CONNECTing Caregivers to Supportive Services (CONNECT): A Technology-Based Intervention to Connect Cancer Caregivers with Supportive Care Resources

Wake Forest Baptist Comprehensive Cancer Center
WFBCCC # 6459

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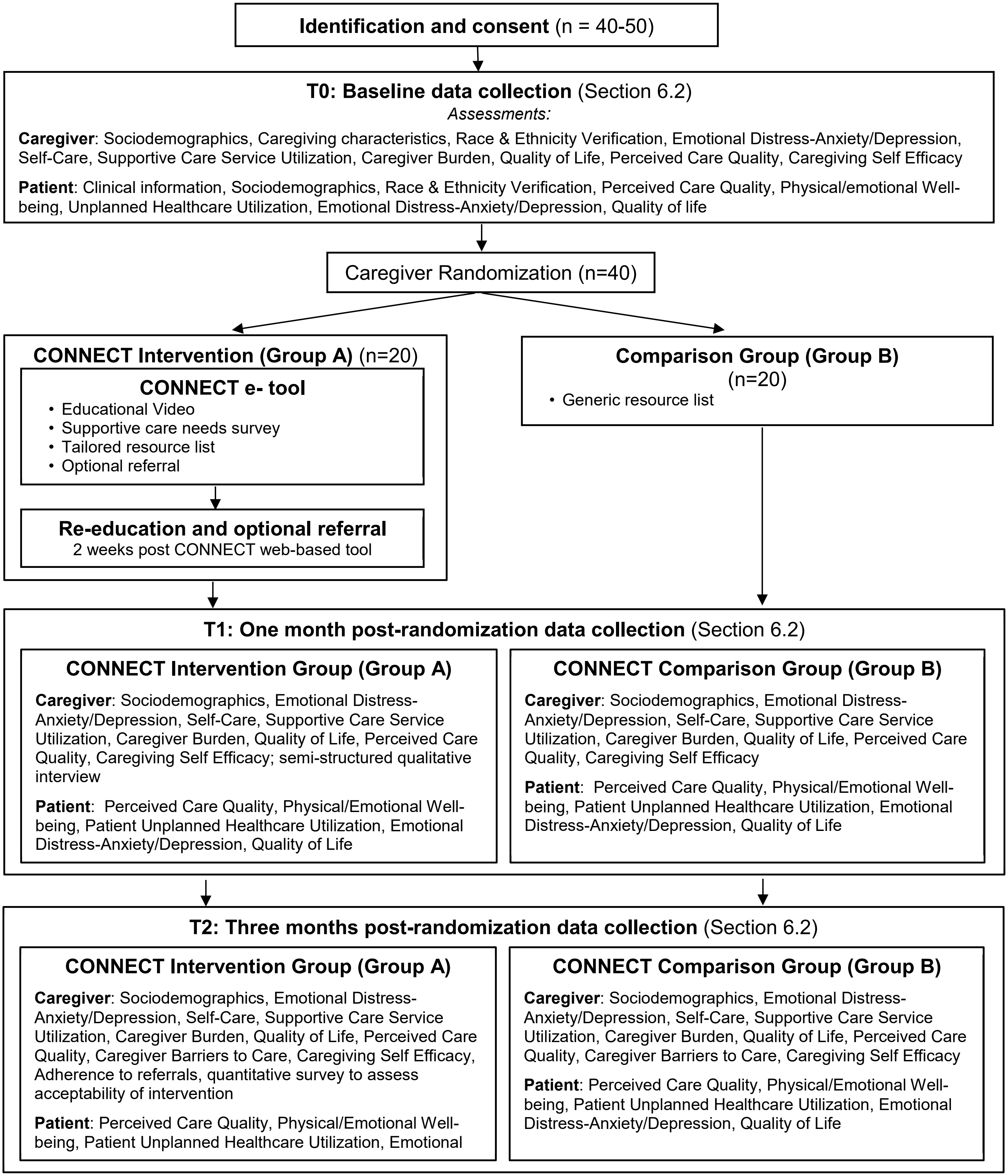
1.0 Schema



Identification and consent (n = 40-50)

T0: Baseline data collection (Section 6.2)

Assessments:

Caregiver: Sociodemographics, Caregiving characteristics, Race & Ethnicity Verification, Emotional Distress-Anxiety/Depression, Self-Care, Supportive Care Service Utilization, Caregiver Burden, Quality of Life, Perceived Care Quality, Caregiving Self Efficacy

Patient: Clinical information, Sociodemographics, Race & Ethnicity Verification, Perceived Care Quality, Physical/emotional Well-being, Unplanned Healthcare Utilization, Emotional Distress-Anxiety/Depression, Quality of life

Caregiver Randomization (n=40)

CONNECT Intervention (Group A) (n=20)

CONNECT e- tool

- Educational Video
- Supportive care needs survey
- Tailored resource list
- Optional referral

Re-education and optional referral
2 weeks post CONNECT web-based tool

Comparison Group (Group B)
(n=20)

- Generic resource list

T1: One month post-randomization data collection (Section 6.2)

CONNECT Intervention Group (Group A)

Caregiver: Sociodemographics, Emotional Distress-Anxiety/Depression, Self-Care, Supportive Care Service Utilization, Caregiver Burden, Quality of Life, Perceived Care Quality, Caregiving Self Efficacy; semi-structured qualitative interview

Patient: Perceived Care Quality, Physical/Emotional Well-being, Patient Unplanned Healthcare Utilization, Emotional Distress-Anxiety/Depression, Quality of Life

CONNECT Comparison Group (Group B)

Caregiver: Sociodemographics, Emotional Distress-Anxiety/Depression, Self-Care, Supportive Care Service Utilization, Caregiver Burden, Quality of Life, Perceived Care Quality, Caregiving Self Efficacy

Patient: Perceived Care Quality, Physical/Emotional Well-being, Patient Unplanned Healthcare Utilization, Emotional Distress-Anxiety/Depression, Quality of Life

T2: Three months post-randomization data collection (Section 6.2)

CONNECT Intervention Group (Group A)

Caregiver: Sociodemographics, Emotional Distress-Anxiety/Depression, Self-Care, Supportive Care Service Utilization, Caregiver Burden, Quality of Life, Perceived Care Quality, Caregiver Barriers to Care, Caregiving Self Efficacy, Adherence to referrals, quantitative survey to assess acceptability of intervention

Patient: Perceived Care Quality, Physical/Emotional Well-being, Patient Unplanned Healthcare Utilization, Emotional

CONNECT Comparison Group (Group B)

Caregiver: Sociodemographics, Emotional Distress-Anxiety/Depression, Self-Care, Supportive Care Service Utilization, Caregiver Burden, Quality of Life, Perceived Care Quality, Caregiver Barriers to Care, Caregiving Self Efficacy

Patient: Perceived Care Quality, Physical/Emotional Well-being, Patient Unplanned Healthcare Utilization, Emotional Distress-Anxiety/Depression, Quality of Life

2.0 Introduction and Background

The 2.8 million informal (unpaid) caregivers of US cancer patients are vital members of the oncology health care team and face tremendous challenges associated with the caregiving experience.[1] Compared to the general population, cancer caregivers have worse mental and physical well-being[2] and are more likely to have high burden compared to other caregiver populations.[3] Head and neck cancer (HNC) patients receive complicated treatment regimens,[4] and experience severe and debilitating physical and psychosocial sequela,[5–7] necessitating exceptionally high care demands for their family members who are integral to their care.[8] Cancer caregivers perform complex care tasks such as administering medications, managing patients' symptoms, and coordinating medical care and report high unmet needs, including psychosocial, medical, daily activity, and financial needs, which is associated with poorer mental health.[9] HNC caregivers in particular, have greater unmet supportive care needs compared to many other cancer caregiver populations and experience high caregiver burden,[8] which leads to poor outcomes for patients as well. Caregiver well-being has been associated with patient healthcare utilization, perceived quality of care, and distress, suggesting that efforts to support caregivers benefit patients as well.[10–12] Supportive care resources (e.g., psychological support interventions, health behavior programs, cancer education) are available, and our research and others has demonstrated cancer caregivers in general, and HNC caregivers specifically, desire these services. [13–16] Yet, healthcare systems fail to systematically assess cancer caregivers' needs and connect them with needed services. Consequently, there is a critical need to identify systems-level strategies to identify and link HNC caregivers to resources to improve both caregiver and patient well-being.

The long-term goal of this program of research is to improve supportive care delivery for cancer caregivers, with the ultimate goal of improving both caregiver and patient well-being. We propose to refine and evaluate a novel web-based intervention, *CONNECTing Caregivers to Supportive Services (CONNECT)*, informed by theory with input from an advisory panel of cancer caregivers, oncology providers, and psychosocial oncology professionals. CONNECT empowers caregivers with needs to seek services by providing education about the benefits of supportive care resources, systematically identifying their unmet needs, and connecting them with tailored supportive care resources. This intervention is designed to be low cost and to capture resources offered in different oncology environments to support future adaptation and dissemination for heterogeneous healthcare settings and populations. Initial testing in the proposed study will take place with caregivers of patients with HNC due to their high unmet needs and burden.

Significance

Cancer caregivers provide critical and challenging care for their loved ones and are at risk for their own negative psychosocial and physical outcomes. Approximately 2.8 million people provide care for a patient with a primary cancer diagnosis in the US.[1] Cancer caregivers have worse mental and physical well-being when compared to population norms[2] and are more likely to have high burden compared to non-cancer caregiver populations.[3] Head and neck cancer (HNC) patients receive complicated treatment regimens,[4] and experience severe and debilitating physical and psychosocial sequela,[5–7] necessitating exceptionally high care demands for their family members who are integral to their care.[8] Caregivers engage in difficult and time consuming care tasks including monitoring patient symptoms, managing patient behaviors, assisting with treatment and end-of-life care decisions, providing emotional support, and engaging in household tasks; yet, report low self-efficacy and being unprepared for their caregiving role. [17–21] HNC caregivers in particular, have greater unmet supportive care needs compared to many other cancer caregiver populations and experience high caregiver burden.[8] In addition, my work and others suggest HNC caregivers report clinically significant and high rates of emotional distress, high levels of caregiver burden, poorer physical and mental health compared to population norms, and deteriorations in psychological well-being and overall quality of life over time.[13] [22,23]

Patient outcomes are interrelated with caregiver's overall well-being. Extensive research has demonstrated that informal caregivers' overall well-being has implications for patients' well-being. The dementia caregiving literature has shown that higher resilience or improved psychological health in caregivers is associated with less frequent institutionalization, delayed nursing home placement, and reduced patient mortality.[24–28] Another study found that caregiver burden and low quality-of-life predicted prolonged hospital stays in dementia patients.[29] In cancer dyads specifically, patients who have caregivers with higher depressive symptoms are more likely to perceive their quality of care to be fair or poor.[11] This is significant given that perceived care quality has been associated with mortality in cancer patients.[30] In addition, caregiver burden has been associated with patient distress in cancer dyads.[12] Further, lower caregiver self-efficacy is associated with physical and emotional symptoms among cancer patients.[20] Although less explored in the HNC population, studies suggest associations between caregiver and patient psychological functioning and quality of life.[31,32] Collectively, these findings support the scientific premise that patient outcomes, including healthcare utilization, perceived care quality, and psychosocial functioning can be optimized by supporting caregivers' overall well-being.

Supportive care services can help mitigate negative outcomes in caregivers, but healthcare systems fail to connect caregivers with these services. Our research[13] and others[14,15,33] demonstrate that HNC caregivers are interested in supportive care interventions (see preliminary data). Supportive care interventions decrease burden and depression and improve well-being, satisfaction, and knowledge and skills in cancer caregivers.[34] Despite availability of supportive care resources at cancer centers and at the community and national level (see preliminary data), receipt of supportive care services among HNC caregivers is low.[35–37] Major barriers to connecting cancer caregivers to appropriate services include lack of systematic identification, assessment, and referral of caregivers by providers. [3,34]

Technology-based interventions offer an ideal solution for connecting cancer caregivers to supportive care resources. Current caregiver interventions are costly to deliver and require significant provider or support staff engagement, resulting in limited translation to clinical practice.[34] Web-based interventions overcome both of these barriers (i.e., cost and provider/staff engagement) and support wide-scale dissemination. Despite this potential, web-based approaches have been under-utilized in the cancer caregiving field and are recognized as a priority for research in this area.[3] Additionally, cancer caregivers have expressed interest in web-based interventions to reduce burden and address other caregiver challenges.[38,39]

This proposed application is innovative because it: (1) aims to improve HNC patient outcomes by intervening with their informal family caregivers, a high burden and understudied population; (2) aims to improve caregiver psychosocial functioning and perceived care quality by leveraging existing evidenced-based supportive care resources that are currently poorly utilized; (3) offers a low-cost solution to efficiently connect HNC caregivers with supportive care resources; (4) evaluates an intervention informed both by theory and by an advisory panel including HNC providers, psychosocial oncology professionals, and caregivers; and (5) includes a flexible e-tool developed to support wide-scale dissemination that can easily be adapted for heterogeneous healthcare settings with varying resources.

Summary. The well-being of HNC caregivers affects patient outcomes, yet caregivers are a vulnerable population with high unmet needs. Although supportive care interventions exist and HNC caregivers have expressed interest in these types of interventions, caregivers are not systematically being connected to these services. Leveraging technology to connect caregivers with existing interventions will support translation of current evidence-based interventions into clinical practice.

Approach. Following initial usability testing in a separate study (IRB00060160**) to** refine a web-based intervention (CONNECT) to empower and connect caregivers of cancer patients to supportive care resources , a randomized pilot study (Fig.1) will be conducted to assess feasibility and acceptability and obtain data on caregiver and patient outcomes. Caregivers and patients (dyads) will be recruited at patients' routine oncology appointments and complete a baseline assessment (T0). Following T0, caregivers will be randomized to CONNECT (n=20) or the comparison arm (n=20). Dyads will complete follow-up assessments at T1 (1-month post-CONNECT) and T2 (3-months post-CONNECT). Though we are recruiting patient-caregiver dyads into the study, **the intervention is delivered to caregivers only**.

Preliminary Data

HNC caregivers report clinically significant depressive symptoms, poor health behaviors, and desire supportive care resources. We assessed psychosocial functioning, health behaviors, and interest in supportive care services for HNC caregivers.[13] HNC caregivers reported a smoking history (42%), depressive symptoms (45%) and anxiety above population norms (33%). Most caregivers were interested in supportive care programs focused on cancer education (66.7%), stress reduction (63.6%), diet/exercise (71.0%), and educational classes on finances, caregiving, and well-being (57.6%). HNC caregivers who were interested in any type of program reported poorer mental health (p=.02) and higher anxiety (p=.01). Findings confirm a need for, and interest in, supportive care resources among HNC caregivers.

Supportive care resources are available for cancer caregivers. Our team contributed questions to a nation-wide assessment of community oncology clinics (through the NCI Community Oncology Research Program [NCORP] 2017 Landscape Assessment). Findings revealed that 62% of practice groups have supportive care resources available for caregivers. In addition, through preliminary work for CONNECT's e-tool development, we have compiled a comprehensive list of supportive care resources for HNC caregivers offered at the Wake Forest Baptist Comprehensive Cancer Center (WFBCCC; where this study will take place), the community, and nation-wide. Findings confirm that there is robust availability of supportive care resources for cancer caregivers; however, lack of a systematic process to connect caregivers inhibits service use.

Our preliminary data provide evidence that: (1) HNC caregivers need and are interested in supportive care resources; (2) resources are available, but a systematic process is needed to connect caregivers to services; and (3) The PI has experience recruiting HNC caregivers and patients.

Theoretical Underpinnings. This research is informed by Longacre's model of Cancer Caregiver Well-being (Fig 2).[22] The underlying premise is that connecting caregivers to supportive care resources will support caregiver well-being, leading to improved outcomes for caregivers (e.g., quality of life), patients (e.g., improved physical well-being), and the healthcare system (e.g., reduced unplanned healthcare utilization for patients).

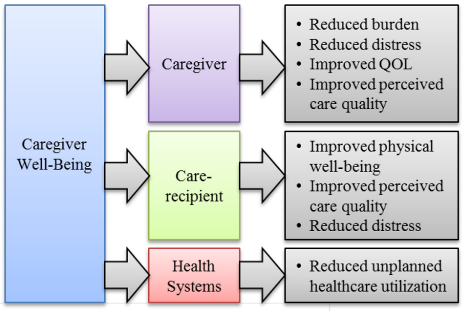


Figure 2. Model of Caregiver Well-being

Impact: This study proposes an innovative web-based intervention (CONNECT) to improve supportive care delivery for cancer caregivers, CONNECT, designed to be low-cost and easily adaptable across heterogeneous healthcare settings to support wide dissemination. This work and pilot data will inform a subsequent R01 proposal to conduct a larger multi-site, nationwide pragmatic trial through the NCI Community Oncology Research Program. CONNECT has the potential to improve outcomes for the 2.8 million US patient-caregiver cancer dyads. Further, there is potential for CONNECT to be adapted to non-cancer caregiver populations such as the more than 15 million Alzheimer's disease caregivers.[40]

3.0 Objectives

3.1 Primary Objectives

3.1.1 To assess feasibility (accrual, participation, and retention) of CONNECT with HNC caregivers (Intervention Group, n=20; Comparison Group, n=20) in a randomized pilot study to support a future pragmatic trial.

3.1.2 To assess acceptability of CONNECT with HNC caregivers (Intervention Group, n=20; Comparison Group, n=20) in a randomized pilot study to support a future pragmatic trial.

3.2 Exploratory Objective(s)

3.2.1 To assess adherence to referrals for supportive care resources (caregiver- and administrator-reported) among intervention caregivers (n = 20) and barriers to supportive care use among intervention and comparison (n=40) caregivers.

3.2.2 To obtain preliminary data on HNC caregiver outcomes (supportive care service use, perceived care quality, burden, and distress, quality of life, caregiving self-efficacy, and self-care) and HNC patient outcomes (physical well-being, unplanned healthcare utilization, perceived care quality, distress, and symptoms)..

3.2.3 To examine changes in the caregiver outcome variables (perceived care quality, burden, distress, quality of life, caregiving self-efficacy, and self-care) with changes in in supportive care resource use.

3.2.4 To examine if patient physical well-being and patient healthcare utilization are associated with change in caregiver burden and distress in intervention arm caregivers.

3.2.5 To characterize the correlation between caregivers and patients with regard to distress and perceived care quality.

4.0 Participant Selection

4.1 Inclusion Criteria

4.1.1 Eligible <u>caregivers</u> include those who are:
  4.1.1.1 Caregivers must be providing some capacity of informal (unpaid) care for a patient meeting patient eligibility criteria. If a patient unexpectedly becomes deceased during the study period, caregivers will be allowed to continue participation in the assigned study arm and complete study assessments if they wish to.
  4.1.1.2 Greater than or equal to 18 years of age.
  4.1.1.3 Ability to access study materials by internet or complete study activities in person as institutional and government policies allow.

4.1.2 Eligible <u>patients</u> include those who:
  4.1.2.1 Have new or recurrent AJCC stage I-IV HNC.
  4.1.2.2 Are receiving cancer treatment or awaiting planned treatment initiation, excluding those receiving neoadjuvant surgery or surgery only
  4.1.2.3 Patients must be ambulatory and up more than 50% of waking hours, as measured by an ECOG Performance Status rating of level 0, 1, or 2.
  4.1.2.4 Greater than or equal to 18 years of age.
  4.1.2.5 Ability to access study materials by internet or complete study activities in person as institutional and government policies allow.
  4.1.2.6 Patients must be receiving some capacity of informal care from a caregiver meeting the above criteria. If the caregiver unexpectedly becomes deceased during the study period, the patient will be un-enrolled from this study as we are evaluating a caregiver-only delivered intervention.

4.2 Exclusion Criteria

4.2.1 <u>Caregivers</u> will be excluded if:
  4.2.1.1 They cannot read/communicate in English

4.2.2 Patients will be excluded if they:
  4.2.2.1 Cannot read/communicate in English

Eligibility to participate in the study for is conditional on participation of both the caregiver and patient.

4.3 Inclusion of Women and Minorities

Men and women of all races and ethnicity who meet the above-described eligibility criteria are eligible for this trial. Based on national head and neck cancer statistics[41] and a current patient-caregiver head and neck cancer protocol (PI: Nightingale; IRB00038084) at the WFBCCC, we estimate that approximately 75% of the patient participants will be male (and 25% female) and approximately 80% of the caregiver participants will be female (and 20% male). Further, we estimate that the majority (75%) of the participants will be non-Hispanic white, consistent with our current HNC patient-caregiver dyad research study conducted at this institution.

5.0 Registration Procedures

All patients entered on any WFBCCC trial, whether treatment, companion, or cancer control trial, **must** be linked to the study in EPIC within 24 hours of Informed Consent. Patients **must** be registered prior to the initiation of the study intervention.

The following steps will be performed to ensure prompt registration of participants:

1. Complete the Eligibility Checklist (Appendices A and B)
2. Complete the Patient Protocol Registration Form (Appendix C) and Caregiver Protocol Registration Form (Appendix D) as well as the Race Ethnicity Verification Form (Appendix E)
3. Register the patient and caregiver in WISER, registering the patient by their MRN

6.0 Study Outcomes and Study Measures

6.1 Primary Outcome

6.1.1 Feasibility and acceptability outcomes for the randomized pilot trial include:

6.1.1.1 Accrual: Number of caregivers who agreed to participate divided by the number of months of recruitment

6.1.1.2 Participation: Proportion of eligible participants who agreed to participate

6.1.1.3 Retention: Number of participants who completed the T2 assessment divided by the number who agreed to participate

6.1.1.3.1 Acceptability: Survey developed for study to assess how much caregivers liked different aspects of CONNECT; and a ~30min (approximately) qualitative interview to further explore acceptability. (Appendices H, I, and J)

6.2 Exploratory Outcomes

6.2.1 Preliminary Data of the following measures:

6.2.1.1 Caregiver Measures

6.2.1.1.1 Supportive Care Service Utilization
Survey developed for the purpose of this study to query participants about utilization of supportive care services assessed as part of the CONNECT Preferences Survey.

6.2.1.1.2 Perceived Care Quality
FAMCARE[42]
20-item instrument with 4 subscales to assess family caregiver satisfaction with information giving, availability of care, physical patient care, and symptom control.

6.2.1.1.3 Caregiver Burden
Caregiver Reaction Assessment[43]
24-item instrument assessing positive and negative aspects of caregiving (esteem, lack of family support, finances, schedule, and health). The CRA has been tested in cancer caregivers; demonstrated validity and reliability[43,44]

6.2.1.1.4 Psychological distress- Anxiety
PROMIS Emotional Distress-Anxiety-Short Form 8a[45]
8-item instrument that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal; widely used in oncology populations.

6.2.1.1.5 Psychological distress- Depression
PROMIS Emotional Distress- Depression-Short Form 8a[45]
8-item instrument that assesses sadness, guilt, self-criticism, worthlessness, loneliness, interpersonal alienation, as well as loss of interest, meaning, and purpose.

6.2.1.1.6 Quality of Life
Caregiver Quality of Life Index-Cancer (CqoL-Canc)[46]
35-item instrument assessing dimensions of caregiver quality of life (burden, disruptiveness, positive adaptation, financial concerns). The Cqol-Canc has demonstrated validity and reliability.

6.2.1.1.7 Self-Care
Caregiver Risk Scale[47]
7-item measure to assess caregiver behaviors for managing self-care.

6.2.1.1.8 Caregiving Self-Efficacy[48]
21-item instrument assessing caregivers' perceived self-efficacy for coping with cancer (managing medical information, caring for care recipient, caring for oneself, managing difficult interactions/emotions); demonstrated validity and reliability.

6.2.1.1.9 Barriers to Supportive Care Use
Survey developed for the purpose of this study to assess caregiver barriers to accessing supportive care resources.

6.2.1.1.10 Caregiver Adherence to Referral
Survey developed for purpose of this study to examine referral details. This includes date referral received by agency, time point of referral (T0/2 week follow up), if participant utilized services, and date those services were initially accessed. In addition, intervention caregivers will also self-report service use by completing an auto-generated REDCap survey to query about utilization of the specific resources that each caregiver expressed interest in accessing

6.2.1.2 Patient Measures

6.2.1.2.1 Physical/Emotional Well-being
SF-12[49]
12-item instrument measuring physical and mental well-being; widely used in oncology populations.

6.2.1.2.2 Unplanned Healthcare Utilization
Survey designed for the study to capture patient self-reported unplanned healthcare utilization. Total score will reflect number of unplanned visits to the emergency room, urgent care, or healthcare provider

6.2.1.2.3 Perceived Care Quality
FAMCARE[42]
20-item instrument with 4 subscales to assess family caregiver satisfaction with information giving, availability of care, physical patient care, and symptom control.

6.2.1.2.4 Psychological distress- Anxiety
PROMIS Emotional Distress-Anxiety-Short Form 8a[45]

8-item instrument that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal; widely used in oncology populations.

6.2.1.2.5 Psychological distress- Depression
PROMIS Emotional Distress- Depression-Short Form 8a[45]
8-item instrument that assesses sadness, guilt, self-criticism, worthlessness, loneliness, interpersonal alienation, as well as loss of interest, meaning, and purpose.

6.2.1.2.6 Head and Neck Cancer Symptoms
MDASI-HNC [50]
28 item instrument to assess head and neck cancer specific and general symptoms and the impact on daily functioning

7.0 Study Plan

7.1 Study Overview

This study includes piloting a novel technology-based intervention (CONNECT) to connect HNC caregivers with needs to supportive care resources (Figure 1) in a randomized trial. Caregivers and their care-recipients (i.e., patients) will be identified by screening provider schedules. They will be recruited by mailed recruitment packet, myWakeHealth message, telephone, and/or in person when presenting for the patient's routine oncology appointment (as allowed by institutional and government policies). Following completion of the consent process, patient/caregiver dyads will complete a baseline assessment (T0) (Appendices F and G). After the T0 assessment, caregivers will be randomized 1:1 to receive CONNECT (n=20) or the comparison arm (n=20). Caregivers and patients will also complete assessments after randomization at T1 (1-month post-CONNECT) (Appendices H and I) and T2 (3-months post-CONNECT) (Appendices J, K, and L).

7.2 Study-Related Activities

	T0	**T1**	**T2**
Caregiver sociodemographics	X	X*	X*
Caregiving characteristics	X	X*	X*
Patient sociodemographics	X		
Patient clinical information data abstraction	X		
Collection of feasibility metrics	X	X	X
Caregiver acceptability			X

	T0	**T1**	**T2**
Caregiver self-reported adherence to referrals for supportive resources			X
Caregiver Supportive Care Service Utilization	X	X	X
Caregiver PROMIS Emotional Distress- Anxiety Short Form 8a (Psychological distress)[45]	X	X	X
Caregiver PROMIS Emotional Distress- Depression Short Form 8a (Psychological distress)[45]	X	X	X
Caregiver Reaction Assessment (Burden)[44]	X	X	X
Caregiver Quality of Life Index-Cancer (CqoL-Canc)[46]	X	X	X
Caregiver FAMCARE (Perceived care quality)[42]	X	X	X
Caregiver Risk Scale (self-care) [47]	X	X	X
Caregiver Barriers to Supportive Care Use			X
Caregiving Self-efficacy[48]	X	X	X
Patient FAMCARE[42]	X	X	X
Patient SF-12 (Mental and physical well-being)[49]	X	X	X
Patient PROMIS Emotional Distress- Anxiety Short Form 8a (Psychological distress) [45]	X	X	X
Patient PROMIS Emotional Distress- Depression Short Form 8a (Psychological distress) [45]	X	X	X
Patient Unplanned healthcare utilization	X	X	X
MDASI- H&N[50]	X	X	X
Study evaluation			X
Service-administrator reported caregiver adherence to supportive care referrals	Administrators for service providers will record this information throughout the study period as referrals are received and services are utilized.		

* A limited set of variables from the survey will be included at this time point.

7.3 Intervention Administration

7.3.1 Recruitment

In collaboration with the treating oncologist, patients will be identified through clinic schedules. Screened patients will be recorded in the Subject Screening Form, an excel document (Appendix M) that will be kept on a protected share drive through the Wake Forest Baptist network and is only accessible to key staff members. Patients will be recruited for the study via a mailed recruitment package (Appendix X) or message sent via myWakeHealth that notifies patients that they may be eligible to participate in the study and provides them with an option to opt out of additional contact regarding the study. Patients will then be contacted either by phone or in person (as institutional and government policies allow). At this time additional information will be provided to the patient regarding the study and their eligibility will be confirmed (see section 3.1.2.6).

For patients that are not able to communicate verbally, there is an option in the letter for them to reply to the message with the name and phone number of a caregiver with whom we can discuss the study if they are interested in learning more.

If patient is interested and has an eligible caregiver who is also interested in participating, study coordinator will proceed with consenting them (see section 6.5). If the caregiver is not present, we will seek permission from the patient to contact the caregiver by phone to discuss study participation.

7.3.2 Randomization Plan

Caregiver participants will be randomized to the CONNECT web-based tool (n=20) or to the generic resource list (n=20) after both the patient and caregiver in a dyad return T0 and will be considered enrolled in the study. We anticipate that some participants may drop out prior to T0, and therefore may recruit up to 50 caregiver-patient dyads to ensure 40 complete T0; this is based on a potential drop out rate of up to 20%, although it is expected be lower. Because this protocol tests a caregiver-delivered intervention, patients will not be directly randomized, though the randomization of a caregiver implies a randomization of a patient. During the enrollment process participants will be informed that they could be randomly assigned to 1 of 2 different supportive treatments (Group A or Group B) with a general description of what these groups will involve, but participants will not be blind to their treatment assignment once they begin the study. Patients will also not be blinded regarding their caregiver’s assignment. Allocation to treatment arm will be computer-generated and concealed by Dr. Tooze (Biostatistician). Study team members will not know group assignment when consenting participants. The Project Manager and PI who assign participants to interventions will be made aware of group assignment after both the patient and caregiver have provided informed consent and returned their baseline questionnaires.

7.3.3 Description and Procedures.

CONNECT is a web-based intervention designed to empower caregivers with needs who are caring for cancer patients to seek supportive care services by providing education about the benefits of supportive care resources, systematically identifying their unmet needs, and connecting them with tailored supportive care resources, based on each caregivers' specific needs. Caregivers will be recruited in conjunction with the patient's routine oncology appointment. Following recruitment, dyads will complete the T0 assessment and caregivers will be randomized to CONNECT or the comparison group. CONNECT includes a multi-component e-tool accessible by a study website. CONNECT includes a multi-component web-based tool with the following: (1) a brief educational video (Appendix N) that seeks to empower and educate caregivers about the importance of self-care and benefits of supportive care resource use; (2) an assessment of multidimensional supportive care needs (e.g., psychological, behavioral, social, financial, educational, spiritual) (Appendix O); (3) a tailored resource list that includes local and national resources corresponding to caregivers' needs (Appendix P) (Table1); and (4) an optional automated referral to a caregiver navigator to facilitate connection to resources (for a limited number of resource options). Caregivers and patients will each receive a $20 gift card for each assessment (T0, T1, and T2).

Table 1. Examples of Supportive Identified Needs and Matched Resources

Identified Need →	Matched Resource
Psychological support	WFBCCC Cancer Patient Support Program
Tobacco cessation	WFBCC Tobacco Cessation Clinic
Financial counseling	Winston-Salem Cancer Support Services
Cancer Education	American Cancer Society handbook for cancer caregivers

After completing the assessment component of CONNECT's web-based tool, caregivers can view their tailored resource list in real time. All caregivers will receive a printed copy of their tailored resource list. Additionally they may indicate if they want the tailored resource list sent to their email address (Figure 1). For caregivers who select the optional referral option, their contact information (name and phone number) will be included in an auto-generated email sent to the resource (e.g., Cancer Patient Support Services) that they indicated interest in receiving a referral for. Two weeks after the caregiver uses goes through the CONNECT web-based tool, the study coordinator will contact caregivers in the CONNECT intervention by phone to provide re-education regarding the importance of caregiver self-care and benefits of supportive care resource use using a semi-structured script and an additional opportunity to receive a referral to facilitate connection to resources (Appendix Q). To extend reach to the minority of caregivers who do not accompany the patient to an appointment and allow research to occur during times when the study team is unable to conduct study activities in person, we will email the caregiver a website link to access CONNECT over the web. Those without home internet access will only have the option to participate when in person study visits are possible given the nature of the intervention.

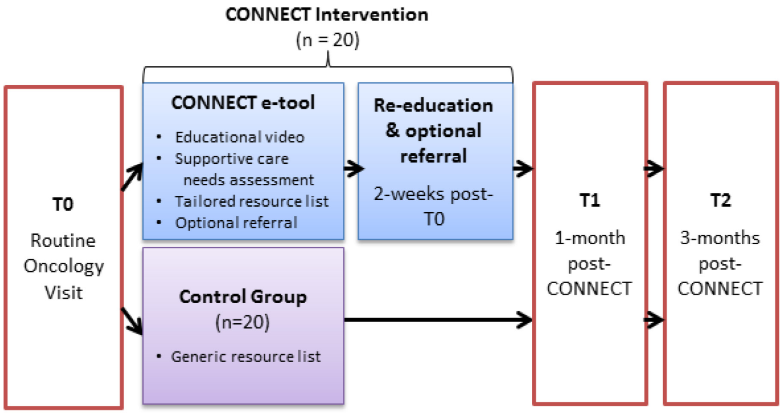


Figure 1. Study and Intervention Schema

Tablets will be available in the clinic (managed by research personnel) for participants to access the web-based tool. CONNECT's web-based tool is hosted on a website and designed to take approximately 15 – 20 minutes to complete. The web-based tool was developed and will be maintained by a programmer with clinical informatics expertise from the Center for Healthcare Innovations.

Comparison Arm. Caregivers not randomized to the intervention group will receive minimally enhanced usual care. This includes a generic (not tailored) printed list of hospital, community, and national supportive care resources (Appendix R). They will not receive the video, complete the web-based tool Preference survey, or have an option for an automated referral. The generic resource list will be printed for participants and emailed to them, if participants have an email address.

Data Collection Procedures. Data collection and instruments are reported in Table 2. At T0, patient and caregiver sociodemographics and caregiving characteristics will be collected and patient clinical information will be abstracted from the electronic health record (EHR) (Appendix S). Feasibility data will be collected throughout the study period (T0-T2). Caregivers and patients will complete self-report quantitative assessments at T0-T2 through REDCap We will email or text a link to complete the REDCap surveys at the appropriate times. To minimize missing data, we will call any participant who fails to complete a survey within 48 hours of the link being sent. In the case that a patient dies, caregivers may choose whether or not continue in the study and complete follow up questionnaires.

Data Management. All screened and approached participants will be recorded in an Excel document Appendix MThe responses of anonymous refusal surveys (Appendices V and W) will be recorded in a separate REDCAP Refusal project. All completed surveys for consented patients and caregivers will be recorded in an third REDCap project.

Qualitative Data Collection: At 2-weeks post-intervention - T1, caregiver qualitative interviews will be completed in person (or by telephone, if participant prefers) to assess acceptability of the intervention (est. 30min) using semi-structured guides with open-ended questions (Appendix T). During interviews, CONNECT elements will be reviewed and open-ended questions will be used to elicit feedback on functionality, strengths, and weaknesses of the web-based tool. All interviews will be audio-recorded and transcribed verbatim.

Adherence to referrals for supportive care services will also be tracked by each participating resource in a study spreadsheet (Appendix U). We will collect name, date referral was received, if service was accessed, and date service accessed. This spreadsheet will be collected by email quarterly throughout the study period.

Refusal Data Collection

If participants refuse to participate in the study, we will ask them to fill out a brief questionnaire with the following information: age, race, ethnicity, gender, marital status, education level, employment status, why the chose not to participate, and rating their distress in the past week (Appendices V and W)

Table 2. Assessment Plan

Assessment	Time	Description
Caregiver sociodemographics & caregiving characteristics *	T0, T1, T2	Age, gender, race/ethnicity, education, employment status and impact, income and financial impact, insurance status, marital status, living with patient (yes/no), relationship to patient, respite assistance (yes/no)
Patient sociodemographics *	T0, T1, T2	Age, gender, race/ethnicity, education, employment status, and insurance status
Patient clinical information	T0	Time since diagnosis, AJCC Stage, and treatment history for current cancer diagnosis
Accrual	T0, T1, T2	Number of caregivers who agreed to participate divided by the number of months of recruitment
Participation	T0, T1, T2	Proportion of eligible participants who agreed to participate
Retention	T0, T1, T2	Number of participants who completed the T2 assessment divided by the number who agreed to participate
Caregiver acceptability	T1	Survey developed for study to assess how much caregivers liked different aspects of CONNECT; and a ~30min (approximately) qualitative interview to further explore acceptability.
Caregiver Measures		
Supportive Care Service Utilization	T0, T1, T2	Survey developed for the purpose of this study to query participants about utilization of supportive care services assessed as part of the CONNECT Preferences Survey. Participants will also self-report service use by selecting (yes/no) from a list of resource options consistent with the e-tool resource list.
FAMCARE[42] (Perceived care quality)	T0, T1, T2	20-item instrument with 4 subscales to assess patient and family satisfaction with information giving, availability of care, physical patient care, and symptom control.
Caregiver Reaction Assessment (Burden)[43]	T0, T1, T2	21-item instrument assessing positive and negative aspects of caregiving (esteem, lack of family support, finances, schedule, and health). The CRA has been tested in cancer caregivers; demonstrated validity and reliability[43,44]
PROMIS Emotional Distress-Anxiety-Short Form[49]	T0, T1, T2	8-item instrument that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal; widely used in oncology populations.
PROMIS Emotional Distress- Depression-Short Form [49]	T0, T1, T2	8-item instrument that assesses sadness, guilt, self-criticism, worthlessness, loneliness, interpersonal alienation, as well as loss of interest, meaning, and purpose
Caregiving Self-efficacy[48]	T0, T1, T2	21-item instrument assessing caregivers' perceived self-efficacy for coping with cancer (managing medical information, caring for care recipient, caring for oneself, managing difficult interactions/emotions); demonstrated validity and reliability.
Caregiver Risk Scale[47]	T0, T1, T2	7-item measure to assess caregiver behaviors for managing self-care
Caregiver Quality of Life[46]	T0, T1, T2	35-item instrument assessing dimensions of caregiver quality of life (burden, disruptiveness, positive adaptation, financial concerns). The Cqol-Canc has demonstrated validity and reliability
Caregiver Barriers to Supportive Care	T2	Survey developed for the purpose of this study to assess caregiver barriers to accessing supportive care
Patient Measures		

SF-12[49] (physical well-being)	T0, T1, T2	12-item instrument measuring physical and mental well-being, though our analyses will focus on physical well-being; widely used in oncology populations.
Unplanned healthcare utilization	T0, T1, T2	Survey designed for the study to capture patient self-reported unplanned healthcare utilization. Total score will reflect number of unplanned visits to the emergency room, urgent care, or healthcare provider.
FAMCARE[42] (Perceived care quality)	T0, T1, T2	see description above
PROMIS Emotional Distress-Anxiety-Short Form[49]	T0, T1, T2	8-item instrument that assesses fear, anxious misery, hyperarousal, and somatic symptoms related to arousal; widely used in oncology populations.
PROMIS Emotional Distress- Depression-Short Form [49]	T0, T1, T2	8-item instrument that assesses sadness, guilt, self-criticism, worthlessness, loneliness, interpersonal alienation, as well as loss of interest, meaning, and purpose
MDASIH&N[50]	T0, T1, T2	28 item instrument to assess head and neck cancer specific and general symptoms and the impact on daily functioning

*A limited set of these variables will be included at T1 and T2.

7.4 Participant Payment

Caregivers and patients will each receive a $20 gift card for each assessment (T0, T1, and T2).

7.5 Informed Consent

This study poses no more than minimal risk and has a waiver of signed consent. During recruitment, dyads will have the study explained to them and have the opportunity to ask questions. Interested dyads will be presented with a form (hard copy or by REDCap) detailing study procedures including written documentation of study procedures and outlining what participation entails. In addition to providing written documentation of study procedures and outlining what participation entails, a statement at the end of the form will indicate that by continuing, the participant agrees to participate in the study. A copy of this information will be sent to participants at the email address they provided for their records. A notice on the REDCap form when the participant continues will read “Thank you. You will received a link to your first survey shortly”.

No study procedures will occur until the consent has occurred.

7.6 Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed six years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

7.7 Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

7.8 Reporting of Unanticipated Problems, Adverse Events, or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

7.9 Duration of Follow Up

Caregiver and patients participate in this study for approximately 3 months. After completing a baseline (T0) assessment and receiving the intervention, they will have 1-month and 3-month follow-up assessments. Participation in the study ends after completing the 3-month follow-up assessment.

7.10 WFUHS IRB AE Reporting Requirements

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

In the rare event that a participant becomes distressed as a result of participating in this study or rather becomes more reflective and wants to talk about these issues in more depth, we will provide referrals to members of the psychosocial support team and/or other clinical staff as appropriate.

8.0 Data Management

Table 3: Data Management	
Protocol registration form	WISER/OnCore
Caregiver measures	REDCap
Patient measures	REDCap

9.0 Statistical Considerations

Statistical Considerations. For the primary objective, the quantitative analyses will provide estimates of accrual, participation, and retention rates. For the secondary objectives, quantitative analyses will provide estimates of the mean and variance of CONNECT for acceptability and outcome variables to refine the protocol for a larger study. Though CONNECT is a caregiver-only intervention, analyses will also examine patient outcomes and relationships between caregiver and patient outcomes.

9.1 Analysis of Primary Objectives

9.1.1 For Objective 2.1.1, participation rate will be the percent of eligible participants who agree to participate. Accrual rate will be the number of caregivers who agreed to participate divided by the number of months of recruitment. Retention rate will be the number of participants who completed measures divided by the number who consented. We will construct 95% confidence intervals around these rates.

9.1.2 For Objective 2.1.2, acceptability will be summarized quantitatively and qualitatively (with assistance from WFSOM Qualitative and Patient-Reported Outcomes [Q-PRO] shared resource). Descriptive statistics (mean, standard deviation) will be used to summarize participants' acceptability rating. A codebook for analyzing qualitative interviews will be developed using a thematic analysis procedure, facilitating coding into discrete categories, and frequent themes pertinent to caregivers' likes/dislikes for CONNECT including the e-tool, message to provide re-education, and optional referral (process and navigator interaction) will be summarized. Qualitative acceptability data will be analyzed following a thematic analysis approach, facilitating coding into discrete categories.

9.2 Analysis of Exploratory Objectives

9.2.1 For Objective 2.2.1, frequencies will be used to summarize the number and type of referrals selected by intervention caregivers. Referral adherence will be defined as completion of referral (i.e. services utilized) within the caregiver's duration of study participation. Frequencies will also be used to summarize the number of intervention caregivers who adhered to referrals selected, among those who selected an automatic referral. This percentage will be calculated for caregiver-reported adherence as well as service administrator-reported adherence and concordance among caregiver- and -service administrator reported adherence will be calculated using McNemar's test. Number of barriers to supportive care use will be summarized using descriptive statistics (mean and standard deviation) and compared between intervention and control caregivers using an independent samples t-test.

9.2.2 For Objective 2.2.2, we will calculate descriptive statistics by arm and the difference between arms for the variables of interest at T0, T1 and T2, and change in variables from T0-T2 to provide estimates of variance for a larger study. We will examine differences by arm but are not powered for hypothesis testing at a 0.05 alpha-level between the two arms.

9.2.3 For Objective 2.2.3, we will examine change in supportive care resource use with change in the caregiver outcome variables (perceived care quality, burden, and distress, quality of life, caregiving self-efficacy, and self-care) using a regression approach to examine whether changes in supportive care resource use are associated with change in the outcomes.

9.2.4 For Objective 2.2.4,we will model changes in patient physical well-being and the patient healthcare utilization score at T1 and T2 as a function of change in caregiver psychosocial functioning from baseline using mixed effects models for the outcomes of interest with the baseline value of the outcome, change in caregiver burden and distress, arm, and time as the predictors.

9.2.5 A mixed model with a random family effect will also be used to characterize dyadic relationships between patients and caregivers for distress and perceived care quality for Objective 2.2.5.

9.3 Power and Sample Size

The sample size is based on feasibility, and we draw on our current patient-caregiver head and neck cancer protocol (PI: Nightingale; IRB00038084) at the WFBCCC, prior recruitment with HNC caregivers, [13,51,52] and clinic estimates. Our primary feasibility measures are participation, accrual, and retention rates. Assuming a negative binomial distribution and true rate of 50%, the probability that we would approach ≥96 dyads to recruit 40 is <0.05. If we approach ≥96 dyads to enroll 40, it is unlikely the true probability is 50% or greater, and we will conclude the study may not be feasible. We anticipate accruing 40 dyads within 9 months (4-5/month). A sample size of 40 achieves 92% power to detect a difference between a mean accrual rate of 4 participants/month and an alternative mean of 3 or fewer participants/month with a significance level of 0.025 using a two-sided one-sample Poisson test. Out of the 40 participants, if the true rate of retention is 70%, we expect 23 or more will be retained (i.e., probability of n≤22 successes is <0.05); we have 85% power to test that the hypothesis that the rate is 70% compared to 50%.

9.4 Estimated Accrual Rate

We anticipate accruing 40 dyads within 9 months (4-5/month) (see section 8.4 above)

9.5 Estimated Study Length

We anticipate recruitment will take approximately 9 months, with data collection complete in 12 months.

9.6 Interim Analysis Plan

N/A

10.0 Appendices

Appendix A	Eligibility Checklist (Patient)
Appendix B	Eligibility Checklist (Caregiver)
Appendix C	Protocol Registration Form (Patient)
Appendix D	Protocol Registration Form (Caregiver)
Appendix E	Race and Ethnicity Verification Form
Appendix F	Patient Survey (T0)
Appendix G	Caregiver Survey (T0)
Appendix H	Patient Survey (T1)
Appendix I	Caregiver Survey (T1 Interv and Comparison)
Appendix J	Patient Survey (T2)
Appendix K	Caregiver Survey (T2 Comparison)
Appendix L	Caregiver Survey (T2 Intervention)
Appendix M	Excel Subject Screening Form
Appendix N	Video Script
Appendix O	Preference Survey
Appendix P	HNC Tailored Resource List
Appendix Q	2 Week Follow Up Reminder
Appendix R	HNC Generic Resource List
Appendix S	Patient Clinical Information
Appendix T	CONNECT Semi Structure Interview Guide
Appendix U	Caregiver Utilization
Appendix V	Patient Refusal Questionnaire
Appendix W	Caregiver Refusal Questionnaire
Appendix X	Participant Recruitment Packet

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