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RESEARCH

# Feasibility and acceptability of C-PRIME: A health promotion intervention for family caregivers of patients with colorectal cancer

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## Abstract

**Purpose** This study aimed to test the feasibility and acceptability of a digital health promotion intervention for family caregivers of patients with advanced colorectal cancer and explore the intervention's preliminary efficacy for mitigating the impact of caregiving on health and well-being.

**Methods** We conducted a single-arm pilot feasibility trial of C-PRIME (Caregiver Protocol for Remotely Improving, Monitoring, and Extending Quality of Life), an 8-week digital health-promotion behavioral intervention involving monitoring and visualizing health-promoting behaviors (e.g., objective sleep and physical activity data) and health coaching (NCT05379933). A priori benchmarks were established for feasibility (≥ 50% recruitment and objective data collection; ≥ 75% session engagement, measure completion, and retention) and patient satisfaction (> 3 on a 1–5 scale). Preliminary efficacy was explored with pre- to post-intervention changes in quality of life (QOL), sleep quality, social engagement, and self-efficacy.

**Results** Participants ($N = 13$) were M = 52 years old (SD = 14). Rates of recruitment (72%), session attendance (87%), assessment completion (87%), objective data collection (80%), and retention (100%) all indicated feasibility. All participants rated the intervention as acceptable (M = 4.7; SD = 0.8). Most participants showed improvement or maintenance of QOL (15% and 62%), sleep quality (23% and 62%), social engagement (23% and 69%), and general self-efficacy (23% and 62%).

**Conclusion** The C-PRIME digital health promotion intervention demonstrated feasibility and acceptability among family caregivers of patients with advanced colorectal cancer. A fully powered randomized controlled trial is needed to test C-PRIME efficacy, mechanisms, and implementation outcomes, barriers, and facilitators in a divserse sample of family caregivers.

**Trial registration** The Caregiver Protocol for Remotely Improving, Monitoring, and Extending Quality of Life (C-PRIME) study was registered on clinicaltrials.gov, NCT05379933, in May 2022.

**Keywords** Family caregivers · Colorectal cancer · Behavioral intervention · Digital health · Feasibility · Acceptability

Family caregivers relieve demands on the healthcare system by performing unpaid tasks that help patients remain at home [1, 2]. Although some caregivers report benefits from their experience (e.g., growing closer to the patient, finding meaning in new priorities) [3], providing care can also be emotionally and physically burdensome. Colorectal cancer is among the most common cancer types in the United States and among the leading causes of cancer deaths for both women and men [4]. Patients with colorectal cancer may rely upon family caregivers for direct, long-term support with medical care, treatment navigation, daily activities, household chores, and psychosocial needs, often resulting in caregiver distress, fatigue, sleep disruption, and feelings of isolation among colorectal cancer caregivers [5]. At

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advanced stages, colorectal cancer may be especially distressing for family caregivers as they cope with the patient's high physical symptom burden and uncertain or poor prognosis [6, 7].

A study of colorectal cancer patients and their caregivers showed that, despite improvements in patient physical health over the first year after diagnosis, caregivers' physical health declined over time [8]. Physical health decline is especially concerning given that family caregivers are often older adults at risk for chronic conditions [2, 9]. Moreover, research suggests that the majority of caregivers maintain their baseline level of distress across the first year post-diagnosis [10]. Negative impacts on caregiver health and well-being are likely attributable to the interdependent effects of the cancer experience, particularly for cohabitating family members and family caregivers changing their own health behaviors to meet patient needs. Indeed, caregivers often report postponing their own health care needs or reducing sleep, exercise, and relaxation [11, 12]. Reductions in health-promoting behaviors have especially been documented in caregivers of patients with advanced colorectal cancer [13–16]. Family caregivers of colorectal cancer patients report disruptions in sleep related to heightened vigilance for ostomy care and patient sleep disturbance [17], decreased activity level in the context of caregiving activities and patient fatigue and mobility impairments [16], and changes in eating habits related to changes in patient nutritional needs [13]. In contrast, caregivers who engage in more health-promoting behaviors are better able to cope with caregiving demands and feel more effective as caregivers [12, 18].

Thus, there is a clear need to support family caregivers in health promotion. Yet, most published caregiver interventions and clinical services focus exclusively on caregiver psychosocial needs (e.g., support groups) or patient health and symptom management, such as digital health interventions to improve patient health-promoting behaviors (e.g., sleep, activity) [19, 20]. Digital health interventions for patients can be used as a model for digital health behavior interventions to improve caregiver health. Wearable sensors are increasingly used to passively collect objective health-promoting behavioral data (e.g., step count, sleep) [21, 22] and are both feasible and provide valid data [23, 24]. Commercially available wearable sensors (e.g., Fitbit devices) provide high-quality and valid data at lower cost and with fewer barriers than those originally designed for clinical purposes [25]. Digital dashboards can then be used to visualize complex data by displaying key indicators for at-a-glance interpretation and provide contextual information (e.g., abnormal vs. normal scores; changes over time), which may improve data interpretability. Such visualization of complex information can organize data, reduce cognitive load, and provide new insights and knowledge [26].

Personalized health coaching further enhances interpretation and actionability of health data monitoring [27]. Health coaches can draw upon empirically supported techniques from cognitive-behavioral theory to assist family caregivers in (1) reviewing and interpreting each week's health-promoting behavior data, (2) supporting family caregivers' motivation to increase health-promoting behaviors through relationship-building, accountability, and person-centered communication tools (e.g., problem-solving, goal setting, motivational interviewing) [28], and (3) using cognitive-behavioral strategies to promote coping (e.g., cognitive restructuring). A meta-analysis of 15 randomized trials in a variety of health contexts demonstrated that health coaching using education, motivational interviewing, and behavior change strategies improves health-promoting behaviors and reduces distress [29]. These effects are consistent among virtual or phone-based lay coaches, enhancing scalability, and some evidence with similar interventions suggests that combining online tools and human contact is ideal [30].

Our goal was to develop a digital health promotion and coaching intervention for family caregivers of advanced colorectal cancer patients and pilot test the intervention's feasibility, acceptability, and preliminary efficacy in the outpatient oncology setting. We hypothesized that by offering digital self-monitoring tools along with health coaching for goal-setting and problem-solving, we would encourage family caregivers to engage in more self-care and health behaviors, ultimately improving family caregiver well-being. For this pilot trial, we specifically hypothesized that a digital health intervention for family caregivers would be feasible and acceptable according to a priori benchmarks. Finally, we explored preliminary efficacy in reducing deterioration in self-reported health and well-being.

## Methods

We conducted a single-arm pilot feasibility trial of C-PRIME (Caregiver Protocol for Remotely Improving, Monitoring, and Extending Quality of Life), an 8-week digital health-promotion behavioral intervention for family caregivers of patients with advanced colorectal cancer. This trial was pre-registered with identifier NCT05379933. This study was approved by the Institutional Review Board and performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

### Participants

Eligible participants were (1) nominated as a caregiver by a patient planning to receive or currently receiving treatment for stage III or IV colorectal cancer in the Gastrointestinal

(GI) Oncology clinic at an National Cancer Institute (NCI)-Designated Comprehensive Cancer Center, (2) self-identified as an unpaid family member or friend who provides healthcare assistance and support, (3) age ≥ 18 years old, (4) English- or Spanish-speaking, (5) able to complete questionnaires and engage in short discussions with coaches, (6) able to identify a primary care provider, and (7) willing/able to use a mobile device provided by the study team or their own personal device.

## Procedures

Participants were recruited through the GI Oncology Clinic using processes developed in our prior work [31]. Patients with upcoming treatment planning appointments (typically occurring two weeks prior to treatment start) were contacted to nominate a single primary family caregiver who typically accompanies them to appointments, provides the majority of hands-on care, and may want to participate in this study.

Nominated family caregivers who consented to participate in the trial were provided a welcome packet including (1) a letter describing the participant's role in the project, (2) a Fitbit to wear for 8 weeks from the day of receipt using an anonymous Fitbit account created for each participant to protect confidentiality, (3) an iPad preconfigured to periodically retrieve data from the Fitbit device and upload these data to the manufacturer's cloud servers, (4) a link and ID code for completing online surveys via secure REDCap database, and (5) a paper version of the baseline survey with a return envelope for participants who preferred not to complete the survey online. Participants then engaged in the 8-week C-PRIME intervention, described in detail below. After the 8-week intervention, participants were sent a follow-up packet including (1) a link and ID code for completing the follow-up REDCap survey, (2) a paper version of the follow-up survey for participants who preferred not to complete the survey online, and (3) a postage-paid package for returning the survey, Fitbit device, and iPad. Family caregiver participants were compensated with $20 electronic gift cards for completion of the baseline survey and follow-up survey.

## Intervention

The C-PRIME intervention consists of three components: (1) monitoring health-promoting behavior, (2) visualizing these data, and (3) health coaching.

1) *Monitoring*. Family caregivers wore Fitbit activity trackers for 8 continuous weeks to monitor health-promoting behavior (e.g., sleep, activity). Participants also completed weekly surveys of self-reported psychosocial and health status (e.g., fatigue, anxiety). Self-report measures have long been an important tool in identifying and self-monitoring health-promoting behavior to improve health outcomes, especially for cancer patients [32]. Study personnel reviewed the data dashboard periodically to screen for missing data.

2) *Visualization.* Wearable sensor and self-reported data were processed and displayed in real time to family caregivers via the C-PRIME digital platform. The C-PRIME digital dashboard pulls Fitbit data automatically throughout the day, integrates self-report data collected via a secure online survey platform (i.e., REDCap), and visualizes these data (see Fig. 1).

3) *Health coaching*. Participants were contacted within 1 week of enrollment to begin weekly remote health coaching, which offers flexibility for family caregivers and has been favorably compared to face-to-face health coaching [33]. Weekly coaching involved brief, 15–20 min phone calls to set goals regarding health-promoting behavior (e.g., increase physical activity) with a trained health coach, supervised by a licensed psychologist. Each coaching session began with an assessment based on the C-PRIME dashboard and update on the previous session's goals. Manualized C-PRIME session content was adapted from a previous manualized caregiver intervention [34] that focused on key domains of the Health-Promoting Lifestyle Profile (HPLP-II) [35] checklist, one of the most common tools to assess caregiver health promotion. Weekly session topics included strategies for (1) taking care of yourself, (2) problem-solving, (3) strategies for help-seeking, (4) stress reduction/relaxation, (5) exercise, (6) nutrition, (7) sleep, and (8) the positive side of caregiving and planning for the future. Sessions were individually tailored to the specific needs of family caregivers for colorectal cancer patients with flexible adaptations based upon patient functioning, treatment, and prognosis, and family caregiver resources to handle changes (see Table 1 for detailed session content). Throughout the sessions, coaches use problem-solving and motivational interviewing techniques to help family caregivers set goals and overcome barriers within the context of colorectal cancer caregiving. This could also include referral to resources, such as social work or nutrition, community programs, exercise classes, or meditation tools.

## Measures

### Participant characteristics

At baseline, caregivers completed self-report measures of age, gender, marital status, race, ethnicity, education, and relationship to patient. Participants also self-reported their height and weight for the calculation of body mass index. Finally, participants completed a self-report version of the Charlson Comorbidity Index, [36] a measure of comorbid medical conditions that has been commonly used to predict long-term mortality. Specific scores are assigned to each comorbidity, and scores are summed to provide an overall Charlson Comorbidity

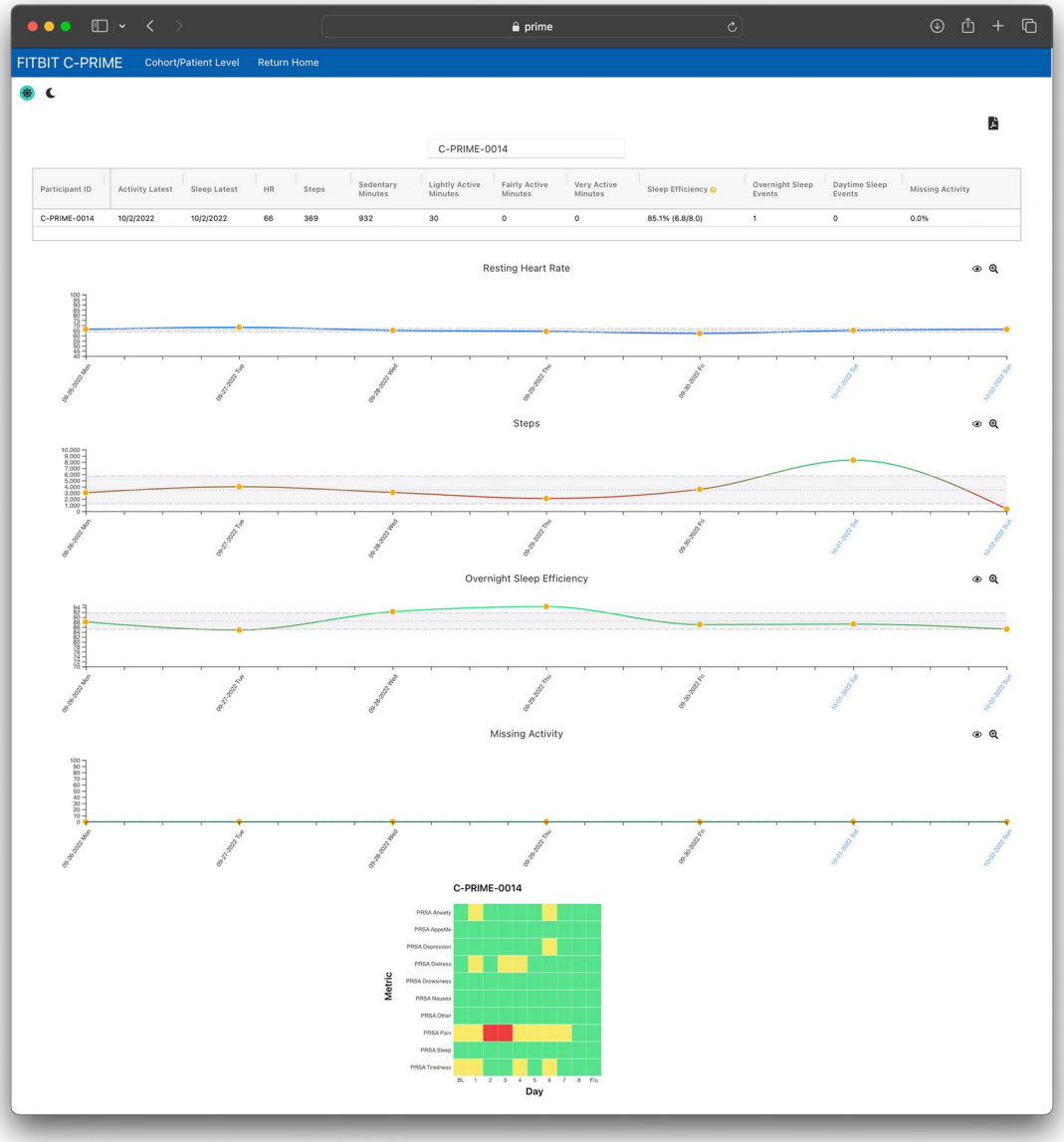


**Fig. 1** C-PRIME digital dashboard with wearable sensor and survey data visualization for family caregivers

Index score for each individual ranging from 0 (*no comorbidities*) to 5 or more (*severe comorbidities*) [37].

## Feasibility and acceptability

Feasibility, acceptability, and appropriateness of the intervention were measured in the intervention follow-up survey using the the 4-item Feasibility of Intervention Measure (FIM), 4-item Acceptability of Intervention Measure (AIM), and the 4-item Intervention Appropriateness Measure (IAM). Scores on these three measures range from 1 (*completely disagree*) to 5 (*completely agree*), with higher scores indicating more positive experiences with the C-PRIME Program. Feasibility was also assessed based on recruitment and retention of participants. Successful feasibility was identified a priori as recruitment of at least 50% of eligible caregivers, caregiver engagement with at least 75% of coaching sessions, completion of at least 75% of weekly assessments, and retention of at least 75% of caregivers who completed baseline measures, as indicated by completion of 8-week questionnaires. Additionally, we assessed the feasibility of collecting objective data on sleep quality and physical activity obtained from Fitbit devices. Our a priori feasibility benchmark was collection of objective data on at least 50% of days on study. Participants were also asked to complete a 30-item acceptability survey adapted for use in this study based on previously published studies [38, 39]. Three of

**Table 1** C-PRIME health coaching session topics

| Session topic | HPLP-II domain | Session content | Colorectal cancer focus |
|---|---|---|---|
| 1 Overview | Health Responsibility | Goals/expectations, C-PRIME dashboard | Identify individual needs, context, and expectations |
| 2 Taking care of yourself | Health Responsibility | Self-care importance and goal-setting | Family caregivers often deprioritize health-promoting behavior |
| 3 Problem-solving | Health Responsibility | Problem identification, solution generation, action planning | Apply tools to individual issues within the family caregiver context |
| 4 Asking for help | Interpersonal Relations | Social support request best practices and rehearsal | Patient embarrassment and isolation often limit family caregiver resources |
| 5 Relaxation and sleep | Stress Management | Stress management skills, sleep hygiene | Nighttime patient care (e.g., infusions) and anxiety impact family caregiver sleep |
| 6 Exercise | Physical Activity | Exercise guidelines, activity goals | Patient fatigue and mobility limitations can limit family caregiver physical activity when providing care |
| 7 Nutrition | Nutrition | Nutrition guidelines, nutritional goals | Patient diet and eating changes; family caregiver anxiety can impact appetite, meals, and overall diet |
| 8 Positive side of caregiving and review | Spiritual Growth | Achievements/growth, strategy maintenance | Making meaning of colorectal cancer caregiving specific to individual context |

*HPLP-II*, Health-Promoting Lifestyle Profile [35] measure

the 30 items ask participants to rate their overall experience with the C-PRIME Program, surveys, and Fitbit use. Our a priori acceptability benchmark was average patient satisfaction scores > 3 on a scale of 1 (*not satisfied)* to 5 (*very satisfied*).

### Preliminary efficacy

Patient-reported outcome (PRO) measures were also assessed at baseline and after the 8-week intervention to expore preliminary efficacy of C-PRIME in the outpatient oncology setting. Outcomes of interest included intervention effects on caregiver self-care behaviors, quality of life (QOL), and sleep. The Health-Promoting Lifestyle Profile-II (HPLP-II) was added after study initiation to assess behaviors likely to promote a healthy lifestyle and indicating greater self-care [40]. HPLP-II responses are categorized into an overall health-promoting lifestyle score incorporating subscales of health responsibility, physical activity, nutrition, spiritual growth, interpersonal relations, and stress management. QOL was assessed using the Global Health Status subscale of the European Organization for Research and Treatment's QLQ-C30 (EORTC QLQ-C30) [41]. Finally, we used Patient-Reported Outcomes Measurement Information System (PROMIS) [42] scales to assess preliminary intervention impacts on sleep disturbance and potential mechanisms of intervention effects (e.g., social engagement, general self-efficacy). PROMIS offers psychometrically sound, flexible, and universal measures [42, 43] with greater precision (i.e., less error) than most other measures using fewer items, which decreases burden on family caregiver participants. Specifically, PROMIS measures were used to assess caregivers' Sleep Disturbance, Ability to Participate in Social Roles and Activities, and Self-Efficacy for Managing Chronic Conditions [44], or caregiver confidence in their ability to carry out goal-driven health behaviors.

## Analyses

We examined primary outcomes of feasibility and acceptability by calculating the proportion of patients who met a priori benchmarks. For preliminary efficacy, we explored the intervention's ability to protect against deterioration in PRO measures. Because the HPLP-II was added after study initiation, only 5 participants completed this measure at both baseline and post-intervention. Thus, HPLP-II data were not examined for pre- vs. post-intervention preliminary efficacy results. Due to the small sample size in this pilot study and risk for unreliable efficacy estimates from pilot trials [45], we focused on the change in the proportion of patients falling in different risk categories at pre- and post-intervention rather than statistical significance. Risk categories were defined a priori for each PRO measure based on published cutoff scores. Meaningful change in EORTC QLQ-C30 Global Health Status was defined as a change of ≥ 10 points from pre- to post-intervention [46]. Meaningful change in PROMIS measures was defined as a change of ≥ 5 points from pre- to post-intervention [47].

## Results

Family caregivers ($N = 13$) who participated in the C-PRIME intervention were on average 52 years old (SD = 14) and predominately non-Hispanic (92%), White (69%), married

(69%), female (62%), and spousal caregivers (39%) with at least a college or university degree (62%) (see Table 2 for participant demographic and clinical characteristics).

## Feasibility

Table 3 shows results of C-PRIME Program feasibility, acceptability, and satisfaction scores compared to a priori benchmarks. Among 18 eligible family caregivers nominated by a patient to participate in the study, 15 caregivers consented (83.3%), and 13 caregivers completed baseline surveys (72.2%). All 13 participants who completed a baseline survey also completed the 8-week follow-up survey, demonstrating 100% retention. Additional details on participant recruitment and retention can be found in the participant flow diagram (Fig. 2). On average, participants completed 6.9 (86.5%) of 8 weekly assessments and 6.5 (81.7%) of 8 C-PRIME intervention modules, and participants attended 6.9 (86.5%) of 8 weekly coaching sessions. Participants were asked to wear the Fitbit throughout the study period of 61 days, and overall adherence to wearing the Fitbit was 79.9% of available study days (or an average of 48.8 days per participant). The average FIM score was 4.2 out of 5 (SD = 0.4), indicating *agreement* that the C-PRIME Program was feasible.

**Table 2** Participant characteristics ($N = 13$)

| Variable | Statistic |
|---|---|
| Age, years; M (SD), range | 52 (14.1), 28–70 |
| Gender; *n* (%) | |
| Male | 5 (38.5) |
| Female | 8 (61.5) |
| Marital status; *n* (%) | |
| Currently married | 9 (69.2) |
| Never married | 2 (15.4) |
| Divorced | 2 (15.4) |
| Race; *n* (%) | |
| White | 9 (69.2) |
| Black/African American | 3 (23.1) |
| Unknown by participant | 1 (7.7) |
| Ethnicity; *n* (%) | |
| Non-Hispanic | 12 (92.3) |
| Hispanic or Latino | 1 (7.7) |
| Education; *n* (%) | |
| High school graduate or less | 3 (23.1) |
| Partial college or specialized training | 2 (15.4) |
| College or university graduate | 6 (46.2) |
| Graduate degree | 2 (15.4) |
| Body Mass Index (BMI); M (SD), range | 30 (9.3), 22–55 |
| Healthy weight (18.5 £ BMI ≤ 25); *n* (%) | 4 (30.8) |
| Overweight (25 £ BMI ≤ 30); *n* (%) | 5 (38.5) |
| Obesity (BMI$^3$ 30); *n* (%) | 4 (30.8) |
| Charlson comorbidity index; M (SD), range | 2.2 (0.6), 2–4 |
| Relationship to patients; *n* (%) | |
| Spouse/partner | 5 (38.5) |
| Parent | 3 (23.1) |
| Child | 2 (15.4) |
| Close friend/others | 3 (23.1) |

Percentages may not sum to 100 due to rounding

## Acceptability

The mean AIM score was 3.8 out of 5 (SD = 0.5) and mean IAM score was 4.0 out of 5 (SD = 0.6), indicating *agreement* that the C-PRIME Program was acceptable. Average overall satisfaction with the C-PRIME program was 4.7 out of 5 (SD = 0.8) with 85% of participants rating their satisfaction as 5 (*very satisfied*). Average acceptability of surveys was 4.8 (SD = 0.6) with 85% of participants rating overall acceptability of surveys as (*very satisfied*). Average satisfaction with wearing the Fitbit was 3.9 (SD = 1.5) with 69.2% of participants scoring above 3 (*satisfied* or *very satisfied*). Average scores on individual acceptability items ranged from 3.4 (SD = 1.5; "The Fitbit is comfortable to wear.") to 5.0 (SD = 0; "I felt comfortable using the tools provided in the C-PRIME Program.").

## Preliminary efficacy

Table 4 presents preliminary efficacy results for intervention outcome measures and measures of proposed intervention mechanisms at baseline and post-intervention. QOL showed meaningful improvement among 15.4% of family caregivers, was maintained among 61.5%, and deteriorated among 23.1%. Sleep showed meaningful improvement among 23.1% of family caregivers, was maintained among 61.5%, and deteriorated among 15.4%. Social engagement showed meaningful improvement among 23.1% of family caregivers, was maintained among 69.2%, and deteriorated among 7.7%. Finally, general self-efficacy showed meaningful improvement for 23.1% of family caregivers, was maintained among 61.5%, and deteriorated among 15.4%.

# Discussion

The C-PRIME intervention for family caregivers of patients with advanced colorectal cancer demonstrated strong feasibility and acceptability. Rates of feasibility and acceptability outcomes exceeded all a priori benchmarks for recruitment, session engagement, assessment completion, objective data collection, retention, and patient satisfaction. In previous research, family caregiver health-promoting behaviors typically showed significant deteriorations. However, 15–23%

**Table 3** C-PRIME program feasibility, acceptability, and satisfaction

| | Components | M (SD) | A priori benchmark | C-PRIME Program[a] |
|---|---|---|---|---|
| Feasibility | Eligible caregivers who consented | - | ≥50% | 83.3% |
| | Consented caregivers with baseline surveys[b] | - | ≥50% | 86.7% |
| | Retention (completion of follow-up survey)[c] | 13 (0) | ≥75% | 100% |
| | Completion of 8 weekly assessments[d] | 6.9 (1.8) | ≥75% | 86.5% |
| | Total study survey completion[e] | 9 (1.8) | ≥75% | 89.2% |
| | Attendance at 8 weekly sessions | 6.9 (1.8) | ≥75% | 86.5% |
| | Adherence to Fitbit use (number of days)[f] | 49 (16) | ≥50% | 79.9% |
| | Feasibility of Intervention Measure (FIM) | 4.2 (0.4) | > 3 | 100% |
| Acceptability | Acceptability of Intervention Measure (AIM) | 3.8 (0.5) | > 3 | 100% |
| | Overall satisfaction with C-PRIME Program | 4.7 (0.8) | > 3 | 84.6% |
| | Overall acceptability of study surveys | 4.8 (0.6) | > 3 | 92.3% |
| | Overall satisfaction with wearing Fitbit | 3.9 (1.5) | > 3 | 69.2% |
| Appropriateness | Intervention Appropriateness Measure (IAM) | 4.0 (0.6) | > 3 | 92.3% |

[a]Proportions represent the percentage of participants ($N = 13$) who met a priori benchmarks for feasibility (i.e., ≥ 50% recruitment and objective data collection and ≥ 75% session engagement, measure completion, and retention) and acceptability (i.e., average patient satisfaction > 3 on a 1–5 scale). [b]Eligible participants were 18 family caregivers who met eligibility criteria, including nomination by a patient to participate in the study. Consented participants were 15 nominated caregivers who consented to participate. Enrolled participants were 13 caregivers who consented to participate and completed the baseline survey. [c]Retention was defined as completion of the follow-up survey; 100% of participants who completed the baseline survey also completed the follow-up survey. [d]The average completion rate for weekly assessments (week 1 to week 8) was 90/(13 * 8) = 86.5%. [e]The total number of possible assessments was 10 assessments * 13 participants = 130 assessments. The total number of completed assessments was 116 (89.2%). [f]The total number of days participants were asked to wear a Fitbit during the study period was 61 days * 13 participants = 793 days. The total number of days with Fitbit data was 634 days (79.9%)

of family caregivers participating in the C-PRIME intervention showed clinically meaningful improvement in important outcomes (e.g., QOL, sleep disturbance) and 23% showed clinically significant improvement in our proposed intervention mechanisms (e.g., social engagement, general self-efficacy). Most caregivers reported improved or maintained outcomes (77–85%) and mechanisms (85–92%). Improvement and maintenance of PROs over the 8-week intervention could provide an early indication of preliminary intervention efficacy to protect against deterioration in caregiver health and well-being, although the small sample size and lack of control group limits conclusions that can be drawn regarding expected change over time. Notably, baseline PROMIS scores were within normal limits, suggesting that caregiver sleep disturbance, ability to engage in social activities, and self-efficacy were not impaired at baseline. C-PRIME intervention effects on these outcomes may have been more detectable among caregivers experiencing impairment at baseline.

Results of this C-PRIME pilot study show promise for future testing in larger randomized controlled trials and potential for improved caregiver outcomes. Importantly, the C-PRIME intervention moves beyond existing caregiver interventions focused solely on psychosocial needs (e.g., support groups) and beyond health promotion interventions for managing *patient* symptoms [20, 48–59], serving as a critical model to specifically target and improve family caregiver health. Those family caregivers who engage in more health-promoting behaviors may be better equipped to cope with caregiving demands and function more effectively as caregivers [12, 18, 60], resulting in indirect benefits for patient outcomes, such as reduced patient distress and even mortality [61–63].

## Strengths

The C-PRIME intervention integrates self-monitoring and coaching interventions to improve health-promoting behavior among family caregivers of patients with cancer. This pilot study is among the first trials to use digital health and coaching components commonly used in other populations to address the needs of family caregivers. C-PRIME also visualizes self-report and wearable sensor data in an interactive digital dashboard. This novel approach empowers family caregivers and health coaches to quickly interpret trends, monitor key objective and subjective outcomes, and inform goal-setting and coaching sessions. Additionally, the C-PRIME intervention aims to improve outcomes largely overlooked in previous family caregiver research. Many health behaviors are interrelated, and improvement in one

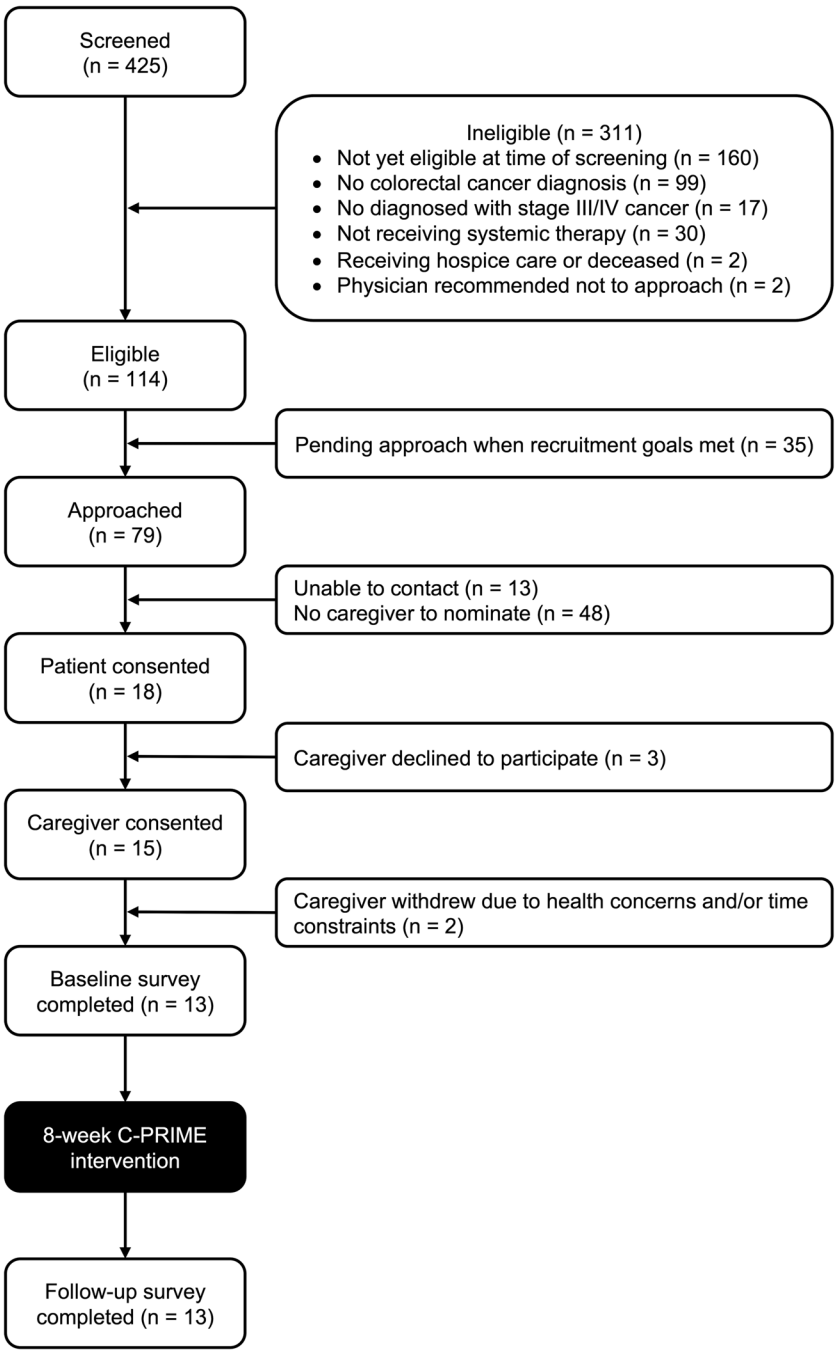


**Fig. 2** Participant flow diagram

area can create synergistic effects [64, 65]. Improving health behavior with objective and subjective secondary outcomes will accelerate the impact of health behavior trials.

## Limitations

This was a single-arm pilot feasibility trial. As such, the current study was limited by a small sample of family caregivers. The sample was also largely homogenous with predominately Non-Hispanic White family caregivers, limiting generalizability. Although Spanish-language materials were prepared for the current study, a Spanish-speaking coach was not available, resulting in the intervention being delivered only in English. Family caregivers in this study were nominated by patients treated at a large comprehensive cancer center with robust support resources, potentially bolstering caregiver health and well-being relative to the average caregiver in the USA. A disproportionately large number of caregivers in this study were close friends and not legal or biological family members; these individuals may have a different experience and potentially encounter less caregiver burden than caregivers

**Table 4** Patient-reported outcome measure scores and pre- to post-C-PRIME intervention meaningful change categories among family caregivers ($N = 13$)

| Outcome measures | Baseline M (SD) | Follow-up M (SD) | Change *n* (%) |
|---|---|---|---|
| EORTC QLQ-C30 Global Health[a] | 81.4 (15.7) | 80.1 (20.8) | |
| Improvement | | | 2 (15.4) |
| Maintenance | | | 8 (61.5) |
| Deterioration | | | 3 (23.1) |
| PROMIS sleep disturbance[b] | 50.2 (9.1) | 48.2 (8.9) | |
| Improvement | | | 3 (23.1) |
| Maintenance | | | 8 (61.5) |
| Deterioration | | | 2 (15.4) |
| PROMIS Ability to Participate in Social Roles/Activities[b] | 54.5 (7.6) | 55.9 (7.1) | |
| Improvement | | | 3 (23.1) |
| Maintenance | | | 9 (69.2) |
| Deterioration | | | 1 (7.7) |
| PROMIS General Self-Efficacy[b] | 52.2 (10.9) | 53.4 (8.8) | |
| Improvement | | | 3 (23.1) |
| Maintenance | | | 8 (61.5) |
| Deterioration | | | 2 (15.4) |

[a]Meaningful change for Global Health Status score was defined as ≥ 10 points. [b]Meaningful change for PROMIS measures was defined as ≥ 5 points

traditionally included in research literature. Given the focus on intervention feasibility and acceptability, results of the current study are limited to the assessment period of pre- to post-intervention. Study results beyond the immediate post-intervention period were not examined, so long-term outcomes could not be determined.

## Future directions

A large-scale randomized clinical trial is needed to test C-PRIME efficacy, mechanisms, and implementation outcomes, barriers, and facilitators in a diverse sample of family caregivers. Few interventions focused on health outcomes are available in Spanish [66], despite Hispanic family caregivers reporting higher intensity caregiving and more impact of caregiving on physical health than non-Hispanic family caregivers [67]. Future trials should advance health equity and improve family caregiver outcomes by providing C-PRIME in both English and Spanish. Providing digital interventions in both languages may also identify potential subpopulations that benefit most. Future trials could also screen for caregivers experiencing significant distress or impairment at baseline to optimize C-PRIME intervention impact among caregivers most in need.

## Conclusion

The C-PRIME digital health promotion intervention demonstrated feasibility and acceptability among family caregivers. Future large-scale trials and dissemination and implementation of C-PRIME hold potential for helping address the urgent public health issue of family caregiver health deterioration [60, 68] and positively impact downstream patient outcomes (e.g., patient distress, hospitalizations, mortality) [61–63].

**Author contribution** L.G.: methodology, formal analysis and investigation, writing—original draft preparation, writing–review, and editing; X.L.: data collection, formal analysis and investigation, writing—original draft preparation, writing—review and editing; A.H.: writing—review and editing; LO.: writing—review and editing; I.l: writing—review and editing; B.S.: writing—review and editing; H.J.: writing—review and editing; Y.R.: data collection, writing—review, and editing; C.B.: regulatory support, writing—review, and editing; K.Z.: data collection, writing—review, and editing; K.W.: data collection, writing—review, and editing; M.R.: conceptualization, methodology, data collection, writing—original draft preparation, writing—review and editing, funding acquisition, resources, supervision; B.G.: conceptualization, methodology, data collection, formal analysis, writing—original draft preparation, writing—review and editing, funding acquisition, resources, supervision.

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**Data availability** Data are available from the corresponding author upon reasonable request. The data are not publicly available due to privacy restrictions.

## Declarations

**Ethics approval and consent to participate** C-PRIME: Caregiver Protocol for Remotely Improving, Monitoring, and Extending Quality of Life – Advarra Institutional Review Board (Pro00062245) / Moffitt MCC21751. All participants provided informed consent to participate in the current study.

**Consent for publication** Not applicable.

**Competing interests** The authors declare no competing interests.

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