A Mobile-Support Program to Facilitate Nutritional Caregiving in Head and Neck Cancer

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PROTOCOL TITLE:

A Mobile-Support Program to Facilitate Nutritional Caregiving in Head and Neck Cancer

Brief Title: The Healthy Eating and Recovery Together (HEART) Study

PRINCIPAL INVESTIGATOR:

Katherine Regan Sterba, PhD

Objectives / Specific Aims

Head and neck (HNC) survivors face devastating treatment consequences[1-3] that lead to severe disruptions in swallowing and speech and directly result in significant weight loss, malnutrition and feeding tube dependence.[4] These rehabilitation concerns are linked to substantial psychosocial challenges including high rates of depression and limitations in social interactions.[5-7] HNC caregivers (family/friends who provide support) therefore encounter taxing and distressing nutritional caregiving tasks and often feel unprepared to carry out critical support efforts at home.[8] After treatment, as survivors and caregivers face persistent symptoms and transitions in care, our research has demonstrated that caregivers report feeling isolated and overwhelmed and have inadequately addressed nutritional support needs. Therefore, it is imperative that survivorship care planning in this high-burden population includes caregivers and focuses directly on nutrition.

Our interdisciplinary team has developed and pilot-tested the survivorship needs assessment planning (SNAP) tool (NCI 1R21CA173271). The tool is administered in the clinic using touch-screen tablet technology to address the specialized needs of HNC survivors and caregivers after treatment by generating personalized care plans. The system has demonstrated high acceptability and feasibility and is a promising platform for HNC survivorship care because it addresses speech challenges, provides an efficient way to collect data from both survivors and caregivers and accommodates HNC clinical variability by generating algorithm-driven plans. SNAP has high potential for expansion to support caregivers' nutritional support efforts beyond the clinic by capitalizing on mobile technology to follow caregivers as they transition home in the high-need recovery period.

The long-term goal of this research is to improve physical, emotional and social post-treatment outcomes in HNC survivors by implementing a nutrition-focused mobile-Support program to prepare and support caregivers. In this unique survivor-caregiver population, we argue for a stepped approach to survivorship care planning by first providing caregivers with tools to support initial nutritional recovery efforts (e.g., adequate nutritional intake, weight loss prevention) to address immediate needs. This research builds on 1) our preliminary studies identifying nutritional challenges (e.g., lean body mass loss, feeding tube dependence) as the most prominent and distressing HNC caregiving focus after treatment, 2) the premise that the translation of key oncology rehabilitation recommendations into caregiver-focused support steps will facilitate dyads' teamwork and 3) our promising SNAP tool technology. The goal of this mSupport intervention is to improve HNC caregiver preparation after treatment to optimize their roles in and accelerate survivors' nutritional recovery.

Emphasizing a transactional caregiving model and building on our pilot work, this research capitalizes on and extends the SNAP tool to address HNC caregiver nutritional support needs on an ongoing basis in the home setting, whereas our current system serves principally as a clinic tool. We will develop and pilot-test a caregiver nutrition support system to: 1) systematically administer survivor/caregiver nutritional needs assessments after completing treatment, 2) generate tailored caregiver-focused nutritional care plans and 3) provide bi-weekly mobile support (encouragement, reminders and tips delivered through messaging and peer videos) to caregivers as they manage nutritional needs and concerns during the initial recovery period.

Specific Aim 1: To develop and pretest a mobile nutritional support system (needs assessment tool, care plan template and mobile messaging program) for HNC survivor-caregiver dyads at the end of treatment.

- **1a).** Identify high-priority caregiver nutritional need domains using key informant interviews with survivors and caregivers and surveys with a national panel of oncology dietitians.
- **1b).** Translate key oncology nutritional rehabilitation recommendations into caregiver-focused support steps and match care plan resources and mobile support messages for each identified need.
- **1c).** Develop and pretest the needs assessment technology, care plan template and mobile support message delivery system with HNC survivors, caregivers and health care providers.

Specific Aim 2: To pilot-test the implementation of the mobile support system in 33 HNC dyads (N=66).

- **2a).** Examine the acceptability of using the mobile support system to assess dyads' nutritional needs, generate personalized care plans and deliver caregiver mobile support.
- **2b).** Examine the feasibility of the mSupport system by evaluating intervention delivery factors (i.e., ease of use, engagement, satisfaction, barriers, unmet needs, preferred data collection modes), resource needs (i.e., staff, time, equipment, extension to community), and study methods (i.e., timing, recruitment, process/outcome measures).
- **2c).** Synthesize findings and refine the mobile support system in preparation for large-scale evaluation.

This research is novel in its dyadic approach to survivorship care planning, its focus on nutritional wellness within the context of an HNC rehabilitation model and its extension of a scalable mobile health support system to reach caregivers. Results will be used to build a large-scale multi-site trial to improve HNC survivorship care planning with high potential for expansion to comprehensive coverage of recovery issues and other cancers.

Background

HNC caregivers face significant challenges after treatment and their involvement in survivorship care planning is essential. In the United States in 2016, approximately 61,760 new HNC cases are expected.[9] HNC includes cancers of the upper aerodigestive tract (oral cavity, pharynx and larynx)[10] and survivors face life-altering post-treatment challenges[1,6,7,11-16] warranting a unique focus on survivorship care planning.[17] Growing research has demonstrated that HNC caregivers also face tremendous burden[18-22] and little is known about optimal strategies for supporting them. When cancer caregivers feel better prepared, patients and caregivers have better outcomes[23-26] yet we currently lack best practices for translating patient recovery challenges into caregiver support tasks, a critical first step to the provision of resources to build caregiver skills.[27] As guidelines develop for the mandated delivery of treatment summaries and care plans to survivors after treatment,[28-32] there is a missed opportunity to capitalize on this required clinical encounter to reach and build competence in caregivers.[33]

Devastating nutritional concerns dominate HNC recovery and a stepped dyadic approach to care planning may optimize HNC caregivers' roles in recovery. HNC functional deficits from multi-modal treatments[34] result in oral complications (e.g., problems with swallowing, speech, dry mouth)[35-37] that impede nutritional intake after treatment[38] and the majority (75-80%) of patients experience significant weight loss.[4,39,40] Weight loss in cancer is associated with infection, treatment delays, hospital admissions and compromised quality-of-life.[41-45] The premise underlying this research is that it may be beneficial to adopt a stepped approach to HNC care planning by first addressing caregivers' pressing nutritional support needs at the end of treatment and following with a comprehensive dyadic survivorship visit[29,46] after the initial recovery period. Addressing early nutritional challenges is likely to expedite next recovery steps[47] and nutritional interventions have proven benefits to quality of life and nutritional status.[48,49] Importantly, in addition to the extremely demanding nutritional care tasks faced by HNC caregivers, discordance in perceptions of nutritional challenges between patients and caregivers has been observed,[8,50] highlighting the potential for mismatched caregiving efforts if dyads' goals are not aligned. Researchers are beginning to consider use of dynamic delivery approaches for dyadic interventions so both patient and caregiver needs can be met in a timely fashion.[51-53]

Mapping HNC recovery targets directly to caregiver skills provides a framework to advance caregiver recovery roles. Oncology-focused rehabilitation[54] seeks to enhance functioning within the limits introduced by cancer.[47] As cancer caregivers are increasingly tasked with provision of physically and emotionally

burdensome care,[24,55-57] it is critical to develop systematic practices to address their concerns and build needed skills. Use of a transactional model of caregiving skills advances this process by outlining key caregiving processes.[27] In this study, we develop a caregiver nutritional care plan by mapping HNC recovery challenges[58-62] explicitly to manageable caregiving tasks.

mHealth offers a platform to facilitate survivorship care transitions. Technological advances have increased opportunities for the assessment of patient-reported outcomes in oncology clinics and these practices are widely accepted.[63-67] Growth of mHealth has enabled new ways to facilitate cancer symptom management outside of the clinic.[68-72] While fewer studies have considered reaching caregivers using technology,[73] this research is growing.[74-76] Web-based interventions for cancer caregivers have shown promising improvements in burden and mood.[77,78] For example, Cancer CarePartners is an online program providing caregivers with patient symptom reports and problem-solving assistance.[74,79] In the current study, we capitalize on mHealth to continue to support HNC caregivers with nutritional recovery support efforts at home.

Summary. In this research, we target the devastating nutritional challenges and their associated quality of life implications[45,48] faced by HNC dyads after treatment. The assumption underlying the proposed intervention is that caregiving skills will be advanced by translating HNC recovery challenges into caregiver tasks (a nutritional care plan to prepare caregivers and build teamwork). We use a sustainable mHealth monitoring approach to support caregivers' roles in nutritional support, seeking to prepare dyads for next recovery steps.

B. Innovation

This study is innovative in its dyadic approach to HNC care and its use of a stepped approach to survivorship care planning starting with nutritional recovery and leveraging mHealth.

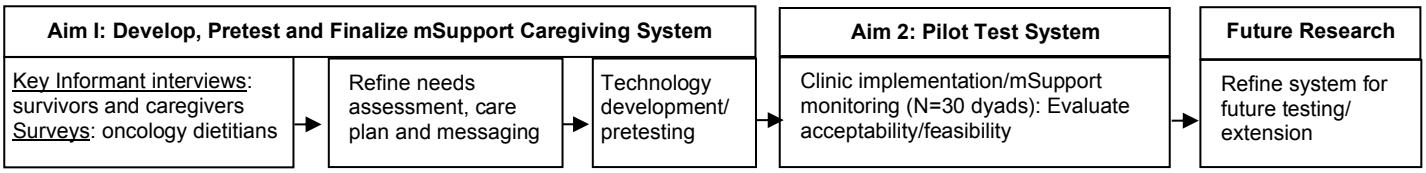
- We focus on an understudied, high burden cancer with intense caregiving burden. HNC survivors and caregivers face unique challenges and require a specialized approach to family-centered care.[1,7,18,19] As the field of survivorship research grows, it is imperative to extend this work to understudied cancers like HNC, particularly as the population of patients with HPV-associated HNCs increases.[80-82]
- Despite cancer center survivorship care planning mandates, limited evidence demonstrates improved outcomes[28,30,31,83-85] and questions remain concerning implementation practices to match survivors' needs. We promote a dyadic/stepped approach in HNC starting with nutritional wellness to accelerate recovery.
- Leveraging mHealth will allow an extension of care planning from clinic to home using our pilot-tested SNAP tool, a flexible platform we will extend to monitor and support caregivers in the treatment transition.

Approach

Overview

We will 1) develop an HNC caregiver mobile nutritional support system and 2) pilot-test the system's feasibility and acceptability (Figure 1). Using dyadic interviews and surveys with oncology dietitians, we will characterize nutritional support needs and develop the mSupport system. We will pilot the finalized system in the clinic with caregiver monitoring for 4 weeks, tracking feasibility/acceptability for our future trial.

Figure 1. Mixed Methods Study Activities



Preliminary Data

HNC dyads are a high-risk group facing significant recovery burden. We recently completed the longitudinal CARE study (*under review*) to examine HNC dyads' experiences (N=73) and identified a diverse group of dyads (57% partners) facing significant health concerns. Caregivers had competing demands (e.g., 60% employed, 43% cared for other family) and both patients and caregivers had significant depression

(CESD≥10) at diagnosis. In 43% of dyads, both the patient and caregiver were depressed and this pattern was more likely when patients had worse symptoms (p=.006) such as dry mouth and swallowing concerns. Caregiver depression was associated with lower dyadic coping, or teamwork in managing cancer (p<.05). Also, >40% of dyads needed help with care coordination and understanding cancer. One-third of caregivers reported symptom management assistance needs and were interested in connecting with a peer caregiver.

Nutrition is the primary caregiving concern and a promising focus for the first step in care planning. The CARE study highlighted significant nutritional recovery concerns (N=65; 47% taking supplements, 29% on feeding tube, 33% lost weight in past week). Also, >50% of survivors reported severe problems with dry mouth, sticky saliva, pain killer use and worry about family. Qualitative interviews showed caregivers provided unique support focused primarily on distressing tasks of food preparation and feeding tube assistance. In another study (MRSG-12-221-01-CPPB), 20 HNC survivors, 14 caregivers and 14 HNC clinicians completed interviews. Distressing nutritional concerns were highlighted as the primary post-treatment concern and intensified all other recovery issues. Caregivers were overwhelmed and intensely focused on nutrition and feeding tube care. They reported putting survivors' preferences first (e.g., eating in another room to give survivor privacy when struggling to eat, doing everything possible to help prevent feeding tube, preparing food several ways to find something appetizing). Dyads reported enthusiasm about a survivorship program but patients preferred waiting 6 months after treatment while caregivers desired earlier intervention. Providers perceived patients experienced the most significant challenges right after treatment (77%).

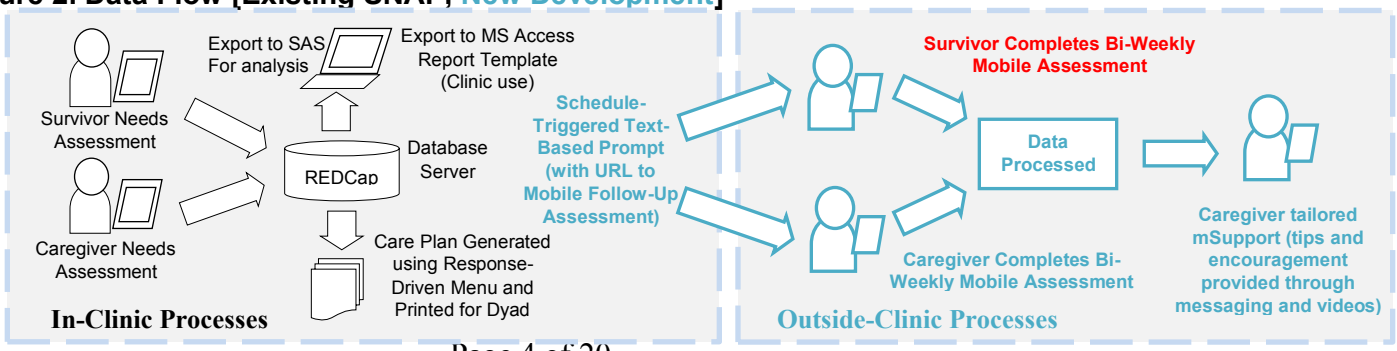
The SNAP tool demonstrated feasibility and acceptability in the HNC clinic. Our team recently completed NCI 1R21CA173271 to pilot-test the SNAP tool (N=25 post-treatment HNC dyads). At least half of survivors endorsed problems with appetite, tasting food, difficulty swallowing and choking/coughing at the survivorship visit; 58% were not taking normal food at this time. While 39% of survivors reported dissatisfaction with their nutritional status, more (54%) caregivers were dissatisfied. The majority (77%) were flagged and offered a referral to the oncology dietitian; caregivers were often more interested than survivors. Dyads reported high SNAP satisfaction with the majority in strong agreement that the session helped prepare them for life after treatment (85% survivors, 81% caregivers) and provided useful practical (88% survivors, 73% caregivers) and emotional (77% survivors, 73% caregivers) aid. Most participants (>95%) reported high comfort reading questions on tablets, moving from 1 question to another and understanding next follow-up care steps. Lastly, nurses conducting survivorship visits reported favorable outcomes, with >90% in high agreement that the session length was appropriate and that dyads were engaged/prepared for next care steps.

Our preliminary studies: 1) justify the focus (caregiver nutritional care plan), content and delivery scheme for the proposed intervention, 2) demonstrate the promise of SNAP, our flexible care planning platform and 3) highlight our team's technology development experience and success in conducting mixed methods studies with HNC dyads and providers.

Intervention to Be Studied

As highlighted above in Figure 1, this 2-phase study will develop (phase 1) and pilot-test (phase II) a mobile-Support program for HNC survivors and their caregivers. The resulting system will include three elements to: 1) systematically administer survivor/caregiver nutritional needs assessments at the end of treatment, 2) generate tailored caregiver-focused nutritional care plans and 3) provide bi-weekly mobile support (encouragement, reminders and tips delivered through messaging and peer videos) to caregivers as they manage nutritional needs and concerns during the initial recovery period (see Figure 2).

Figure 2. Data Flow [Existing SNAP, New Development]



Study Endpoints
Overview

This study involves two phases. In the first phase, we will conduct 15 key informant interviews with HNC patients and their primary caregivers and administer surveys to an expert panel of oncology dietitians (N=35). We will also conduct cognitive interviews to pretest our mSupport program with 2 patients and their caregivers (N=4) and 2 nurses. In the second phase of this study, after patients and caregivers complete a baseline survey, we will implement and test the delivery of the mSupport system in the HCC clinic with 33 patients and their primary caregivers (N=66) and follow with 4 weeks of mobile monitoring and support. Participants will complete a follow-up interview 6 weeks following the clinic session. Finally, we will hold individual or small group interviews with health care providers (N=10) to pilot test the mSupport system.

The sections that follow are organized by study phase. As described in detail below, all patients and their caregivers will be recruited through the HCC Multi-Disciplinary Head and Neck Tumor Program. Patient and caregiver data will be collected by self-report in key informant interviews, in-person clinic interviews and telephone, mailed or emailed follow-up interviews. In addition, we will collect patient clinical data from the electronic medical record. Multi-disciplinary health care specialists involved in the care of HNC patients will be recruited at the HCC and around the state of South Carolina and provide data in web-based surveys and interviews.

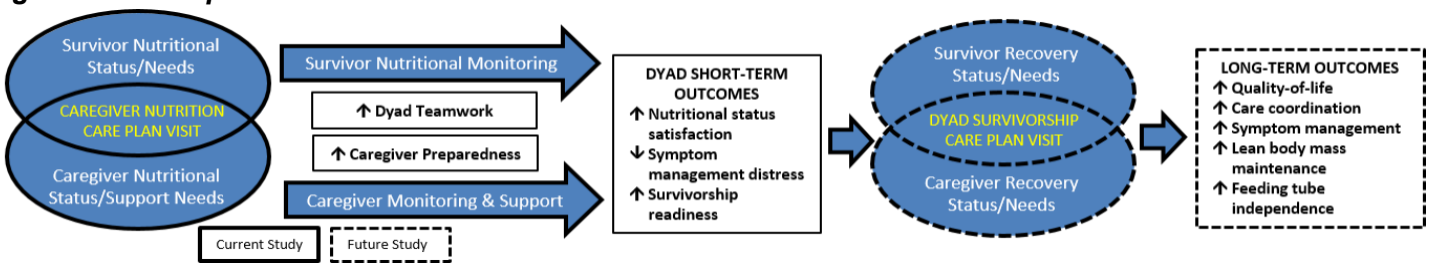
Phase 1 Outcomes:

1. We will characterize post-treatment nutritional experiences (e.g., expectations, challenges, interactions between survivors, caregivers and providers and experiences returning home after treatment) and gather feedback about the timing, content and format of our mSupport tool using key informant interviews with HNC survivors and caregivers.
2. We will assess oncology dietitian perceptions of HNC caregivers' nutritional support demands and psychosocial concerns using a cross-sectional survey of a panel of dietitians.

Phase 2 Outcomes:

1. We will pilot test the feasibility and acceptability of the mSupport system.
2. We will pilot test the use of our study instruments to prepare for a future larger-scale study and examine potential changes over time in dyadic efficacy/teamwork, caregiver preparedness, nutritional status satisfaction, symptom management distress, survivorship readiness, unmet needs and quality of life caregiver self-care, caregiver task concerns and caregiver burden (see Figure 3) after completing the intervention.

Figure 3. Conceptual Model of the Intervention



Inclusion and Exclusion Criteria/Study Population

Aim 1 Key Informant Interviews

Men and women from all racial/ethnic backgrounds with stage I-IVA HNC receiving care at the HCC Multi-Disciplinary Head and Neck Tumor Program will be identified and mailed a letter or approached by study staff at routine follow-up appointments using standardized recruitment protocols. We will recruit

individuals who completed their primary treatment (i.e., any combination of surgery, chemotherapy, and/or radiation therapy) between 6-24 months prior to the interviews and who report having experienced nutritional challenges at the end of treatment. This timeframe will permit recovery time after treatment but will allow adequate recall for participants to reflect about their experiences at the end of treatment. Patient inclusion and exclusion criteria are listed below.

Patient Inclusion Criteria:

- 18 years and older
- Patients with stage I-IVA HNC of the upper aerodigestive tract (including lip/oral cavity, nasopharynx, salivary gland, oropharynx, hypopharynx, paranasal sinus, and larynx cancers)
- Completed primary treatment (i.e., any combination of surgery, chemotherapy and radiation therapy)
- Experienced nutritional challenges at the end of treatment as assessed in a 6-item screener

Patient Exclusion Criteria:

- HNC patients who do not undergo treatment
- Patients who do not read or understand English
- Patients who are cognitively impaired and cannot complete interviews, as judged by the referring health care provider

Those patients who are interested in participating will go through a screening interview to select a caregiver (*i.e.*, spouse, family member, friend) to participate in caregiver focus groups. Caregivers will be defined as the one individual on whom patients rely primarily for support with their illness. Caregiver inclusion and exclusion criteria are listed below.

Caregiver Inclusion Criteria:

- 18 years and older
- Provide care for a loved one with stage I-IVA HNC who has completed treatment

Caregiver Exclusion Criteria:

- Caregivers who do not read or understand English
- Caregivers who are cognitively impaired and cannot complete interviews, as judged by the referring health care provider

We will recruit approximately 15 patients and 15 caregivers for the interviews but continue to complete interviews until theme saturation is achieved. The average number of newly diagnosed HNC patients per year at HCC in 2013-2014 was approximately 200 (~16/month) which will allow us to feasibly achieve our desired sample size. As 70% of HNC patients are male, we will oversample women (40%) to assure ability to explore experiences in female patients.

Aim 1 Oncology Dietitian Surveys

Oncology dietitians who provide care for cancer patients (N=35) will be recruited to participate in online surveys. Participants will be recruited through the Oncology Nutrition Dietetic Practice Group of the Academy of Nutrition and Dietetics listserv (https://www.oncologynutrition.org/). Volunteers will be contacted by email and screened for eligibility with one question concerning whether they currently provide care for HNC patients.

Aim 1 Cognitive Interviews

Using similar criteria and methods described above for key informant interviews, we will recruit HNC patients and their caregivers to participate in cognitive interviews to pretest the mSupport system. We will recruit individuals who completed their primary treatment (i.e., any combination of surgery, chemotherapy, and/or radiation therapy) within the last 24 months and conduct a screening interview with each enrolling patient to select his or her primary caregiver. We will recruit 2 patients and 2 caregivers. We will also recruit 2 HCC nurses who have been practicing for at least 6 months at the HCC to participate in cognitive

interviews. Potential participants will be contacted by study investigators by email and volunteers will be invited to reply with interest.

Aim 2 mSupport Pilot Study with Patients and Caregivers

Using similar methods described above for key informant interviews, we will recruit HNC patients and their caregivers to participate in phase II. HNC patients (see inclusion and exclusion criteria listed below) who are in the last several weeks of treatment or completed their primary treatment (i.e., any combination of surgery, chemotherapy, and/or radiation therapy) within the past 3 months who own and use smartphones will be recruited and a screening interview will be conducted for the selection of a caregiver.

Patient Inclusion Criteria:

- 18 years and older
- Patients with stage I-IVB HNC of the upper aerodigestive tract (including lip/oral cavity, nasopharynx, salivary gland, oropharynx, hypopharynx, paranasal sinus, and larynx cancers) and cutaneous cancers of the head and neck region
- In the last several weeks of treatment to 3 months following completion of primary treatment (i.e., any combination of surgery, chemotherapy and radiation therapy)
- Experienced nutritional challenges at the end of treatment as assessed in a 6-item screener

Patient Exclusion Criteria:

- HNC patients who do not undergo treatment
- Patients who do not read or understand English
- Patients who are cognitively impaired and cannot complete interviews, as judged by the referring health care provider

Caregiver Inclusion Criteria:

- 18 years and older
- Provide care for a loved one with stage I-IVA HNC who has completed treatment

Caregiver Exclusion Criteria:

- Caregivers who do not read or understand English
- Caregivers who are cognitively impaired and cannot complete interviews, as judged by the referring health care provider
- Do not have a smartphone for use in the study

We will recruit 33 patients and their 33 caregivers to participate in the pilot study. To accommodate attrition during pilot testing, we will over-recruit by 3 (10%). The dyads will be diverse by race, cancer site and nutritional challenges (i.e., feeding tube status). The average number of newly diagnosed HNC patients per year at HCC in 2013-2014 was approximately 200 (~16/month) which will allow us to feasibly achieve our desired sample size. As 70% of HNC patients are male, we will oversample women (40%) to assure ability to explore experiences in female patients.

Aim 2 mSupport Pilot Study with Health Care Providers

Using similar methods described above for the cognitive interviews with nurses, HCC multi-disciplinary health care providers who provide care for HNC (N=10) will be recruited to participate in individual or small group discussions to pilot test the mSupport tool. Providers in various HNC clinics (i.e., surgery, radiation oncology, medical oncology, maxillofacial prosthodontics, speech pathology, dietetics, behavioral medicine) with at least 3 providers from the community setting who provide care for HNC patients will be recruited. All providers will have been practicing for at least 6 months.

Number of Subjects

Study Activity	**Number of Subjects**
HNC Dyad Key Informant Interviews	15 patients and 15 caregivers (N=30)
Oncology Dietitian Surveys	N=35 dietitians
Cognitive Interviews	2 patients, 2 caregivers, 2 nurses (N=6)
mSupport Pilot Testing	33 patients and 33 caregivers (N=66)

mSupport Pilot Study with Health Care Providers	N=10
Total	147

Setting

- Hollings Cancer Center at MUSC
- The panel of dietitians will be recruited through the Oncology Nutrition Dietetic Practice Group listserv.

Recruitment Methods and Consent Process

Phase I Key Informant Interviews. We will conduct key informant interviews with patients and their caregivers in person in a private interview room. As in our previous studies, research staff will review clinic rosters to identify potentially eligible patients who meet study criteria and are scheduled for a follow-up care appointment at the Hollings Cancer Center. These potential participants will be approached in the clinic or mailed a study recruitment letter and provided with written study information. After reviewing the study and answering any questions, we will schedule interviews with those who are eligible and interested in participating in the study.

During recruitment, patients will be asked to select their primary caregivers (i.e., spouse, family member, friend), or the individual on whom they rely primarily for support; if patients are unable to identify a supporter, they may still participate in the study. All potential patients and caregivers will be allowed to discuss the study individually or in pairs based on their preferences. If caregivers are present in the clinic, study staff will provide the caregiver the opportunity to ask questions if interested in participating in the study. If the caregiver is not present, patients will be asked to consult with their nominated caregiver before providing caregiver contact information to study staff for invitation to participate in the study. Once caregiver contact information is obtained, research staff will attempt to contact the caregiver by ground mail or telephone. If a home address is obtained for the caregiver, a letter will be mailed to the caregiver. An information letter will describe the study in more detail and will ask the caregiver to contact study staff to answer any questions they may have. Similarly, if the caregiver is contacted by telephone, the study staff will describe the study in more detail and answer any questions. If we do not receive a response from the caregiver, we will then follow up the mailing with no more than ten attempted phone calls at different times. We will leave no more than two messages. A copy of all recruitment correspondence will be kept on file.

Informed consent and HIPAA forms will be signed in person before the interview is conducted after individuals have time to read over the consent on their own and the research staff describe the elements of the study and answer any questions. All participants will receive copies of consent and HIPAA forms for their records. The Principal Investigator, trained Study Coordinator, Research Assistant and health care providers on our study team will administer consents. Participants (patients and caregivers) will receive $25 gift cards to Walmart and parking vouchers.

Phase I Oncology Dietitian Surveys. Participants (N=35) will be recruited through the Oncology Nutrition Dietetic Practice Group (https://www.oncologynutrition.org/) of the Academy of Nutrition and Dietetics listserv. Volunteers will be contacted by email and linked to a web-based 20-minute REDCap (Research Electronic Data Capture),[94] survey. A waiver of written or signed consent has been requested and participation in the interview will indicate implied consent. Participants will be enrolled in a gift card lottery for a $25 Amazon gift card to thank them for efforts.

Phase I Cognitive Interviews. Using similar criteria and methods described above for key informant interviews, we will recruit HNC patients, caregivers and clinic nurses to participate in cognitive interviews to pretest the mSupport tool. We will recruit individuals who completed their primary treatment (i.e., any combination of surgery, chemotherapy, and/or radiation therapy) within the past 24 months and conduct a screening interview with each enrolling patient to select his or her primary caregiver. We will recruit 2 patients, 2 caregivers and 2 nurses to participate in the cognitive interviews. Patients and caregivers will receive a $25

gift card to Walmart and parking voucher to thank them for their time and effort in the study. Nurses will receive a $25 gift card to Target to thank them for their time.

Informed consent and HIPAA forms will be signed in person before the interview is conducted after the research staff describe the elements of the study and answer any questions for patients and caregivers. All participants will receive copies of consent and HIPAA forms for their records. The Principal Investigator, trained Study Coordinator, Research Assistant and health care providers on our study team will administer consents. Participants (patients and caregivers) will receive $25 gift cards to Walmart and parking vouchers. A waiver of written or signed consent has been requested for the cognitive interviews with clinic nurses; information about the study will be provided prior to scheduling and beginning the small group discussion and participation will indicate implied consent.

Phase II mSupport Pilot Study with Patients and Caregivers. As in our previous studies, research staff will review clinic rosters to identify potentially eligible patients who meet study inclusion and exclusion criteria. These potential participants may be approached in the clinic (if safe and feasible based on clinic requirements during the COVID-19 pandemic) or provided written study information via a flyer or mailed study recruitment letter. Staff will follow-up with potential participants either by phone or email to review the study and answer any questions.

If eligible and interested, study staff will use the REDCap combined e-consent/HIPAA template to conduct the informed consent process. Informed consent and HIPAA forms will be signed after individuals have time to read over the consent on their own and the research staff describe the elements of the study and answer any questions.

- If a participant is being enrolled virtually, the participant and study staff will access the consent form online. Participants will walk through the study purpose, procedures, risks and benefits and have the opportunity to ask questions. Participants will electronically sign forms, study staff will also electronically sign the forms, and participants will receive copies of consent and HIPAA forms for their records by mail/email.
- If a participant is recruited in-person, study staff will follow a similar process. Using a tablet, the participant and study staff will access the consent form online. Participants will walk through the study purpose, procedures, risks and benefits and have the opportunity to ask questions. Participants will electronically sign forms, study staff will also electronically sign the forms, and participants will receive copies of consent and HIPAA forms for their records by mail/email.

The Principal Investigator, trained Study Coordinator, Research Assistant and health care providers on our study team will administer consents. These procedures will be done on our research team's laptop and/or tablet, but no data will be stored on either device; all data will be stored securely in REDCap.

If technology challenges arise, study staff may also use a combined consent/HIPAA hard copy form (printed from REDCap), either in-person or sent through the mail. During the consent/assent phone call, research staff will ensure all questions are answered. The participant will sign and date the forms and return to the study staff. Study staff will sign and date the forms and will mail/email a copy to the participant. No study activities will be conducted until both the participant and study staff have signed and dated the informed consent/HIPAA documents.

After enrollment, participants will be given the option to complete the baseline/needs assessment survey by telephone, mail, or online. After this survey is complete, study staff will schedule either: an in-person clinic session (if safe and feasible based on clinic requirements during the COVID-19 pandemic); or a virtual session. Either will be conveniently timed for participants schedule. In either scenario, participants will receive and review a tailored care plan, which includes messages, referrals and educational materials. In-person study activities will take place in a private clinic office or conference room in a location that is convenient for the participants and will conform to university COVID-19 safety recommendations. The virtual visit will be conducted via telephone or doxy.me with care plans being provided electronically or by mail.

Based on the caregiver's preference (either within the session or at a later date), he/she will receive an overview of the mobile app and links to training videos. After the study session, study staff will prepare the final care plan with referrals and educational materials and mail a study packet with gift cards to participants. Six-eight weeks later, participants will complete follow-up surveys by telephone, mail or email. Both the patient and caregiver participants will receive $50 (two $25 gift cards) after completing the initial survey and clinic/virtual session ($25) and the follow-up survey ($25).

Study Design / Methods

Aim 1 Methods

HNC Dyad Key Informant Interviews. We will conduct dyadic interviews[90] with HNC survivors and caregivers. Using a structured interview guide, we will explore post-treatment nutritional expectations, challenges, nutritional support task demands, interactions between survivors, caregivers and providers and experiences returning home after treatment. We will ask about survivor and caregiver nutritional recovery expectations and emotional and practical nutritional caregiving challenges faced. After a demonstration of the mSupport tool, care plan, and viewing of example messages and a peer support video on a mobile device, participants will provide feedback about the format, content and delivery and offer improvement recommendations. We will continue to conduct interviews until we reach saturation in themes. All interview participants will be asked to complete a short demographic survey (<5 minutes) to characterize group participants. In addition, information about each patient's medical history will be obtained from the electronic medical record. Interviews will last approximately 30 to 45 minutes.

Dr. Sterba will moderate the 30-45 minute audio-taped interviews using a structured interview guide to explore post-treatment nutritional expectations, challenges, interactions between survivors, caregivers and providers and experiences returning home after treatment. We will ask about survivor and caregiver nutritional recovery expectations and emotional and practical nutritional caregiving challenges, including nutritional support task demands. After demonstrating the mSupport tool, care plan, and viewing messages and a peer support video on a mobile device, participants will provide feedback and offer recommendations. We will continue to conduct interviews until we reach theme saturation.[93]

Oncology Dietitian Surveys. Building on findings from initial dyad interviews, a cross-sectional survey will be refined with guidance from our Clinical Advisory Board, cognitively pretested and administered to a panel of dietitians. We will assess key caregiver nutritional support tasks and perceptions of caregiver nutritional support demands, psychosocial concerns and barriers (Table 1). Participants will view/rate a mock care plan and video, offering suggestions to improve content.

Table 1. Survey Measures for Oncology Dietitian Experts (Aim 1)

Domain	Description/Rationale
Primary nutritional support tasks	• Ratings of importance (Not at All to Extremely), perceived task demand difficulty (Not at All to Extremely), and clarity of wording (Poor to Excellent) of key HNC nutritional caregiving support tasks and healthcare barriers.
Resource priority	• Ranking of key caregiver resources identified to support HNC nutritional needs (adapted from our prior work).
Barriers to meet caregiver needs	• Barriers to meeting needs of caregivers (e.g., time, specialized training, leadership support) in a variety of care settings will be assessed using a tool designed by our team in prior research (see Preliminary Data).
Acceptability	• After review of mock care plan, messages and video, participants will complete ratings concerning acceptability adapted from our prior SNAP measures (Not at All Satisfied to Extremely Satisfied).
Demographics	• Specialty, patient volume, years in practice, age, gender, race/ethnicity.

Aim I Data Management and Analysis. Interviews will be transcribed and analyzed using rigorous content analysis methods for systematic theme identification.[95,96] Themes will be compared within/across survivor-caregiver groups. Transcripts will be coded by Dr. Sterba and study staff and regrouped and reorganized until investigators agree on categories. This initial theme identification process will be followed by team meetings to finalize themes and implications for the intervention design. Expert survey responses will be summarized and guide the content, format and delivery of the mSupport system.

Intervention Development. Building on Aim 1 interview/survey findings, final needs assessment domains that

can appropriately be addressed through mobile support will be developed along with associated messages and tips by our Clinical Advisory Board. Brief (3-6) minute peer videos of volunteer HNC dyads and nurses will be developed by the MUSC Office of Instructional Technology to share encouragement, support and meal preparation tips. Table 2 outlines caregiving skills from the transactional model mapped to HNC recovery domains and example tailored mSupport elements. The finalized system will undergo pretesting[97] with dyads (N=2, $25 gift card) and nurses (N=2, $25 gift card) to gather feedback on content, layout and assessment experiences. A convenience sample of dyads will complete the mSupport protocol and a cognitive pretesting guide will be used to examine users' experiences.[97] After a demonstration, nurses will provide feedback about clinic feasibility. Findings will guide the team to finalize the system.

Table 2. Caregiving Processes Mapped to HNC Support Tasks: Preliminary Intervention Guide

Caregiving Process[27]	***Caregiver Nutritional Support Domain Examples[A]***	***mSupport Intervention Elements***
Monitor Interpret	Tracking nutritional intake and problems with swallowing, dry mouth and distress (attend to frequency, changes, patterns)	Alerts to monitor symptoms/when to call provider, support/reinforcement messages
Make decisions Adjustments	Weighing competing demands, adjusting food timing/amount, considering support consequences, planning ahead	Encouragement through tips and peer videos
Access resources	Seeking/coordinating needed nutritional support resources	mSupport reminders/prompts
Hands-on care	Food preparation, wound care, encouragement	Symptom management tips, peer videos
Work together with ill person	Planning together, achieving shared understanding of recovery preferences, constructive communication	Clinic discussion, teamwork tips provided through peer videos
Navigate health system	Evaluating/seeking nutritional care, advocating for survivor	Care plan content, provider video

[A]These domains will be refined by Clinical Advisory Board in Aim 1

Technology Development. Our Software Systems Developers from the MUSC Technology Applications Center for Healthy Living (TACHL) developed the SNAP tool and care plan template. The HIPAA and FERPA-compliant SNAP tool is an Enterprise Data Management System with a data collection application and personalized care report delivery component. The web-based interfaces feed into REDCap [94] a secure application supporting validated data entry, audits, import/export procedures and branching logic. A wireless touchscreen tablet device renders a web-based interface designed for ease of data collection with color displays, large font, pictures, and skip patterns. The system authenticates to a data tracking system, registers assessments, records data and, based on administrator-designated logic, generates a tailored care plan with a care summary page followed by tailored messages, referrals and listing of educational materials mapped to reported concerns, symptoms and behaviors of patients and caregivers. Capitalizing on our current SNAP Tool, in this study we will tailor the system to focus on nutrition and enhance the tool to incorporate mSupport (see Figure 2 above). The IT development phase will include needs assessment customization, mSupport App interface design, and testing. Future deployment will be supported by SNAP's web-based access for easy community dissemination.

The mobile intervention will support caregivers at home and reinforce caregiving skills discussed at the clinic. mSupport will include 4 weeks of bi-weekly monitoring of survivor nutrition status and caregiver distress, needs and perceptions of survivors' nutrition status. Based on timing preferences, a schedule of prompts will be delivered to each dyad; based on real-time responses to nutritional status and distress items, tailored links to App resources will follow. mSupport will provide a platform for real-time assessment of nutritional challenges and will address needs through coaching with support messages and videos. Survivor-caregiver communication will be facilitated by prompting symptom management discussion. Guided by our Clinical Advisory Board, the system will be optimized to assess/address actionable support needs that can be linked to mobile support resources; this will set the stage for cost-effective future dissemination. For tracking purposes and to assure connection with the study Social Worker if needed, participants will be queried weekly for unmet needs.

Aim 2 Methods

mSupport System Pilot Testing. Patients and caregivers will complete a 30 minute baseline and needs assessment survey by telephone, mail or online. They will then be scheduled for either an in-person or virtual (via doxy.me or telephone) visit at a convenient time. We will then deliver the intervention in a 30-45 minute in-person or virtual session. The intervention includes several activities, including a care plan discussion with a

Nurse Practitioner (in person, telephone or using doxy.me), and app training for caregivers, which will be accomplished with a series of short training videos. App training will be followed by 4 weeks of App use with bi-weekly real-time prompts and feedback for caregivers. Approximately 6-8 weeks later, patients and caregivers will complete 30 minute follow-up surveys. Due to the COVID-19 pandemic, the majority of study events will be offered to patients in multiple formats based on preference and safety protocols in the clinic.

For convenience and safety, study activities may be split up over time to accommodate participant scheduling preferences. And though some sessions will take place at the clinic, we may deliver some activities by telephone, doxy.me or in an alternate location. Specially, because many HNC families reside in the American Cancer Society Hope Lodge during radiation therapy, we may conduct research activities in a private conference room in this location. In in-person or virtual scenarios, a tailored care plan will be generated and reviewed with our Nurse Investigator.

Within the virtual or in-person session or at later date based on preference, caregivers will receive training on mSupport technology through a series of short training videos. Caregivers will then be prompted twice a week for 4 weeks to report symptoms, nutritional status and distress with algorithm-driven links to 3 support sources, including messages, tips and peer videos (see Table 2 above). We may contact caregivers by phone weekly to ensure that there are no technical issues with the app. Participants will also complete a 10-15 minute follow-up interview by telephone, mail or email six to eight weeks following the clinic session to gather self-reported data about unmet needs, whether and how the care plan and referrals were used after the clinic session, satisfaction with the session, care plan, and mSupport program and preferences concerning the timing and content of the clinic session and delivery of the mSupport program.

In order to collect feedback on care plan discussions and to further refine methods and processes for future studies, we would like to conduct in-depth interviews with nurse practitioners who participate in the pilot study visits. (N=2, $100 gift card)

Lastly, after completing the pilot, we will conduct 45-minute audiotaped individual/small group interviews with 8 HNC health care providers (a surgeon, medical oncologist, radiation oncologist, nurses, dental, speech, and nutrition specialists, and community providers) to evaluate feasibility and recommendations for future system extension for broader reach in other care settings. (N=8, $25)

Aim 2 Data Management and Analysis. Descriptive statistics across and within dyads will characterize patient and caregiver needs and system acceptability. Preferences by race, sex, stage and cancer site will be explored using descriptive statistics and graphics (bar charts, plots) to highlight future intervention directions. To explore potential effect sizes for future research, average change in future trial outcome variables from baseline to follow-up will be estimated and 95% confidence intervals calculated. Content analysis will be used to examine themes in open-ended responses provided by dyads (with differences explored by sex) and providers. Finally, tracking records will be reviewed to assess program delivery, adherence and preferences (Table 3).

Table 3. Measurement Plan

Factor	Indicators	Data Source
Demographic and Clinical Data		
-Patient and caregiver demographics	-gender, age, race/ethnicity, education, marital/employment/insurance status, caregiver type (spouse, child, friend), years relationship, living arrangement	-Clinic PS/CS
-Patient clinical factors	-cancer site/stage, treatment, co-morbid health conditions, smoking/drinking behaviors[98]	-MR
-Provider demographics	-specialty area, years in practice, gender, race/ethnicity, age	-PI
-Nutritional status	-nutritional status satisfaction, BMI, lean body mass, feeding tube dependence, symptoms[92]	-Clinic PS/CS, MR
Patient-Caregiver Acceptability Data		
-Ease of use	-comfort and ease in reading questions on tablet, holding/manipulating tablet, navigating from question to question, responding to mSupport prompts, following mSupport steps[66]	-Clinic and 6 week PS/CS
-Satisfaction/perceived importance	-ratings of mode, timing, content and quality of the needs assessment, care plan, and mSupport messages, and perceived importance of assessing needs and receiving monitoring and home support	
-Care plan/mSupport use	-understanding and perceived utility of care plan and mSupport monitoring	

-Short-term impact/ preferences	-whether/how care plan and resources/referrals used after session, satisfaction with session/plan/monitoring/timing/content, recommendations to improve	-6 week PS/CS
Health Care Provider Acceptability and Feasibility Data		
-Ease of use	-perceptions concerning patient ease of tablet and mSupport system use and own ease of use in clinic	-PI
-Satisfaction/unmet needs	-ratings of mode, timing, content, quality, frequency/type of needs not addressed in mSupport	-PI
-Provider readiness	-perceived importance of each mSupport program element, implementation barriers, needed adaptions to expand dissemination and reach to other dyad types and clinical settings	-PI
Process Monitoring Data		
-Resources Needed	-staff time, session length, equipment challenges, mobile connection success, support calls initiated	-TL
-Intervention Delivery -reach/fidelity -preferences -user engagement	 -percentage of sample recruited/completing full clinic session/mSupport monitoring, extent to which intervention (assessment/care plan/mSupport) delivered as planned, topics discussed/ recommendations and resources distributed during session and monitoring -timing/content recommendations to improve session/mSupport monitoring/future directions, data collection preferences -percentage responding to monitoring prompts and engaging in support messages/videos	 -TL -TL -6-wk PS/CS, PI, system tracking
-Future Study Design -study protocol -short and long-term outcome measures	 -willingness to participate in a study, how much time willing to devote, timing preferences -testing outcome instruments (dyadic efficacy/coping,[99] caregiver preparedness,[100] nutritional status, unmet needs,[101,102] symptoms/distress,[91] self-efficacy,[103] quality of life,[104] survivorship readiness)[105], caregiver self-care, caregiver task concerns, caregiver burden	 -6 week PS/CS

PS/CS=patient/caregiver survey by tablet/phone, PI=provider interview, MR=medical record, TL=Coordinator/Nurse tracking logs

Risks to Subjects

During all phases of this study, including key informant interviews, online surveys, cognitive interviews, pilot-test sessions, telephone surveys and discussion groups, there are no physical, legal or financial risks to participating in this study. However, there is the possibility participants (patients, caregivers and health care providers) could feel uncomfortable or upset talking about their (or their patients') cancer during study interviews. In addition, participants will provide information during study interviews that they may consider confidential or private and there is the potential for a loss of confidentiality.

Protections of Risk

To help ensure subject privacy and confidentiality for all phases of this study, only a unique study identifier will appear on all data collection forms and files. Key informant and discussion group participants will be asked not to share information discussed in the study with others. Information obtained during this study will be stored in a locked file cabinet in a locked office. For all phases of this study, only study staff will have access to individually identifiable private information about human subjects (i.e., patients, caregivers, and health care providers). All data collected for the study will be coded with a study identification number for confidentiality and all study records will be stored in a locked file cabinet in a locked study personnel's office. Patient data will be entered and stored using REDCap (Research Electronic Data Capture), a secure, web application designed to support data capture for research studies at MUSC, providing user-friendly web-based case report forms, real-time data entry validation (e.g. for data types and range checks), audit trails and a de-identified data export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). The database is hosted at the MUSC Datacenter and the system is protected behind a login and Secure Sockets Layer (SSL) encryption. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study. Virtual visits will be conducted over telephone or using doxy.me, a HIPAA compliant video chat application.

Study staff will complete a screening log to verify eligibility for all participants. The screening log will be kept with signed informed consent forms in a locked cabinet in a locked office and will be kept separate from all other study materials, which will be assigned a study ID in an effort to protect patient confidentiality. The screening log will be completed for patients and caregivers who agree to participate in the study and will include information including age, distance from hospital, contact information, and patient-caregiver relationship. In addition, patients will have their MRN, type of cancer, date of diagnosis, date of last treatment, and whether this cancer diagnosis is a primary diagnosis or a

recurrent diagnosis recorded on the screening log. A screening decline log will be kept for patients and caregivers that are approached regarding the study, but decline participation. The screening decline log will not include any identifiable information, but it will provide information including age, race, distance from hospital, cancer site and stage, days since final treatment, and reason for decline if the individual wishes to provide that information to study staff.

For all phases of this study, one's decision to take part in this research will be voluntary and individuals may refuse to take part, or choose to stop taking part at any time. Participants will also be encouraged to take their time when answering questions and may decline to answer any question at any time. If patients or caregivers become upset talking about their cancer and their needs, they will be offered a referral to the HCC Behavioral Medicine program (which is covered by most health insurance programs) or the HCC Social Worker who will offer links to other HCC and community resources.

Potential Benefits to Subjects or Others

In this research, receiving information about survivorship and nutritional recovery may or may not benefit patients, caregivers and health care providers personally in the study. It is hoped that the information learned in this study will benefit other HNC patients in the future by expanding what is known about strategies for improving survivorship care and support for nutritional caregiving efforts at the end of treatment.

Study Monitoring

The principal investigator will be responsible with assistance from other study staff for the overall monitoring of the data and safety of study participants. Any unanticipated problems, adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the MUSC Institutional Review Board.

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