peer relationships, including association with peer-reported friendships, likeability, and social reputation	T score (mean = 50; SD=10); higher scores indicate better peer relationships.
PROMIS® Pain Interference v2.0	4-item Short Form that assesses pain interference.	T score (mean = 50; SD=10); higher scores indicate worse pain interference.
PROMIS® Sleep Disturbance v1.0	4-item Short Form assesses perceptions of sleep quality, sleep depth, and restoration associated with sleep.	T score (mean = 50; SD=10); higher scores indicate worse sleep disturbance.

Table S2 Feasibility and acceptability of ONC Roadmap

Fitbit®							
	Totally disagree	Disagree	Sometimes agree/disagree	Agree	Totally agree	Agree + Totally Agree	Net Favorability <i>Totally agree + Agree – Totally disagree + Disagree</i>
Instructions for the Fitbit® were easy to understand.	5.3%	5.3%	10.5%	65.8%	13.2%	79.0%	68.4%
The Fitbit® was easy to set up.	5.3%	0.0%	15.8%	71.0%	7.9%	78.9%	73.6%
The Fitbit® was easy to use.	7.9%	0.0%	13.2%	73.7%	5.3%	79.0%	71.1%
The Fitbit® was comfortable to wear.	2.6%	7.9%	7.9%	73.7%	7.9%	81.6%	71.1%
The Fitbit® was easy to sync with my phone.	7.9%	5.3%	18.4%	57.9%	10.5%	68.4%	55.2%
I was confident using the Fitbit®	2.6%	10.5%	10.5%	65.8%	10.5%	76.3%	63.2%
ONC Roadmap							
	Totally disagree	Disagree	Sometimes agree/disagree	Agree	Totally agree	Agree + Totally Agree	Net Favorability
The instructions for the Roadmap app set up were easy to understand.	0.0%	2.6%	21.1%	63.2%	13.2%	76.4%	73.8%
The Roadmap app was easy to download and set up	2.6%	2.6%	10.5%	60.5%	23.7%	84.2%	79.0%
The Roadmap app was easy to use.	0.0%	5.3%	18.4%	57.9%	18.4%	76.3%	71.0%
I was confident using the Roadmap app.	2.6%	7.9%	26.3%	47.4%	15.8%	63.2%	52.7%
	Poor	Fair	Good	Very Good	Excellent	Very Good + Excellent	Net Favorability
What is your overall rating of the design of the screens on the app, including the colors and layout?	0.0%	7.9%	28.9%	44.7%	18.4%	63.1%	55.2%
Assessments							
	Totally disagree	Disagree	Sometimes agree/disagree	Agree	Totally agree	Agree + Totally Agree	Net Favorability
The survey questions were easy to understand.	0.0%	5.3%	21.1%	52.6%	21.1%	73.7%	68.4%
The survey questions were easy to answer.	0.0%	0.0%	21.1%	57.9%	21.1%	79.0%	79.0%
How likely would you be to engage in a similar study that lasted...							
	Extremely unlikely	Unlikely	Neutral	Likely	Extremely likely	Likely + Extremely likely	Net Favorability
6 Months?	2.6%	10.5%	21.1%	31.6%	34.2%	65.8%	52.7%
1 Year?	10.5%	15.8%	21.1%	26.3%	26.3%	52.6%	26.3%
Study Expectations							
	A lot worse	A little worse	About the same	A little better	A lot better	About the same + A little better + A lot better	Net Favorability
Compared to what you expected, how you would rate your experience in participating in this research study?	0.0%	5.3%	50.0%	34.2%	10.5%	44.7%	39.4%

Percentages calculated from N=38 respondents at end of study (day 120).

Table S3 Average daily steps, sleep, and mood data by user and age cohort

	Caregivers	Care Recipients (Patients)
Entire Cohort N=49 Dyads		
Steps	7069 (3179)	5261 (2846)
Sleep (hours)	6.8 (1.2)	7.2 (2.0)
Mood	7.2 (1.4)	7.5 (2.0)
5–11 Years (Patient Age) N=25 Dyads		
Steps	7328 (3572)	6107 (3148) [§]
Sleep (hours)	6.8 (1.4)	6.8 (2.3)
Mood	7.8 (1.1)*	8.5 (1.9) [¶]
12–17 Years (Patient Age) N=18 Dyads		
Steps	6036 (2390)	3411 (1503)
Sleep (hours)	6.9 (1.0)	7.5 (0.9)
Mood	6.5 (1.4)	6.4 (1.5)
18+ Years (Patient Age) N=6 Dyads		
Steps	8872 (2470)	5268 (1630)
Sleep (hours)	6.9 (0.8)	8.6 (1.3)
Mood	6.5 (1.3)	6.1 (1.3)

Data presented as mean (standard deviation). *Caregiver Mood (patient age 5–11 years vs. 12–17 years): P=0.003; Caregiver Mood (patient age 5–11 years vs. 18+ years): P=0.022; Caregiver Mood (patient age 12–17 years vs. 18+ years): P>0.05. [¶] Patient Mood (age 5–11 years vs. 12–17 years): P<0.001; Patient Mood (age 5–11 years vs. 18+ years): P<0.001; Patient Mood (age 12–17 years vs. 18+ years): P=0.533. [§] Patient Steps (age 5–11 years vs. 12–17 years): P=0.014; Patient Steps (age 5–11 years vs. 18+ years): P=0.942; Patient Steps (age 12–17 years vs. 18+ years): P=0.113.

Table S4 Assessments by Family Caregivers and Care Recipients (Patients) at Day 30 & Day 120 vs. Baseline

CAREGIVER 18+ Years	Baseline, Mean (SD)	Day 30, Mean (SD)	Day 120, Mean (SD)	Day 30 vs. Day 0 Change			Day 120 vs. Day 0 Change		
Complete Surveys	N=50	N=43	N=38	Mean (SD)	C.I.	P value	Mean (SD)	C.I.	P value
Global (Mental) Health	45.2 (7.5)	48.1 (9.1)	46.0 (7.8)	2.705 (5.992)	(1.168, 4.242)	0.005	0.047 (5.175)	(-1.284, 1.379)	0.955
Global (Physical) Health	47.2 (7.6)	48.3 (8.8)	46.1 (7.9)	1.037 (5.758)	(-0.440, 2.514)	0.244	-2.071 (5.723)	(-3.543, -0.599)	0.032
Caregiver Anxiety	50.8 (7)	48.8 (6.8)	47.7 (6.3)	-1.77 (5.179)	(-3.098, -0.440)	0.030	-1.987 (5.619)	(-3.432, -0.541)	0.036
Caregiver Strain	51.4 (8)	49.6 (6.1)	47.3 (6.2)	-1.953 (6.732)	(-3.680, -0.227)	0.064	-3.150 (5.769)	(-4.634, -1.666)	0.002
Positive Affect	53.3 (5.2)	53.2 (7.0)	51.9 (6.1)	-0.069 (4.219)	(-1.165, 1.027)	0.916	-1.889 (3.857)	(-2.893, -0.885)	0.005
Anxiety	58.3 (8.9)	55.8 (7.9)	54.8 (8.3)	-2.026 (6.68)	(-3.760, -0.292)	0.056	-3.061 (7.454)	(-5.001, -1.120)	0.016
Depression	53.4 (7.8)	51.7 (7.5)	51.7 (7.5)	-1.229 (5.422)	(-2.637, 0.179)	0.150	-1.242 (5.857)	(-2.767, 0.283)	0.199
Fatigue	53.7 (9)	54.4 (8.8)	53.1 (9.8)	0.200 (5.15)	(-1.137, 1.537)	0.803	-0.842 (7.31)	(-2.745, 1.061)	0.482
Pain Interference	47.6 (8.3)	47.3 (7.5)	47.3 (7.9)	-0.051 (4.574)	(-1.254, 1.152)	0.943	0.716 (7.735)	(-1.322, 2.754)	0.572
Physical Function	52.1 (6.8)	52.1 (6.6)	53.6 (6.0)	0.286 (6.127)	(-1.285, 1.858)	0.761	0.861 (6.755)	(-0.877, 2.598)	0.437
Ability to Participate	48.7 (8.5)	50.1 (8.6)	50.8 (9.0)	1.493 (6.833)	(-0.282, 3.267)	0.164	1.063 (9.43)	(-1.392, 3.518)	0.491
Sleep Disturbance	52 (5.6)	51.6 (5.4)	51.8 (6.0)	-0.267 (4.577)	(-1.455, 0.922)	0.708	-0.755 (6.272)	(-2.388, 0.878)	0.463
Companionship	50.5 (8.3)	49.1 (7.5)	51.8 (7.4)	-1.033 (6.572)	(-2.718, 0.653)	0.309	0.579 (8.625)	(-1.640, 2.798)	0.681
Managing Symptoms	49.2 (7.3)	50.2 (7.7)	50.0 (7.1)	0.140 (4.597)	(-1.053, 1.334)	0.844	-0.726 (7.339)	(-2.637, 1.184)	0.546
Managing Daily Activities	49 (6.5)	49.6 (6.9)	49.2 (7.0)	0.760 (5.103)	(-0.565, 2.085)	0.340	-0.042 (6.233)	(-1.665, 1.581)	0.967
Emotional Support	45.2 (7.6)	46.0 (10.4)	46.0 (9.4)	0.326 (7.637)	(-1.633, 2.284)	0.781	-1.132 (6.54)	(-2.814, 0.551)	0.293
PATIENTS									
8-17 Years									
Complete Surveys	N=27	N=15	N=11	Mean (SD)	C.I.	P value	Mean (SD)	C.I.	P value
Global Health	40.2 (9.4)	41.6 (8.8)	40.4 (9.5)	-0.527 (6.027)	(-3.267, 2.214)	0.740	-1.187 (7.489)	(-4.592, 2.219)	0.549
Positive Affect	42.6 (8.5)	44.1 (7.1)	42.7 (12.1)	0.778 (6.418)	(-3.201, 4.756)	0.726	-1.000 (9.165)	(-6.600, 4.600)	0.738
Anxiety	56.4 (9.4)	50.7 (12.1)	54.5 (10.9)	-2.847 (12.329)	(-8.454, 2.760)	0.386	-4.027 (9.103)	(-8.287, 0.233)	0.173
Depression	57 (8.8)	51.6 (10.3)	51.6 (10.9)	-3.013 (3.284)	(-4.507, -1.520)	0.003	-4.318 (7.491)	(-7.824, -0.813)	0.085
Fatigue	55.3 (9.5)	53.8 (8.7)	54.7 (12.6)	1.593 (8.554)	(-2.297, 5.483)	0.483	-0.427 (7.099)	(-3.749, 2.895)	0.846
Pain Interference	49.9 (9.5)	50.1 (8.9)	48.4 (9.2)	-1.707 (11.292)	(-6.842, 3.429)	0.568	-3.273 (10.763)	(-8.309, 1.764)	0.337
Physical Function	41.1 (7.1)	40.1 (7.2)	41.5 (4.1)	0.333 (6.864)	(-2.788, 3.455)	0.854	-1.373 (8.469)	(-5.336, 2.591)	0.603
Peer Relationship	48.1 (8.5)	47.9 (11.0)	48.9 (10.6)	-0.587 (7.617)	(-4.051, 2.877)	0.770	1.518 (5.115)	(-0.875, 3.912)	0.348
Parent Proxy									
8-17 Years									
Complete Surveys	N=27	N= 22	N=19	Mean (SD)	C.I.	P value	Mean (SD)	C.I.	P value
Global Health	36.5 (9.7)	34.6 (6.9)	36.6 (9.1)	-2.091 (7.374)	(-4.796, 0.614)	0.198	-0.111 (6.733)	(-2.600, 2.379)	0.944
Anxiety	56.4 (9.1)	53.7 (12.7)	52.2 (12.3)	-2.405 (8.038)	(-5.353, 0.544)	0.175	-3.563 (8.437)	(-6.682, -0.444)	0.082
Depression	55.8 (9.1)	52.9 (10.8)	51.3 (11.4)	-1.673 (5.221)	(-3.588, 0.243)	0.148	-3.747 (6.669)	(-6.213, -1.282)	0.025

Table S4 (continued)

Table S4 (continued)

Fatigue	59.5 (10.3)	58.7 (11.2)	54.6 (11.3)	-0.277 (7.489)	(-3.025, 2.470)	0.864	-4.458 (8.233)	(-7.502, -1.414)	0.030
Pain Interference	51.9 (9.4)	52.5 (10.5)	49.4 (9.6)	2.273 (11.743)	(-2.036, 6.581)	0.374	-2.474 (8.384)	(-5.573, 0.626)	0.215
Physical Function	38.7 (8)	36.6 (6.1)	40.9 (8.9)	-2.336 (7.01)	(-4.908, 0.235)	0.133	1.084 (8.721)	(-2.140, 4.308)	0.595
Peer Relationships	44.9 (9.3)	44.0 (11.5)	46.2 (8.7)	-0.795 (9.731)	(-4.366, 2.775)	0.705	1.105 (9.159)	(-2.281, 4.491)	0.605
Sleep Disturbance	58.3 (8.6)	56.7 (8.0)	59.0 (8.4)	-0.927 (9.036)	(-4.242, 2.388)	0.635	-0.484 (8.23)	(-3.527, 2.558)	0.801
Parent Proxy 5-7 Years	Baseline, Mean (SD)	Day 30, Mean (SD)	Day 120, Mean (SD)	Day 30 vs. Day 0 Change			Day 120 vs. Day 0 Change		
Complete Surveys	N=14	N=13	N=12	Mean (SD)	C.I.	P value	Mean (SD)	C.I.	P value
Global Health	37.8 (8)	40.3 (6.2)	40 (8.2)	2.317 (5.679)	(-0.628, 5.261)	0.185	2.192 (5.408)	(-0.612, 4.995)	0.188
Anxiety	51.9 (10.1)	45.0 (8.6)	46.0 (8.9)	-7.092 (12.334)	(-13.49, -0.700)	0.072	-5.969 (14.765)	(-13.570, 1.627)	0.171
Depression	48.7 (6.6)	46.1 (7.4)	49.0 (5.7)	-2.642 (5.726)	(-5.610, 0.327)	0.138	0.308 (5.793)	(-2.673, 3.288)	0.851
Fatigue	52 (9.8)	55.1 (9.1)	50.0 (7.9)	1.758 (9.85)	(-3.348, 6.865)	0.549	-2.023 (6.995)	(-5.622, 1.576)	0.318
Pain Interference	50 (11.2)	48.1 (7.7)	45.0 (7.8)	-2.792 (8.827)	(-7.368, 1.784)	0.297	-5.015 (10.322)	(-10.33, 0.295)	0.105
Physical Function	45.1 (9.4)	41.9 (6.8)	47.1 (7.8)	-2.300 (6.032)	(-5.427, 0.827)	0.213	2.015 (5.406)	(-0.766, 4.797)	0.204
Peer Relationship	48.4 (8.4)	48.7 (10.7)	50.5 (7.9)	0.458 (7.349)	(-3.352, 4.268)	0.833	2.092 (6.449)	(-1.226, 5.410)	0.265
Sleep Disturbance	52.8 (7.3)	51.8 (8.6)	52.0 (6.9)	-0.708 (3.626)	(-2.588, 1.171)	0.513	-0.115 (6.499)	(-3.459, 3.228)	0.950
PATIENTS 18+ Years	Baseline, Mean (SD)	Day 30, Mean (SD)	Day 120, Mean (SD)	Day 30 vs. Day 0 Change			Day 120 vs. Day 0 Change		
Complete Surveys	N=7	N=5	N=4	Mean (SD)	C.I.	P value	Mean (SD)	C.I.	P value
Global (Mental) Health	39.2 (7.6)	41.8 (7.7)	40.8 (7.3)	2.560 (1.61)	(1.025, 4.095)	0.024	2.625 (4.241)	(-1.839, 7.089)	0.304
Global (Physical) Health	35 (10.4)	42.0 (8.7)	40.0 (9.6)	5.480 (6.465)	(-0.680, 11.643)	0.131	4.90 (10.43)	(-6.080, 15.877)	0.417
Positive Affect	48.8 (5.6)	51 (6.9)	49.9 (3.1)	1.320 (1.925)	(-0.516, 3.156)	0.200	1.525 (2.883)	(-1.509, 4.559)	0.368
Anxiety	65.2 (8.2)	61.0 (6.1)	61.9 (6.2)	-3.000 (5.083)	(-7.846, 1.846)	0.257	-3.80 (4.401)	(-8.432, 0.832)	0.183
Depression	57.1 (11.4)	54.0 (9.1)	54.9 (9.5)	-0.120 (2.308)	(-2.320, 2.080)	0.913	-0.60 (3.769)	(-4.567, 3.367)	0.771
Fatigue	59.3 (13.1)	54.3 (10.8)	52.1 (12.8)	-3.860 (6.114)	(-9.689, 1.969)	0.231	-7.90 (6.509)	(-14.75, -1.050)	0.094
Pain Interference	59.3 (8.3)	53.2 (8.4)	51.0 (11.6)	-5.920 (11.155)	(-16.56, 4.715)	0.301	-9.075 (19.33)	(-29.42, 11.269)	0.417
Physical Function	43.4 (13.7)	46.1 (7.8)	47.0 (7.4)	0.540 (11.699)	(-10.610, 11.69)	0.923	4.300 (11.551)	(-7.857, 16.457)	0.511
Ability to Participate	46.4 (9.7)	49.6 (10.0)	37.7 (9.0)	1.780 (3.866)	(-1.906, 5.466)	0.361	-9.775 (19.514)	(-30.31, 10.762)	0.390
Sleep Disturbance	56.8 (9.9)	53.4 (4.22)	49.5 (3.2)	-2.380 (9.217)	(-11.170, 6.407)	0.595	-6.200 (11.814)	(-18.634, 6.234)	0.371
Companionship	55.9 (6.4)	58.4 (6.9)	52.4 (7.3)	1.740 (5.602)	(-3.601, 7.081)	0.526	-2.625 (3.266)	(-6.063, 0.813)	0.206
Managing Symptoms	43.2 (4.7)	47.0 (6.3)	49.0 (9.1)	3.300 (5.456)	(-1.902, 8.502)	0.248	5.600 (4.833)	(0.514, 10.686)	0.103
Managing Daily Activities	44.1 (6.6)	48.3 (10.1)	44.8 (6.5)	3.020 (5.785)	(-2.495, 8.535)	0.308	0.300 (3.772)	(-3.670, 4.270)	0.884
Emotional Support	51.3 (12.4)	51.8 (10.5)	49.5 (3.1)	-2.000 (5.523)	(-7.265, 3.265)	0.463	-2.250 (2.872)	(-5.273, 0.773)	0.215

All PROMIS Assessments available at: Assessment Center [Internet]. [cited 2022 Jun 9]. Available from: <https://www.assessmentcenter.net/>.

Table S5 Spearman correlations between baseline Health-Related Quality of Life and Month 1 App Use

CAREGIVER 18+ Years	Month 1 App Use	P value
Baseline Health-Related Quality of Life domain	N=49	
Global (Mental) Health	0.211	0.145
Global (Physical) Health	0.248	0.089
Caregiver Anxiety	-0.331	0.02
Caregiver Strain	-0.233	0.107
Positive Affect	0.166	0.256
Anxiety	-0.021	0.886
Depression	-0.016	0.913
Fatigue	-0.031	0.830
Pain Interference	-0.199	0.175
Physical Function	0.181	0.212
Ability to Participate	0.148	0.310
Sleep Disturbance	0.018	0.901
Companionship	0.061	0.675
Managing Symptoms	0.232	0.109
Managing Daily Activities	0.142	0.332
Emotional Support	0.241	0.096

Table S6 Longitudinal Regression Model of Family Caregiver Global Mental Health and Care Recipient (Patient) Depression Over Time

	Estimate	C.I.	P value
Caregiver (18+ Years) Global Mental Health			
Age (caregiver), per 1 year	-0.354	(-0.660, -0.048)	0.024
Caregiving Hours > 40 hrs (caregiver)	1.671	(-2.601, 5.943)	0.435
Gender (caregiver), male vs. female	-0.640	(-6.698, 5.419)	0.832
Any mental conditions (caregiver), any vs. non	-5.373	(-9.530, -1.217)	0.013
Day 30 vs. Day 0	2.766	(1.069, 4.463)	0.002
Day 120 vs. Day 0	0.306	(-1.468, 2.081)	0.732
Patient (8–17 Years) Depression			
Age (patient), per 1 year	0.842	(-0.364, 2.049)	0.162
Caregiving Hours > 40 h (carer)	-1.287	(-10.522, 7.948)	0.775
Gender (patient) Male vs. female	-4.041	(-11.615, 3.534)	0.281
Any mental conditions (caregiver), any vs. non	-4.557	(-11.985, 2.872)	0.217
Day 30 vs. Day 0	-3.687	(-6.969, -0.405)	0.029
Day 120 vs. Day 0	-4.512	(-8.228, -0.797)	0.019

Linear mixed model was used with time as repeated measurement; random intercept was fitted and grouped by each subject (caregiver or patient, respectively).

Table S7 Actor Partner Interdependence Model (APIM) of Family Caregiver (Carer) and Care Recipient (Patient) Interactions on Global Mental Health Assessments at Day 120

Dyad: “Caregiver Anxiety (X’) + Patient Anxiety (X)” → “Caregiver Global Mental Health (Y’) + Patient Global Health (Y)”.

APIM parameters	Estimate	C. I.	P value
Actor effects			
X’ → Y’	-0.872	(-1.375, -0.369)	0.002
X → Y	-0.769	(-1.313, -0.225)	0.008
carer age (per 1 year) → Y’	-0.567	(-1.089, -0.045)	0.037
carer any mental disorder → Y’	-3.881	(-9.086, 1.324)	0.142
patient gender (M vs. F) → Y	-2.591	(-12.007, 6.824)	0.581
Partner effects			
X’ → Y	-0.270	(-1.044, 0.504)	0.485
X → Y’	0.165	(-0.156, 0.487)	0.306
caregiving > 40hrs → Y	-3.766	(-14.624, 7.092)	0.487

Dyad: “Caregiver Depression (X’) + Patient Depression (X)” → “Caregiver Global Mental Health (Y’) + Patient Global Health (Y)”

APIM parameters	Estimate	C.I.	P value
Actor effects			
X’ -> Y’	-0.611	(-0.942, -0.28)	0.001
X -> Y	-0.776	(-1.12, -0.433)	0.0001
carer age (per 1 year) → Y’	-0.162	(-0.731, 0.408)	0.569
carer any mental disorder → Y’	0.548	(-5.35, 6.446)	0.852
patient gender (M vs. F) → Y	-1.390	(-8.099, 5.319)	0.677
Partner effects			
X’ → Y	-0.553	(-0.972, -0.135)	0.013
X → Y’	-0.103	(-0.471, 0.266)	0.576
caregiving > 40hrs → Y	0.791	(-8.379, 9.962)	0.862

Linear model was fixed by generalized least squares method (function gls() in R). Symmetric covariance structure was assumed to apply only to observations within the same dyad. (corSymm[form=~1|Dyad.Number]); observations with different dyads were assumed to be uncorrelated; and within-group heteroscedasticity structure was assumed by allowing different variance in carers and care recipients.