Grant Proposal: Funding a Program Evaluation of the Healing Foods Program at UCSD Moores Cancer Center

by
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A paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Public Health in the Department of Nutrition

Chapel Hill, NC

December 7, 2017

Approved by:

12-1-2017  Date
ABSTRACT

The Healing Foods Program (HFP) seeks to link patients and caregivers at University of California at San Diego (UCSD) Moores Cancer Center with evidence-based nutrition information through informational seminars, food demonstrations and a nourishment cart for patients receiving therapies in the infusion and radiology centers. The objective of this program is to improve quality of life for patients undergoing cancer treatment. More specifically, the program has established the following specific aims:

1. Increase the number of active HFP participants (those who have attended at least one class over the last six months) to 300% of the number of active participants at baseline (targeted completion date of June 30, 2019).
2. Complete a formal evaluation of the HFP that assesses the program’s ability to improve subjective quality of life measures for patients in treatment (targeted completion date of June 30, 2020).

In order to achieve these objectives, the HFP plans to expand its participant reach through new program offerings, a targeting marketing campaign, and a weekly nourishment cart for patients receiving therapies at the cancer center. In addition, the HFP plans to conduct a formal evaluation of its efficacy at meeting its stated objectives. This evaluation will involve administering the WHO-5 well-being screener, a validated tool for assessing subjective quality of life measures, to patients attending classes. Surveys will be administered at baseline (at the start of each class) and three weeks after the classes via an online survey platform. The results of the surveys will be analyzed to assess whether the HFP is making progress toward meeting its long-term objectives, as well as to generate lessons learned for other cancer centers looking to develop nutrition education programs for patients and caregivers.

PROJECT NARRATIVE

The evaluation of the Healing Foods Program (HFP) project seeks to contribute to the field of public health by providing guidance for other cancer centers developing comparable nutrition education programs. This will have the long-term impact of improving quality of life for patients undergoing cancer treatment.
BUDGET JUSTIFICATION

Personnel Justification

Program Director: Christine Zoumas, MS/RD

- Percent Effort: 2.4 calendar-year person-months
- Knowledge, Skills & Experience: Ms. Zoumas obtained her MS in Nutritional Science from Pennsylvania State University. She has overseen the Healing Foods Program (formerly the Healthy Eating Program) at UCSD Moores Cancer Center since its inception. She also teaches nutrition science at various San Diego universities and colleges.
- Roles: The Program Director is responsible for program oversight and decision-making; interfacing with the Board of Visitors and corporate partners; internal (within UCSD Health) and external outreach; and for providing direct supervision to the Program Manager. The Program Director will also teach at least one nutrition seminar per week.

Program Manager: Currently Hiring

- Percent Effort: 6.0 calendar-year person-months
- Desired Knowledge, Skills & Experience: The Program Manager will have an academic degree and/or professional accreditation in nutrition (preferably a Registered Dietitian). The Program Manager will also have previous experience in program management, preferably in a public or private healthcare context.
- Roles: The Program Manager is responsible for general program administration, including managing registration, marketing, preparation for classes (with the exception of the responsibilities of the culinary instructor), and organizing volunteer staffing. The Program Manager will be responsible for teaching nutrition seminars not taught by the Program Director (based on an agreed-upon schedule). The Program Manager will oversee the Research Assistant during the program evaluation (Budget Period 2).

Culinary Instructor: Currently Hiring

- Percent Effort: 2.4 calendar-year person-months
- Desired Knowledge, Skills & Experience: The Culinary Instructor must have an academic degree in culinary arts. In addition, he or she must have experience and skills in group education.
- Roles: The Culinary Instructor will be responsible for developing the curriculum and preparing for the food demonstrations. He or she will teach at least four food demonstrations per month, and will be responsible for managing volunteers assisting with the demonstrations.

Research Assistant: Will Be Hired Prior to Budget Period 2

- Percent Effort: 2.4 calendar-year person-months
- Desired Knowledge, Skills & Experience: The research assistant will be a graduate student pursuing a degree in public health, nutrition, or a related field. The research assistant will be proficient at data entry and statistical analysis.
- Roles: The Research Assistant will be responsible for managing administration of the baseline and follow-up surveys (including collecting informed consent from participants), as well as for data entry and analysis. He or she will report to the Program Manager and Program Director.

Volunteers

- Percent Effort: N/A
- Desired Knowledge, Skills & Experience: The HFP will recruit volunteers through Moores Cancer Center Volunteer Services. All volunteers complete extensive online training and an in-person
orientation that covers professionalism, interacting with patients, and safety precautions, among other topics. No additional special skills are required.

- **Roles:** The volunteers will assist the Culinary Instructor with the food demonstrations, including preparation, check-in and clean-up. In addition, the volunteers will take the nourishment cart down to the infusions and radiology centers to provide snacks to patients and promote the HFP’s class offerings.

**Additional Narrative Justification**

**Equipment**

- All kitchen equipment is provided in-kind by Moores Cancer Center.

**Supplies**

- A total of $5,400 per year is budgeted for supplies.
- This includes $1,200 per year ($100 per month) for office supplies, such as paper, binders, pens/pencils, envelopes, folders and printer cartridges. This also includes another $1,200 per year ($100 per month) allocated for professional printing services to print our monthly marketing materials (including fliers, brochures and stackcards).
- The supplies total includes $600 per year ($50 per month) for kitchen supplies, including disposable dishes, utensils, napkins and gloves; plastic bags, plastic wrap and foil for storing food; and cleaning supplies.
- The supplies total includes $2,400 per year ($200 per month) for ingredients needed for the food demonstrations. This is based on an estimate of $50 per class for four classes per month.
- Snacks for the nourishment cart are provided in-kind by our corporate partners. Please see letters of support attached to this grant application.
- Computers, printers and copiers are provided in-kind by Moores Cancer Center.

**Gas Mileage**

- A total of $100 is budgeted for mileage expenses. This is based on a calculation of $0.50 per mile for 200 miles, required for purchasing ingredients and supplies for the food demonstrations, as well as community outreach and other off-site events.

**Other Expenses**

- All other expenses are provided in-kind. This includes office space (workstations), and facilities for classes (conference room space for seminars and kitchen space for food demonstrations).
- The WHO-5 screener is freely available for public use.

**Note:** PHS 398 Modular Budget Form (for projects requesting less than $250,000 per budget period) only requires a Personnel Justification, but for the mock grant application, a full budget justification was developed.
RESEARCH PLAN

Specific Aims

A 2012 systematic review of 26 studies found a strong body of evidence supporting the correlation between poor nutrition status and impaired quality of life during cancer treatment.¹ Thus, cancer centers nationwide are taking steps to incorporate nutrition education and counseling programs into their patient offerings, but very few offer comprehensive nutrition education and even fewer incorporate food demonstrations into their nutrition education initiatives, nor do many offer education through all phases of cancer treatment and survivorship.

The UCSD Moores Cancer Center Healing Foods Program seeks to pilot a program that fills these critical gaps in patient offerings. Our rotating curriculum includes nutrition seminars, food demonstrations and one-on-one patient encounters via our nourishment cart for patients receiving therapies in the infusion and radiology centers. We hypothesize, based on a growing body of evidence supporting the use of nutrition interventions to improve cancer patient outcomes²³⁴⁵, that our unique program offerings will improve subjective measures of wellbeing among patients in treatment. We plan to conduct a formal program evaluation to test these hypotheses and to publish the evaluation results as guidance to other cancer centers implementing comparable programs to support the nutrition needs of patients as they go through treatment.

We have established the following specific aims:

• **Aim 1 will increase the number of active HFP participants (those who have attended at least one class over the last six months) by 300% relative to baseline (targeted completion date of June 30, 2019).** We currently estimate our baseline participant population to be approximately 300 and therefore aspire to increase active participation to approximately 900 participants. This will be accomplished through new program offerings, a targeted marketing campaign, and a nourishment cart for patients receiving therapies at the cancer center. Aim 1 will ensure that the HFP’s participant base is sufficient in reach and representation of our target population in order to support our program evaluation.

• **Aim 2 will complete a formal program evaluation of the HFP (targeted completion date of June 30, 2020).** This will be accomplished through baseline (prior to class attendance) and follow-up (post-class) assessments of subjective wellbeing measures among patients currently in treatment. Aim 2 will test our research hypothesis and generate “lessons learned” for other cancer centers looking to implement comparable programs.

The Healing Foods Program takes an innovative, hands-on approach to educating cancer patients and caregivers on nutrition through all phases of cancer treatment and survivorship. We anticipate that the program evaluation will evidence meaningful improvement in quality of life among patients in treatment. The evaluation will generate valuable assessment data to guide other cancer centers with implementation of comprehensive nutrition education programs. Consequently, the expected impact of this program is contribution of knowledge to the field of education on nutrition and cancer, with the long-term goal of improving the mental and physical wellbeing of cancer patients during treatment.
Research Strategy

Significance

The prevalence of malnutrition among cancer patients is estimated to be between 15% and 80% of patients.\textsuperscript{6} There is a strong body of evidence supporting the correlation between poor nutrition status during cancer treatment and impaired quality of life. Indeed, a 2012 systematic review found a statistically significant inverse relationship between quality of life measures and poor nutrition status in 24 of 26 studies considered\textsuperscript{1}. Thus, it is critical that cancer centers implement accessible programs designed to address the nutrition needs of patients during treatment.

The Healing Foods Program (HFP) at UCSD Moores Cancer Center offers free nutrition education to patients and caregivers in an effort to improve quality of life during treatment. The program’s mission is predicated on the strength of the evidence supporting the correlation between nutrition interventions for patients prior to or during cancer treatment and improved quality of life and health outcomes, particularly for patients with colorectal\textsuperscript{3,5}, and head and neck cancers\textsuperscript{2,4}. The program seeks to contribute to scientific knowledge by publishing the results of our program evaluation to guide other cancer centers implementing comparable programs to support the nutrition needs of patients receiving cancer treatment.

Innovation

The HFP challenges current clinical practice paradigms for nutrition and cancer. Unlike traditional outpatient nutrition counseling, participation in the HFP does not require a physician referral. This provides patients with an increased perception of control over their clinical experience by allowing them to bypass some of the bureaucratic challenges of the health system. In addition, by offering food demonstrations, the program seeks to provide evidence-based nutrition education in a practical context. While many patients may have a general idea of what comprises a healthy diet, many lack the self-efficacy or culinary knowledge to implement sound nutrition principles in the kitchen. Consequently, the program seeks to make nutrition education more approachable to patients and caregivers by providing the knowledge and skills necessary to prepare simple, healthy recipes at home.

The HFP seeks to improve in several ways current models for nutrition education interventions for cancer patients. The HFP offers a multimodal approach to nutrition education through several different patient touchpoints: nutrition seminars, food demonstrations and a nourishment cart for patients receiving therapies in the infusions and radiology center (an opportunity for short patient consultations with a dietitian or dietetic intern). All of our offerings are free, do not require physician referrals and are located within the cancer center, mitigating potential access issues. Finally, the program expands the breadth of typical nutrition education offerings with nutrition guidance for all phases of cancer treatment and survivorship.

There are numerous advantages to the HFP’s novel approach to nutrition programming for cancer patients. Bypassing the physician referral system increases patient autonomy and perception of control over their healthcare. Offering the classes at no cost (donation-based) to participants at a location accessible via public transportation eliminates potential socioeconomic barriers. The discussion-based class format is designed to encourage conversation, with the goal of fostering a support community between patients and facilitators. Finally, offering food demonstrations to supplement our seminar offerings translates nutrition education from knowledge to practical skillsets that can be applied in home kitchens.
Approach

We plan to first grow the HFP’s participant base (Aim 1) and then to evaluate the program’s efficacy in improving quality of life for patients receiving treatment for cancer (Aim 2).

Aim 1 – Increase Program Participation:

- **Strategy**
  - The program’s growth strategy is comprised of the following components:
    - New food demonstration and nutrition seminar offerings
    - Strategic marketing via mailing (via e-mail) lists, program fliers, and community outreach events
    - Nourishment cart for patients receiving therapies at the cancer center
  - We will conduct an ongoing process evaluation using our registration software to assess our progress in achieving Aim 1.

- **Methodology**
  - **Experimental Design:** We will use a non-experimental pre-post evaluation design to assess our progress in achieving Aim 1. This evaluation will be performed over a one-year period (June 30, 2018 to June 30, 2019).
  - **Feasibility:** The primary high-risk aspect of our chosen methodology is concern over HIPAA considerations, which we will mitigate by anonymizing all data once it is downloaded from our registration software and ensuring adequate information security protocols are in place to protect collected data.
  - **Rigor and Reproducibility:**
    - **Scientific Premise:** See “Significance” section above.
    - **Scientific Rigor:** Because our Aim 1 evaluation relies exclusively on quantitative registration data directly from the registration software, there is a lower risk of introducing bias during the administrative and analytical procedures. We will develop a standard protocol for data entry, data analysis and data interpretation. We will ensure that all data is anonymized and that data analysis is performed and interpreted by two independent parties.
    - **Relevant Variables:** We plan to collect the following demographic information as part of our class registration process: whether the participant is a first time registrant (in order to assess whether we are expanding our reach); zipcode (as a proxy for income status); and whether the participant is a patient, caregiver or other (as well as which San Diego hospital they are being treated at because our classes are not limited to Moores Cancer Center patients). We will expand our data collection during the registration process to include age, gender and ethnicity. We feel that these additional variables will inform our marketing strategy, as well as provide a snapshot of the reach and representativeness of our participant population for our program evaluation (Aim 2).

- **Analysis**
  - **Data Collection:** Our online registration software, HS Events, automatically tracks registration and class attendance, with additional functionality to collect demographic data (as outlined under “Relevant Variables” above).
  - **Data Analysis:** The registration data is periodically downloaded to a spreadsheet and added to our database (this process is already in place at the HFP). To address HIPAA concerns, all data will be anonymized once downloaded from HS Events. In order to measure our progress towards meeting Aim 1, we will collect participant data at baseline (June 30, 2018) and then monitor our growth during the evaluation period. No additional analysis is required.
  - **Data Interpretation:** An independent party from the person performing the collection and analysis will interpret the data. This process will be performed on an ongoing basis to inform the marketing campaign.

- **Potential Issues**
  - We identified the issue of walk-ins and no-shows as a potential challenge for accurate monitoring of our progress towards meeting Aim 1. In order to mitigate this issue, we have noted that HS Events has the functionality to mark class attendance for pre-registered participants.
For walk-in participants, we have developed an alternative manual procedure to collect the demographic information we need; this information can be entered into HS Events to ensure that we have accurate class attendance data.

• **Benchmarks for Success**
  o **Reach:** Our first benchmark for success will be expanding our reach to meet the goal established in Aim 1: increasing the number of active HFP participants (those who have attended at least one class over the last six months) by 300% relative to baseline. Program reach will be assessed on an ongoing basis during the program growth phase to ensure that we are on-track to meet Aim 1 by June 30, 2019.
  o **Representativeness:** Our second benchmark for success will be to maximize how representative our participant base is of our target population (patients at Moores Cancer Center). While the HFP classes are available to the public, we are foremost a service for Moores patients and caregivers. Consequently, we have set a goal to have 80% of our active participant base be Moores patients and caregivers. Program representativeness will be assessed on an ongoing basis during the program growth phase to inform and tailor our marketing campaign.

• **Alternative Approach**
  o If we are not on-track to meet our benchmarks for success, our alternative strategy will be to hold a focus group with our target population to better understand the best way to increase program participation, whether it be to change our marketing strategy, adjust our class schedule to better accommodate patient needs or to change our class offerings. If an adjustment in marketing strategy is needed, we will also consult with Program Development who assist with development and growth of Moores Cancer Center programming.

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**Aim 2 – Program Evaluation**

• **Strategy**
  o We plan to conduct a formal program evaluation of the HFP to assess whether it is leading to meaningful improvement in subjective measures of wellbeing among patients in treatment. This will be accomplished through a survey for program participants administered at baseline (beginning of class) and follow-up (post-class).

• **Methodology**
  o **Experimental Design:** We will use a non-experimental pre-post evaluation design to assess our progress in achieving Aim 2. This evaluation will be performed over a one-year period (June 30, 2019 to June 30, 2020).
  o **Feasibility:** The primary high-risk aspect of our chosen methodology is concern over HIPAA considerations, which we will mitigate by anonymizing all data and ensuring adequate information security protocols are in place to protect collected data. We will obtain informed consent from participants prior to survey administration.
  o **Rigor and Reproducibility:**
    - **Scientific Premise:** See “Significance” section above.
    - **Scientific Rigor:** We will develop a standard protocol for baseline and follow-up survey administration, data entry, data analysis and data interpretation (as well as protocols for nonresponse follow-up and other contingencies). To ensure the most accurate results, we will be using the WHO-5, a validated tool for subject assessments of wellbeing. Survey administration will be managed by a research assistant whose job functions are independent of class administration.
    - **Relevant Variables:** We have identified the following variables as potentially relevant to interpretation of our results: age, gender, ethnicity, type and stage of cancer, type of therapy, number of rounds of therapy received in the past (to assess whether previous experiences with therapy impact subjective wellbeing scores), type of class attended (seminar vs. food demonstration) and number of classes over the one-year period. We will collect information on demographics, as well as the type and stage of cancer and therapy, as fields on our surveys. We will track the number of classes each participant has attended using data from HS Events.
• Analysis
  o Data Collection: We will administer the survey to all participants at the beginning of each class once we obtain informed consent. Patients will complete the short five-question WHO-5 screener. Three weeks after class, we will send consenting participants a follow-up survey via an online survey platform with the same five-question screener to assess whether the classes lead to meaningful improvement in subjective measures of wellbeing. This will be performed for all consenting participants for all classes (food demonstrations and seminars), which may provide multiple data points for the same participant over time.
  o Data Analysis: Data will be entered and maintained in a centralized database by the research assistant. We will first filter for surveys received for patients (at Moores Cancer Center or another facility). While we are collecting baseline surveys from all participants (to avoid singling out patients in class), our target population is patients receiving treatment. For the target population, we will input the results of the survey, as well as the demographic data collected. Follow-up surveys will only be sent to our target population (current patients).
  o Data Interpretation: We will perform comparisons between baseline and follow-up data, as well as trends for patients who attend multiple classes. Additionally, we will examine how our relevant variables (type and stage of cancer, treatment type, round of treatment, type of class and number of classes attended) impact our results. We will use the results of our data interpretation to inform “lessons learned” for other cancer centers looking to implement comparable programs.

• Potential Issues
  o We identified the potential issue of collecting unnecessary data for class participants that are not in our target population. To mitigate information security concerns, all unused surveys will be immediately shredded in a HIPAA-compliant manner. To avoid collecting unnecessary follow-up data, we will only be sending the e-mail surveys to our target population (patients).
  o We also identified the issue of missing data as a potential issue. We will follow-up personally with participants who do not complete fields on the manual baseline survey. For participants who do not complete the follow-up survey, we will e-mail them a survey reminder three days later, followed up by a phone call an additional three days later. If we are not able to collect a follow-up survey within four weeks of class attendance, we will discard the baseline survey.

• Benchmarks for Success
  o Our first benchmark for success will be to collect a robust dataset to support our program evaluation. We have established a benchmark goal of 385 evaluation participants (completed both baseline and follow-up surveys) in order to achieve 95% confidence with a 5% confidence interval. Given our current participation rate and number of classes offered per month (typically eight to 10), as well as our anticipated expansion with Aim 1, we believe this goal is realistic.
  o Our second benchmark for success will be to complete data analysis and interpretation of the collected data.

• Alternative Approach
  o Similar to our alternative approach for Aim 1, if our preliminary data is not evidencing meaningful improvement in wellbeing scores, we will hold focus groups with survey participants to better understand what might be preventing the results we were anticipating. We will use the results of the focus group to identify the changes we need to make (to the program itself or to our evaluation approach). Based on these findings, we will develop an alternative strategy to ensure that we meet the objective established in Aim 2.
REFERENCES CITED


