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Evaluating the Impact of Financial Navigation on Financial Catastrophe and Distress for Cancer Care: A Randomized Control Trial- COST-FIN

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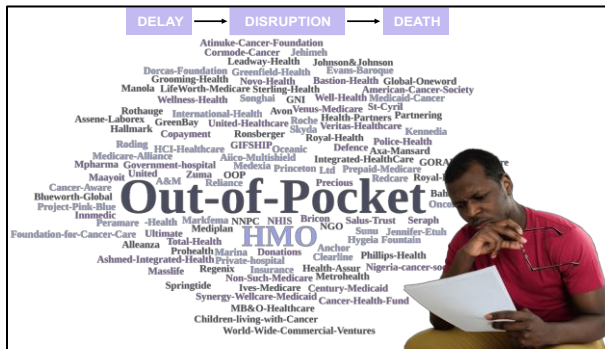
Research Strategy

A. Significance

A.1. Cancer disproportionately affects people in low- and middle-income countries (LMICs),¹ which by 2030 will account for an estimated 75% of new cancer cases and 65% of cancer deaths worldwide.² The highest rate of premature death from cancer is in Sub-Saharan Africa (SSA), and in Nigeria—the most populous country in the region and home to the second largest population of extreme poor in the world—more than 100,000 new cancer cases occur every year.¹ Amongst the most common types are breast (BC), prostate (PC), and colorectal cancer (CRC).³ **Outcomes for Nigerian cancer patients are dismal, with overall 5-year survival rates estimated to be less than 50%,^{4–10} compared to up to 90% for the most common cancers in high-income countries.^{11–13} This has led to renewed interest in cancer prevention and control in Nigeria, and the government has established the National Cancer Control Plan (NCCP), a \$300 billion USD investment to centralize and provide access to multidisciplinary care by strengthening resources at existing facilities (2023–2027).¹⁴ Though this may improve capacity for cancer care, treatment will remain largely inaccessible, as 40% of the population live below the national poverty line of \$2.15 per day.¹⁵ Recent estimates of out-of-pocket costs (OOP) for cancer treatment in Nigeria exceeds the per capita GDP of the country.^{16–19} Without financial assistance programs, many families will face financial catastrophe (FC) or experience significant financial distress (FD) because of cancer care. Therefore, to achieve the goals of the NCCP to reduce these health disparities and improve access, research on innovative methods to eliminate cost barriers to care is urgently needed.**

A.2. Impact of Financial Catastrophe (FC) on Clinical Outcomes

Nigeria has no universal screening programs for cancer prevention, which has significant implication for the clinical presentation of patients.²⁰ More than 80% of patients present with advanced disease, and in 60–70% of cases the delay in presentation reflects the patients' inability to pay for diagnostics and treatment.¹⁶ Even when



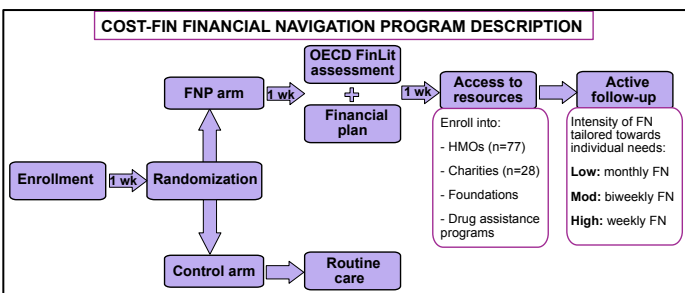
care is available, patients remain at high risk for **poor treatment outcomes** due to delays in presentation and treatment disruption. Furthermore, rates of treatment initiation and adherence to recommended therapies are low.^{20–22} In a systematic review of 319 Nigerian patients with BC, more than half did not complete chemotherapy or received their doses at irregular intervals, and multimodal treatments were severely underutilized.²¹ In a retrospective study conducted at Lakeshore Cancer Center (LCC) in Lagos by our co-investigator, nearly 70% of patients with a new cancer diagnosis did not complete treatment.²² Our studies and others in SSA suggest that between 75–95% of cancer and surgical

patients would risk FC,^{16,23–27} defined by the WHO as OOP that exceed 10% of the household income (HHI), 25% of the household expenditures (HHE) or 40% of non-subsistence expenditures (HSE).²⁸ The National Health Insurance Scheme (NHIS) —a government sponsored insurance founded in 2003 whose mission was to provide financial access to quality care for all Nigerians—has yet to achieve its goal in 20 years or reduce the risk of FC for cancer.²⁹ *In fact Nigeria ranks below the 30% percentile for effective Universal Health Coverage (UHC) which has been shown to reduce cancer-specific mortality.*^{30,31} Most families therefore are left to find means to self-navigate community resources or forgo treatment.^{32,33} A 2019 study at a tertiary health institution in Nigeria found that among 306 surgical cancer patients, 99% of patients used their savings and 43% borrowed to cope with treatment costs.³⁴ More recently, a study on OOP associated with BC treatment at a teaching hospital in Nigeria by our co-investigators found that 72% of households had to borrow money, 18% lost their job, and 9% interrupted their children's education to finance treatment.²⁴ In addition to significant implications for household wealth and the risk of impoverishment, **FC can also affect the quality and outcomes of cancer care through reduced treatment adherence and delays or interruptions in care.**^{35,36} Our co-investigator, in an exploratory analysis of BC and CRC patients, showed 30–40% of patients declined recommended treatment due to costs.^{17,24} The ABC-DO, a prospective multi-country cohort study on survival after BC diagnosis in five SSA countries found that 47% of patients did not undergo curative surgery due to OOP, with Nigeria representing the highest number of patients that went untreated.³⁷

A.3. Precedence for the Innovation

In a study of 274 NCI Community Oncology Research Program practices in the U.S., 96% offered financial assistance to help patients pay for their treatment.³⁸ While it is expected that cancer centers help patients navigate their cost of care, these efforts have been hampered by inconsistent strategies and inadequate financial

counseling. In the U.S., structured financial navigation programs (FNPs) have been developed to address these issues. In one study, FNPs helped oncology patients save an average of over \$30,000 annually³⁹ and reduced financial toxicity among hematologic cancer patients and caregivers.⁴⁰ Typically, FNPs help patients prepare for OOP, create payment plans, optimize health insurance, and maximize access to financial resources such as



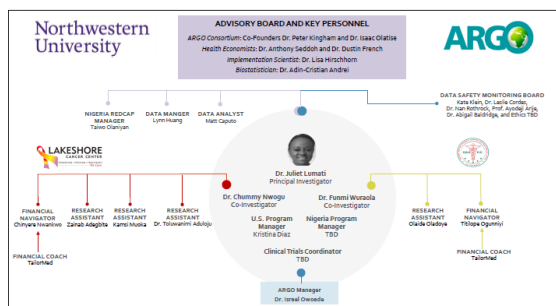
foundations, pharmaceutical programs, and community assistance.^{39,41,42} The feasibility and acceptability of FNPs have been established in the U.S.^{41,43–46} *but have not been studied in SSA.* We propose to conduct a pragmatic randomized controlled trial of 200 patients with newly diagnosed BC, CRC, or PC at two cancer centers in Nigeria, Lakeshore Cancer Center (LCC) and Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC). ***Specifically, we will test the hypothesis that a FNP will expand access to care and improve***

treatment adherence by reducing the risk of FC and the level of FD for cancer patients. The FNP will bridge the important gap in fragmentation and lack of knowledge of the eligibility, coverage and services of the HMOs, charitable organizations, and foundations that currently exist in Nigeria. Recognizing from prior studies conducted by our co-investigators, the NHIS alone is insufficient to address the OOP of care for cancer patients.²⁴

We believe the novel results of this pragmatic randomized control trial will provide a foundational basis for the implementation and adoption of FNP in Nigeria and may have significant impact on clinical outcomes. Our pilot survey of stakeholders which included executives and providers across both sites using the implementation science RE-AIM framework⁴⁷ showed more than 90% of respondents responded positively to the feasibility, implementation, and perceived benefits of the adoption of a FNP. Nigeria is an ideal setting to assess the effects of an FNP, given the renewed interest of the government in cancer reform,¹⁴ and we have already established robust partnerships to facilitate the study. The proposed study will reveal whether a FNP will reduce the risk of FC and levels of FD. Given the government's interest in improving access to cancer care, the findings of our study will inform national health policy. Our findings may also influence other cancer centers in SSA to establish FNPs to eliminate financial barriers to care. Finally, this study will provide foundational data for an R01-level study to evaluate the implementation, optimization, and benefits of FNPs in Nigeria and other countries in SSA.

B. Innovation

FNPs have never been studied in Nigeria. Thus, our study will provide unprecedented information on the costs and benefits of establishing a FNP in SSA. Specifically, our study will evaluate for the first time in SSA whether a FNP can improve access to multidisciplinary cancer treatment by reducing financial barriers and reduce the risk of health-related FC and FD for households with cancer patients in Nigeria. This information will be vitally important for health care policymakers in Nigeria and other LMICs. Findings from this study align with the mission of the **National Cancer Control Plan framework of the NCI to eliminate inequities and deliver optimum care.**



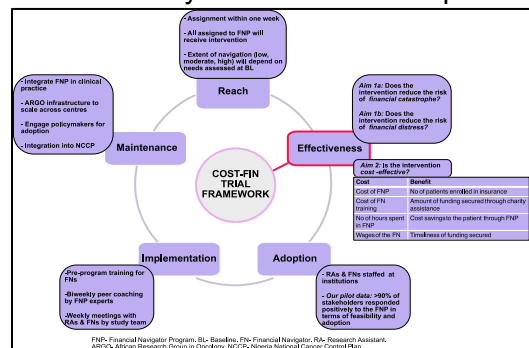
C. Approach

C.1. Track record with collaborating institutions. Over the last five years, the PI, Dr. Juliet Lumati, has worked as a surgical oncology consultant at LCC and participated in the care of cancer patients through a Multidisciplinary Tumor Board in Nigeria. Dr. Lumati has helped LCC promote screening for cancer as an early intervention program and has co-hosted informational sessions, including lectures and radio talks, on the importance of early diagnosis in reducing cost barriers. She has worked on healthcare

financing studies in SSA (Ghana & Nigeria) over the last 10 years and is currently licensed to practice in Nigeria. She was a former Fogarty-Fulbright Fellow and principal investigator through the UC-GLOCAL consortium on her work which centered upon evaluating the impact of the NHIS of Ghana on the risk of financial catastrophe for surgical care (NCT03604458).²⁵ This was in collaboration with the University of Ghana, Center for Surgery and Public Health, Boston MA, and UCSF. She is currently the PI of a retrospective study of OOP associated with treatment of 400 patients at LCC in partnership with the University of Lagos.^{18,19} Our co-investigator, Dr. Nwogu, has published on cancer incidence and presentations at LCC.²² Similarly, our co-investigator at OAUTHC, Dr. Wuraola, has published research on treatment characteristics and OOP for BC care at their institution.^{5,24} Both OAUTHC and LCC are part of the African Research Group in Oncology (ARGO) consortium,

an NCI-designated consortium of 30 cancer centers in Nigeria with established U.S. collaborations, interest in financial interventions, and infrastructure supporting multiple ongoing multicenter clinical trials.

C.3. Role of financial navigator. The FNP will offer access to a financial navigator (FN) at each of the two sites. The FN will educate patients on financial literacy, insurance plans and payment options available through charities and financial assistance programs. In addition to providing financial counseling, the FN will verify patient insurance documents, maintain records of financial agreements, and coordinate payments with insurance companies. The FN must not only be empathetic and responsive to patients' concerns and questions but must also stay up to date on billing regulations, insurance policies, and compliance standards. The extent of navigation will be tailored to the needs of the patients and the economic burdens they face, which can change over the course of treatment. We anticipate a spectrum of low-level navigation to high-level navigation necessary within our cohort. A preset communication plan will be determined by the FN based on the intensity of the navigation necessary to assist the patients in funding their treatment. Importantly, support of the FNP at the Nigerian cancer centers will be provided in partnership with established financial navigation organizations—TailorMed and NaVectis Groups.^{48,49} These organizations provide training for healthcare providers and hospitals on how to improve patient financial navigation services. Their solutions have been shown to result in decreased FD for patients, and a reduction in financial losses for healthcare organizations. A study of four U.S. hospitals with FNs trained by the NaVectis Group found that the hospitals were able to obtain an annual average of \$3.5 million



coaching.

C.4. Specific Aim 1: To conduct a pragmatic randomized clinical trial (RCT) of a financial navigation program at two sites in Nigeria. Subaim 1a: Evaluate the effect of the FNP on financial catastrophe in patients with cancer. Subaim 1b: Determine whether the FNP reduces financial distress for patients with cancer.

economic burden of treatment over time *highlighting the need for a prospective RCT to address this gap in knowledge.*

C.4.b. Study design and methods. We will conduct a prospective RCT of 200 patients with newly diagnosed BC, CRC, or PC at two sites in Nigeria. Participants will be randomized to the intervention arm (FNP) or the control arm, and then followed for 1 year. The effect of the FNP will be analyzed through repeated collection of sociodemographic characteristics, clinical characteristics, prescribed treatments, financial data on treatment, and measures of FC and FD. OOP costs will be collected continuously throughout the study period, while FD will be measured with the FACIT-COST tool at 3 months, 6 months, and 1-year post-randomization.

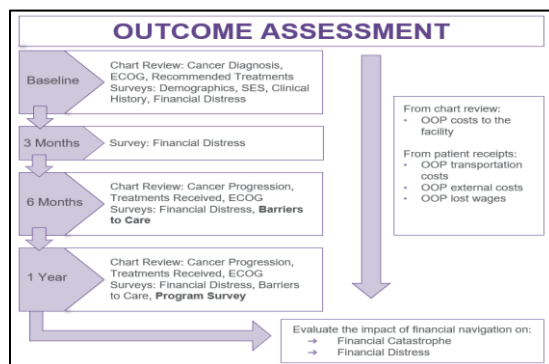
C.4.c. Patient eligibility and recruitment. All patients aged 18 years or older with a new diagnosis of BC, CRC, or PC within 6 weeks of presentation at a study site will be eligible for enrollment, regardless of cancer stage. All other patients will be ineligible.

C.4.d. Assignment to treatment or control group. One hundred participants will be randomized to the intervention arm and receive the FNP, and 100 will be randomized to the control arm. Group assignments will be made by blocked randomization with stratification for cancer type, stage, and study site. Since FNP, patients, and providers must interact, they will not be blinded to group assignments. The principal investigator and outcome assessors will be blinded to the study allocation.

C.4.e. Survey Procedure and Data Collection

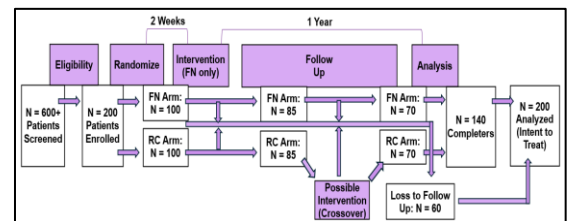
Demographics, socioeconomic status (SES), and patient-reported outcomes. A research assistant (RA) will conduct a structured, questionnaire-based interview of study participants. The questionnaire will consist of validated measures, including the Nigerian Demographic Health Survey, FACIT-COST, SF-12, WHO STEPS questionnaires, and Standard & Poor's Global FinLit survey.^{54,55} The questionnaire will elicit information on demographics (baseline only), SES, clinical history, financial literacy, financial distress, and health-related quality of life. It will be administered at baseline, 3 months, 6 months, and 1-year post-randomization. **Cancer diagnosis and treatment data.** Diagnostic information (method of diagnosis, cancer stage, and immunohistochemistry), recommended treatments, and received treatments will be extracted from medical charts by the RAs and confirmed by their medical oncologist. These data will be collected at baseline and 6-months and 1-year post-randomization. **Out-of-pocket cost data.** Direct internal costs (costs incurred by the patient at the study site facility) will be abstracted from billing data by the RAs. Participants will be asked to keep receipts for external costs related to their cancer treatment (direct costs for treatment at other facilities). Indirect costs such as transportation costs and lost wages and productivity for both patients and caregivers will be obtained from structured interviews by the RAs. Estimated lost wages will be calculated from average daily wages obtained from the interview multiplied by days missed from work because of cancer treatment. Participants will report these to the RAs throughout the study period.

C.4.f. Data collection and storage. All data will be collected and stored in a REDCap database at OAUTHC. This database has been used for data management since 2016 for multiple ARGO studies.



C.4.g. Statistical analysis. General considerations:

Data summaries by trial arm will include mean, standard deviation, median, and quartiles, as appropriate. By arm comparisons we will employ two-sample t-tests, Wilcoxon's, or tests for proportions. All statistical analyses will be completed in R v 4.1 or higher (R Foundation). The primary outcome will be **financial catastrophe (FC)**, defined as health expenditures



that exceed 10% of the HHI, 25% of HHE, or 40% of non-subsistence expenditure.²⁸ To assess FC, we will sum all direct and indirect OOP related to cancer treatments and represent this as a proportion of their HHI, HHE, and HSE. We will also calculate the risk of FC for those that stop treatment due to their inability to pay. To assess the impact of the FNP on FC, we will use two-sample tests for difference in proportions, at a one-sided alpha level of 5%. Additionally, we will perform multiple logistic regression with LASSO variable selection to identify factors associated with FC. The pool of independent variables will include treatment arm, cancer type, cancer stage, age, sex, site, and SES. The household wealth index⁵⁶ using a validated 10-item household living instrument that includes dwelling characteristics and ownership. From this SES wealth quintiles will be estimated.

Financial distress (FD) will be measured with the FACIT-COST instrument, which is based on 12 Likert-scale

questions and has been validated for cancer patients in multiple countries and has been applied in Nigeria.^{57,58} To determine differences in FD by trial arm, we will compare FACIT-COST questionnaire scores (range 0-44) using a two-sample t-test and declare statistical significance at a one-sided alpha level of 5%. A corresponding 95% confidence interval will be calculated. These calculations will be based on scores at 6 months. In cases of missing 6-month scores, 3-month scores will be included. Additionally, we will perform multiple linear regression with LASSO variable selection, with predictors selected among treatment arm, cancer type, cancer stage, age, sex, and SES.

C.4.h. Exploratory secondary analysis. We will perform an exploratory sub-group analysis to evaluate the impact of FNP on cost-related non-adherence. We will collect data on delays in presentation, treatment initiation, and deviation from recommended treatment via structured interview of the participants and the treating medical oncologist by the RAs at 6 months. For each treatment modality, we will calculate the proportion of participants that were prescribed the treatment but did not pursue it. We also will capture whether it was not pursued due to cost. We will compare these proportions between the treatment and control groups using 95% confidence intervals and utilize multivariable logistic regression modeling with relevant variables.

C.4.i. Sample Size Determination. All sample size calculations are based on a 5% alpha level, 80% power, and a 1:1 control vs treatment allocation ratio. **Financial Catastrophe (FC).** Sample size was estimated based on 1) HHI, 2) cost of treatment, and 3) cost-savings from FNP. Calculations were repeated for multiple income distributions (entire country, Lagos state, and studies from SW region). The expected average cost of cancer care was derived from two large studies ($n > 200$ patients each) in the SW region and estimated at \$4,754 ($SD = \$5,046$).^{16,59} The estimate for cost-savings, \$2,500, is based on the fixed effect of insurance (HMOS) on OOP and the extent of cost-sharing. Our estimates are based on verified plans that cover cancer patients and do not exclude based on pre-existing conditions. The effect of self-navigation through borrowing and foundations may vary. Based on these estimates, we expect that approximately 80% of the control arm and 64% of the treatment arm would experience FC. To detect this difference at a one-sided alpha of 5% using a test for proportions requires 95 participants per arm (190 total). **Financial Distress (FD).** A previous study of PC patients in Nigeria found a mean COST-FACIT score of 26.5 ($SD = 10.08$).⁵⁸ Studies on FNPs in the U.S.^{50,51,60} have reported 7-point FD improvements on average, though these samples had worse baseline scores ($COST < 19$), so we expect a smaller effect in our sample. We expect an average score of 26.5 ($SD = 10.08$) in the control arm and 31.5 ($SD = 10.08$) in the experimental arm. To detect this difference at a one-sided 5% alpha level using a two-sample t-test, and account for 20% attrition to the 3-month follow-up questionnaire, requires 60 participants per arm (120 total). Using the largest sample size requirement for analysis of the above outcomes, our total recruitment target for this study will be 200 participants (100 in each arm).

C.4.j. Crossover from Control to Treatment Arm. An interim analysis will be conducted once 50% of the recruitment target (100 participants total) have completed at least 6-months of follow-up, which is estimated to occur around 1 year from study start. Applying our power calculations for 100 participants, we would need to observe a 23% difference in incidence of FC and a 5.6-point difference in FD scores between trial arms at one-sided 5% significance. If these significant differences are observed, this will be sufficient evidence for the effectiveness of the FNP and all enrolled participants in the control arm will be given access to the FNP. We would continue to collect endpoint-related data until study completion (1 year follow-up for all enrolled participants).

C.4.k. Sex as a biological variable. Both men and women will be enrolled in the study, and differences in outcomes will be analyzed by sex. Sex will be included in multiple regression models.

C.5. Specific Aim 2: Conduct a budget impact and cost-effective analysis of the FNP.

C.5.a. Preliminary data. In a baseline feasibility survey of 19 stakeholders at LCC, 95% agreed or strongly agreed that the FN would be beneficial, 95% liked the idea, and 90% agreed or strongly agreed that a FN is suitable. Among providers, 83% agreed or strongly agreed that assigning a FN seems like a good match and 90% felt that it would be feasible. Similarly, at OAUTHC, where nine stakeholders responded, 90% agreed or strongly agreed that the FN would be beneficial and 90% welcomed the idea and felt it was feasible. LCC leadership perceived the benefits of the FNP to be high, thus hired a FN permanently on staff prior to the inception of this study.

C.5.b. Study design and methods. The study sites will collect longitudinal data on the activities of the FN, time and money spent on implementing and providing financial navigation, and the financial benefit to the patients and sites as a result of the FNP.

C.5.c. Primary outcomes and analysis. Activities. The FN will keep a weekly log of the time spent on different activities such as communicating with patients, contacting charitable organizations, and registering patients for insurance. **Patients insured.** The FN will track the number of patients they registered for insurance. **Cost of**

FNP. We will collect data on the salaries of the FNs and any costs associated with implementing the program, such as hiring, training, and consultation fees. **Funding secured.** For participants in the treatment arm, FNs will track the total amount of funding obtained from charitable organizations or insurance claims for newly insured patients. To analyze cost-benefit, we will compare the total cost of providing the FNP with the total amount of funding secured at each site. The primary outcomes will be cost of the FNP, amount of funding secured, number of participants insured.

D. Anticipated Challenges and Alternative Strategies

Cost to participate. Participation in the study will require frequent telephone communication. Therefore, we will provide telephone transfer credit to participants. Telephone credits in this setting can also function as cash transfer for use for other treatment related activities.

Loss to follow-up and missing data. We estimate that 20% of the enrolled patients will die from their cancer within the 1-year follow-up period based on studies on cancer survival in Nigeria.^{4,7,9} Loss-to-follow-up for reasons other than death (stopped treatment, transfer of care, or withdrawal) is estimated to be about 10% over the 1-year study period,^{7,9,37} resulting in a completion rate of 70%. Given the minimal risk of the intervention and the perceived benefits to the participants undergoing treatment, we expect that the drop-out rate in the intervention arm will be minimal. Furthermore, the timeline of our outcome assessment in line with the timeline of follow-up and treatment for CRC, PC, and BC, which will facilitate follow-up. Informative dropout may occur as participants at higher risk of FC or FD may decide to discontinue participation. We will collect information on the reasons for dropout. If informative dropout appears plausible, we will conduct additional statistical analyses that addresses this aspect.^{61–63} We will provide cross-tabulations of the proportions of missing values on all baseline characteristics, as well as on the primary outcome measures. To assess whether there are systematic differences between those lost-to-follow-up and those not—and thus whether these factors should be included in analysis—we will model missingness at follow-up as a function of baseline covariates, including the intervention. **Participants language and literacy.** There may be challenges in language and literacy given the large catchment area of both sites. The RAs and FNs are fluent in English and speak some of the native languages. The questionnaire will be in English for standardization, but the questions may be asked in the language of the patient's preference. The use of the interviewers will minimize variations in the patients' ability to understand the questions—they are not expected to be able to read or write, as all data will be collected in a structured interview format. The RAs are staff members at both institutions and have significant experience in conducting surveys. A study-specific training through ARGO will be conducted with all RAs, project managers, and FNs before the study's inception.

E. Timeline. Based on figures for newly diagnosed BC, CRC, and PC patients at the study sites in recent years, we estimate that it will take 6-9 months to recruit the 200 participants needed accomplish Specific Aim 1. Enrollment may be extended as needed to reach the target recruitment and complete data collection within the award's length. With a 1-year follow-up period, we estimate that it will take between 18-21 months to collect all the data needed to accomplish Aim 1. The cost-benefit analyses for Aim 2 will be done as soon as data from Aim 1 is available.

F. Deliverables. We plan to conduct an interim analysis of our findings at six months on FC and FD and disseminate these results through a publication. We plan to present our findings at national and international conferences and to the ministry of health of Nigeria. We will provide a layman summary of the findings to the participants in the study prior to crossover. We will provide a progress report of the activities of the study at both sites to the Data Safety Monitoring Board. The results of the study will be published at the conclusion of the study.

G. Future directions. This research- the first of its kind will inform the role of FNP in eliminating barriers to cancer care and improving treatment outcomes in Nigeria. It will also show if there are differences based on financial risk protection of the FNP and identify cost factors that may impact treatment-related outcomes. After establishing the efficacy and effectiveness of the FNP. We would like to investigate the influence of contextual factors using RE-AIM framework to study the implementation and adoption of FNP through a RO1 or UGH/UH3 grant mechanism. We plan for this to be the first of a series of pragmatic studies to address these significant gaps in universal health coverage for cancer care in SSA.

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