Mount Zion Health Fund

1. Applicant/s name; title; UCSF Mount Zion academic affiliation; Community Partner affiliation (if applicable)

   Applicant: Dr. Shannon Fogh, Associate Professor, Faculty: Osher Center for Integrative Health and Radiation Oncology

   Community Partner: Maple Tree Cancer Alliance

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3. Project Title: Implementation of a Structured Exercise Program for Oncology Patients

4. Brief Project Description (including the following elements):

List of Goals:

1. Demonstrate the feasibility of patient participation and adherence to a prescribed exercise program. Specifically, the percent of patients exercising >150 minutes per week at baseline, 6 and 12 weeks and frequency and type of adverse events.
2. Understand and validate the best exercise strategies for patients with cancer and modifications appropriate for different places in the patients' disease and treatment.
3. Measure and evaluate the functional outcomes of participation, including Timed-up and Go (TUG) test, 30 Second Chair Stand, Four Stage Balance Test and BMI.
4. Evaluate patient-reported health-related quality of life as measured by the global QOL, physical functioning, role functioning, and social functioning domains on the EORTC Quality of Life Questionnaire (QLQ-C30).
5. Understand unique patient preferences and barriers to participation for patients with varying functional status and across different demographics.
6. Assess relationships between functional outcomes and quality of life.
7. Assess health care utilization, including ER visits and hospitalizations of participants.

Summary of healthcare-related needs being addressed:

Cancer is a significant national health problem. The long-term physical and psychological side effects of cancer and its treatment negatively impact the cancer survivor's quality of life, causing cancer to be classified as a chronic disease by the Centers of Disease Control. Survival, while the most common outcome measure, may not address components of a patient's quality of life. How toxicities of treatment are managed makes a great difference in quality of life both during and after treatment.

Exercise has been demonstrated to positively impact patients with cancer, and government and leading health organizations such as the American Institute for Cancer Research, American Cancer Society (Clark et al), and the American Society of Clinical Oncology (Ligibel et al 2022) have included exercise among cancer-prevention guidelines. The 2019 Exercise Guidelines for

Cancer Survivors was based on a consensus statement from an International Multidisciplinary Roundtable recommending a combination of aerobic and resistance exercise based on multiple studies demonstrating benefit in cancer patients across multiple symptom domains from fatigue and functional status to mood and quality of life. Importantly, many studies have also demonstrated an overall survival benefit when exercise guidelines are met. Conversely, studies have demonstrated a fivefold increase in death in patients who are not active.

Despite these recommendations, most hospitals and clinics have not implemented personalized cancer exercise programs due to workforce, funding, and infrastructure limitations. This represents a quality gap between what we know benefits patients with cancer and the implemenation of an intervention which has continuously demonstated a positive impact on patients. Specifically, when provided as part of a comprehensive cancer plan, individualized exercise has clear benefits, including reductions in treatment-related side effects, higher chemotherapy completion rates, improved physical fitness and functionality, and increases in health-related quality of life. Further, reductions in health care utilization have been reported. This is noteworthy as unplanned hospitalizations contribute half of the cost of cancer care. Nevertheless, 85% of patients are sedentary at the time of their diagnosis, and shockingly, less than 5% engage in exercise programs during cancer treatment. Furthermore, less then 5% of cancer patients are ever referred to an exercise program, and approximately 2% of patients meet the published exercise recommendations.

Challenges inherent to creating a generalizable program for all patients include the wide range of physical deficits patients can present with, depending on the location of the cancer and prior and current treatments and medications. This can lead to considerable variability in baseline strength, balance, and muscle mass. Steroid use, as well, can deplete muscle mass and create difficulty with completing traditional exercises. This is exacerbated by fluctuating side effects, including radiation-induced fatigue, arguing for an individualized and flexible program providing patients with options when side effects of treatment are more prevalent.

The UCSF Cancer Exercise Counseling Program has led an important effort within the Cancer Center to offer one-on-one fitness counseling to adult cancer patients and survivors. During a one-hour session with an exercise counselor, patients receive education and training on activities related to cardio, strength, balance, and flexibility. These efforts are entirely supported by gift funds, and there is no cost to patients. While this program has been an incredible asset to patient care, important limitations include:

1) Exclusion of patients who do not speak English as a primary language.
2) Availability: Currently only one exercise specialist is available with 8 clinic slots per week.
3) Exclusion of many of our patients based on physical abilities: This service is limited to fully functional patients who are able to safely perform these activities at a baseline level.
4) A focus on exercise counseling vs. implementation of a true exercise intervention.

These limitations exclude many of our patients who have graduated from physical therapy and could benefit from a structured exercise program. Specific examples include patients who do not speak English as a primary language, as well as patients who have deficits from their primary tumor or treatment. This includes patients who are non-ambulatory or who have pain or neurologic symptoms, including cognitive changes, motor function, balance, visual symptoms, and other physical deficits which can be amplified by traditional treatments including surgery, systemic therapy, and radiation therapy.

While there are challenges inherent to creating a generalizable program for all patients, the Maple Tree Cancer Alliance has created exercise programing for patients with both physical limitations and has made substantial efforts to offer exercise programs to patients who do not speak English. Maple Tree has developed trainers with experience in working with patients with functional deficits, including patients who are not ambulatory or have pain or other physical limitations. Additionally, they have developed materials that are available in Spanish, Mandarin, Portuguese, and Arabic. They are actively hiring trainers proficient in multiple languages and are comfortable offering sessions with the assistance of an interpreter, as well.

The purpose of this proposal is to demonstrate the feasibility of implementing individualized exercise programs for patients with cancer and their impact on functional measures and patient reported quality of life and cognition. We will also assess patient exercise preferences, barriers to activity and modifications appropriate for different functional limitations. Our long-term goal is to develop programs for every patient in the cancer center, regardless of their functional limitations, primary language, or socioeconomic status, and to engage them as early as possible and support them through their treatment journey.

5. Roles of UCSF and Community Partner(s), if applicable

The exercise program will be offered through a partnership with Maple Tree Cancer Alliance, a 501(c)(3) non-profit organization that has developed a unique, evidence-based model of exercise programming that has gained national attention.

6. Name(s), title(s), agency/department/division(s) of individuals who will lead the project, with brief background information relevant to ability to accomplish the project activities

Dr. Shannon Elizabeth Fogh is a Radiation Oncologist and Integrative Oncologist. After completing her fellowship in Integrative Medicine, Dr. Fogh joined the faculty at the Osher Center for Integrative Health with a practice focused on integrative approaches for all patients living with a cancer diagnosis. Her research interests are centered on developing and implementing integrative treatments to improve survival, reduce treatment toxicities and improve quality of life and preservation of neurocognitive function. She was integral to the efforts to implement and study the impact of a dedicated exercise program for patients with primary brain tumors and is dedicated to implementing individualized exercise programs for patients living with and beyond cancer.

Karen Wonders, Ph.D., FACSM, is the Founder of Maple Tree Cancer Alliance. She also serves as a Professor of Exercise Physiology at Wright State University and Program Director over the undergraduate Exercise Science Program. The primary focus of her research is on the physiological and financial impact of exercise during cancer treatment.

Other Investigators/Collaborators:
Kavita Mishra; Integrative Oncologist, Osher Center Faculty
Donald Abrams: Integrative Oncologist, Osher Center Faculty
Natalie Marshal: Integrative fellowship graduate with expertise in implementation of exercise programs for cancer patients.

7. Note which of the six MZHF <u>values</u> the project embodies:

- Service (Avodah): A major goal of this project is serving all patients with a cancer diagnosis who can and should be able to benefit from the impact exercise can have on survival, functional status, and quality of life.
- Social Justice (Tikkun Olam): This project seeks to create inclusive exercise programing by including patients with physical limitations and patients who do not speak English as a primary language.
- Innovation (Hidush): We seek to be one of the first cancer centers in the United States to implement exercise programming and to measure the qualitative and quantitative impact of formal exercise programing.
- Compassion (Rahamin): By creating programs that do not exclude participation based on physical ability, socioeconomic status, or language barriers.

8. Project start date and duration (earliest start date is January 1, 2023):

March 1, 2023-March 2024

9. Estimate of total budget required and the amount requested from MZHF.

$75,000

Proposal:

1: Specific Aims:

The aims of the proposed project are to understand the feasibility of and barriers to implementing a comprehensive exercise program for patients with cancer, as well as the program's impact on functional outcomes and health related quality of life. We will also assess patient exercise preferences, barriers to activity and modifications appropriate for different functional limitations. Our long-term goal is to develop programs for every patient in the cancer center and engage patients as early as possible and support them through their treatment journey.

The hypothesis will be tested by addressing the following aims:

1. Demonstrate the feasibility of patient participation and adherence to a prescribed exercise program. Specifically, the percent of patients exercising >150 minutes per week at baseline, 6 and 12 weeks and frequency and type of adverse events.
2. Understand and validate the best exercise strategies for patients with cancer and modifications appropriate for different places in the patient's disease and treatment.
3. Measure and evaluate the functional outcomes of participation including Timed-up and Go (TUG) test, 30 Second Chair Stand, Four Stage Balance Test and BMI.
4. Evaluate patient-reported health-related quality of life (HRQOL), as measured by the global QOL, physical functioning, role functioning, emotion functioning and social functioning domains on the EORTC Quality of Life Questionnaire (QLQ-C30). In addition, to measure patient-reported cognitive function, as measured by the cognitive functioning subscale of the EORTC QLQ-C30.
5. Understand unique patient preferences and barriers to participation in patients with varying functional status and across different cultures and socioeconomic status.
6. Assess relationships between functional outcomes and quality of life.
7. Assess health care utilization including ER visits and hospitalizations of participants.

Experimental Design and Methodology:

This is an observational, mixed methods implementation science pilot study examining the feasibility, adherence, and impact of a tailored exercise program for patients with cancer.

Patients will be referred to a certified exercise specialist by e-mail or through the electronic medical record (EMR). Following this referral, a patient intake appointment is completed to assess baseline functional and quality of life status, health concerns, health history, current fitness/activity levels, available resources, and desired goals. Patients will be assessed for function and quality of life at 3 time points throughout the duration of the trial. These include at initial assessment and at 6 weeks and 12 weeks, after starting the program. Completion of quality-of-life forms will be done electronically or by patient interview. **Quality of life forms are offered in multiple languages and support will be provided to patients who may not have access to computers or other means to complete the survey and/or patients who might struggle with navigating an online survey.**

As this program is intended to complement and supplement existing exercise resources, we will work closely with relevant stakeholders to maximize availability of services to patients. Priority will be given to vulnerable patient populations including but not limited to, patients with physical limitations or impairments, patients with limited access to exercise resources and patients who do not speak English.

Based on the results of the initial assessment, an exercise prescription is developed. This exercise intervention is individualized according to the patient's current health status and goals and is in-line with ACSM's published guidelines on exercise for cancer patients. Exercises will include cardiorespiratory endurance, muscular strength, and balance. Exercise duration and intensity are systematically progressed based on patient tolerance. All sessions are completed one-on-one with a trainer who holds a minimum of a bachelor's degree in an Exercise Science-related field and a nationally accredited Exercise Oncology Instructor certification. The individualized program will be sent to the patient through the EMR with links to the appropriate resources for further assistance.

The individualized exercise program will last 6-12 weeks depending on the individual plan created for the patient.

After completion of the program, participants will repeat the assessments done at baseline pertaining to functional status, cognitive function, and quality of life. Patient adherence will also be measured. These assessments will be repeated at 12 weeks following the start of the program to assess for sustainability of program recommendations for exercise and functional and quality of life outcomes.

Primary Objectives/outcomes:

- Patient demographics including age, diagnosis, sex, previous and current treatment, and medications including dose and duration of steroids and antiepileptic medications.

- Number of patients referred and individual and overall adherence with the program, including number of prescribed sessions completed percent of patients exercising >150

minutes per week at baseline, 6 and 12 weeks *(as able*).

- Patients' ability to complete prescribed exercise as well as any feedback about challenges or difficulties they faced in completing certain exercises. We will track modifications based on this feedback. This will allow us to understand and validate the best exercise strategies for individual patients and modifications appropriate for different places in the patient's disease and treatment. This qualitative data will be collected by interviews, open text boxes for feedback as part of electronic surveys and ongoing dialogue with the exercise counselor during visits.

- Cardiovascular fitness/functional status will be measured by:
  Timed-up and Go (TUG)
  30 Second Chair Stand
  Four Stage Balance Test

- Body Mass Index (BMI) based on height and weight recorded at a clinic visit within 3 months or self-reported

- Current weekly steps as self-reported by a mobile fitness app (if available)

- Patient-reported health-related quality of life (HRQOL), as measured by the global QOL, physical functioning, role functioning, emotion functioning and social functioning domains on the EORTC Quality of Life Questionnaire (QLQ-C30).

- Patient-reported cognitive function, as measured by the cognitive functioning subscale of the EORTC QLQ-C30.

- Adverse events: Determined by frequency, type or absence of significant adverse events recorded during the study period to include experiencing chest pain, shortness of breath, falls, and dizziness (without falls) during exercising. Minor adverse events could include muscle pain and use of OTC pain medication after exercising.

- Health care utilization including ER visits and hospitalizations of participants.

Primary Objective:

The primary objective of this investigation is to assess the feasibility, recruitment, adherence, and impact of a patient's participation in a supervised, individualized exercise program for oncology patients. The intervention will be considered feasible and with a high adherence if this study produces less than 20% exercise dropout rate and 70% completion of prescribed exercises over the 6-week program.

Secondary Objectives:

Changes in functional outcomes from baseline to post-intervention at 6 weeks and 3 months including

- Timed-up and Go (TUG)
- 30 Second Chair Stand

- Four Stage Balance Test
- Body Mass Index (BMI) based on height and weight recorded at a clinic visit within 3 months or self-reported
- Current weekly steps

Changes in patient-reported health-related quality of life (HRQOL), as measured by the global QOL, physical functioning, role functioning, emotion functioning and social functioning domains on the EORTC Quality of Life Questionnaire (QLQ-C30) post-intervention (6 weeks) and 3 months.

Changes in patient-reported cognitive function, as measured by the cognitive functioning subscale of the EORTC QLQ-C30 at initial assessment and at three months from baseline.

Quality of Life and Functional Outcomes assessment tools

The EORTC QLQ-C30 is the instrument most frequently used to measure quality of life (QOL) in cancer patients. Importantly, it is offered and is validated in over 50 languages.

The **Timed Up and Go** (TUG) test is a performance-based measure of functional mobility that was initially developed to identify mobility and balance impairments in older adults. It measures both static and dynamic balance and is used to help determine current performance level and how safe it is to complete certain activities. It will be used in this patient population to help determine the appropriate exercise program and to monitor progress throughout the program. [https://www.cdc.gov/steadi/pdf/TUG_test-print.pdf]

The **Four-Stage Balance Test** is used in conjunction with other measures such as the 30 second Chair Stand Test and TUG test as an assessment of postural hypotension which can help indicate if a patient is a risk of falling. In this test, patients are asked to perform four progressively more challenging positions without the help of an assistive device. Specific positions each held for 10 seconds with patients eyes open include a parallel stance, semi-tandem stance, tandem (Heel-Toe) stance and one-legged stance. [https://www.cdc.gov/steadi/pdf/4-Stage_Balance_Test-print.pdf]

The 30 **Second Chair Stand**, combined with other tests can help evaluate risk of postural hypotension and a patient's risk of falling in addition to leg strength and endurance. The number of times patients can rise to a full standing position and return to a seated position during a 30 second interval is documented. This can be helpful in creating an appropriate exercise program as well as monitoring progress as patients increase activity. [https://www.cdc.gov/steadi/pdf/STEADI-Assessment-30Sec-508.pdf]

Data collection:

Data will be collected by electronic survey and patient interviews and stored in a REDCAP database.

Plan for evaluation and data analysis:

Primary endpoint:

The primary endpoint is feasibility, defined by adherence of patient's participation in a customized exercise program for patients with cancer. The intervention will be considered feasible with a less than 20% drop out rate and 70% completion of exercises in patients enrolled. We anticipate enrolling 50 patients in one year.

Secondary endpoints:

Changes in patient functional outcomes from baseline, post-intervention and 3 months assessed for each individually:

- Timed-up and Go (TUG)
- 30 Second Chair Stand
- Four Stage Balance Test
- Body Mass Index (BMI) based on height and weight recorded at a clinic visit within 3 months or self-reported
- Current weekly steps as self-reported by a mobile fitness app (if available)

Improvement in patient-reported health-related quality of life (HRQOL), as measured by the global QOL, physical functioning, role functioning, emotion functioning and social functioning domains on the EORTC Quality of Life Questionnaire (QLQ-C30) at baseline, post-intervention and at 3 months. Since higher scores indicate better functioning, an increase of 10% from baseline indicates an improvement in function.

Improvement from baseline to post-intervention and 3 months following the intervention in the following subscales will be assessed and compared using Fisher's exact test: global QOL, physical functioning, role functioning, emotional functioning, and social functioning domains along with fatigue and pain items.

Exploratory Outcomes:

Assess barriers for participants to participating in an exercise program by a survey conducted within the first 2 weeks of study participation. Results of a survey will be presented using descriptive statistics.

Aim five focuses on understanding the barriers and facilitators to uptake and successful completion of the exercise program by a demographically diverse group of participants. Pilot data we have collected indicates that exercise preferences and barriers differ across patients from different cultures, functional and socioeconomic status. To ensure diversity of responses we will perform one-on one interviews with 15 Mandarin, Spanish and English-speaking patients selected for varying levels of completion of the pilot program. Additionally, we will interview 15 patients with high functional status (defined as KPS of 90 or above) and compare to patients with low functional status $\leq$ KPS of 80) or with an identified physical deficit. All patient interviews and surveys will be additionally stratified by socioeconomic factors including but not limited to income and education level.

Interviews will focus on asking patients if they were able to exercise as much as they had planned, what barriers they faced to exercising, their satisfaction with the program, what factors associated with the program helped them exercise more, how the program helped them cope with cancer and how their quality of life was affected by the program.

Additionally, we hope to assess relationships between functional outcomes and quality of life.

Finally, we hope to analyze hospitalizations and urgent care visits of participating patients to develop pilot data for understanding the impact of exercise on health care utilization.

2. Anticipated benefit for underserved or vulnerable communities in San Francisco:

One in three people will develop cancer in their lifetime and between 54.4-90% will have some physical or functional limitations depending on the location of the cancer and prior and current treatments and medications. This can lead to considerable variability in baseline strength, balance, and muscle mass. Steroid use can deplete muscle mass and create difficulty with completing traditional exercises. This is exacerbated by fluctuating side effects including radiation-induced fatigue. This can lead to challenges leaving the home, social isolation, navigating physical barriers at home such as stairs and even completing activities of daily living, creating vulnerabilities in this patient population. Importantly, approximately 40% of patients diagnosed with cancer do not speak English and 20% are at or below the poverty level without financial means to pay for in-house therapy, personal trainers, access to gyms or exercise equipment.

The UCSF Cancer Exercise Counseling Program has led an important effort within the cancer center to offer one-on-one fitness counseling to adult cancer patients and survivors. During a one-hour session with an exercise counselor, patients receive education and training on activities related to cardio, strength, balance, and flexibility. These efforts are entirely supported by gift funds. While this program has been an incredible asset to patient care, important limitations include:

- Exclusion of patients who do not speak English as a primary language.
- Availability: Currently only one exercise specialist is available with 8 clinic slots per week.
- Exclusion of many of our patients based on physical abilities: This service is limited to fully functional patients who are able to safely perform these activities at a baseline level.
- A focus on exercise counseling vs a true exercise intervention.

These limitations exclude many of our patients who have graduated from physical therapy and could benefit from a structured exercise program. Specific examples include patients who have deficits from their primary tumor or treatment, such as patients who are non-ambulatory, have pain or neurologic symptoms including cognitive changes, motor function, balance, visual symptoms, and other physical deficits which can be amplified by traditional treatments including surgery, systemic therapy, and radiation therapy. Importantly, this also excludes patients who do not speak English as a primary language.

Role of Community Partner:

While there are challenges inherent to creating a generalizable program for all patients, the Maple Tree Cancer Alliance has created exercise programing for patients with both physical limitations and has made substantial efforts to offer exercise programs to patients who do not speak English. They have developed trainers with experience in working with patients with functional deficits, including patients who are not ambulatory or have pain or other physical limitations. Additionally, they have developed materials that are available in Spanish, Mandarin,

Portuguese, and Arabic. They are actively hiring trainers proficient in multiple languages and are comfortable offering sessions with the assistance of an interpreter as well.

3: How the project addresses UCSF Mount Zion priorities and compelling San Francisco healthcare needs.

This project would provide a critical service free of charge to underserved and vulnerable patients diagnosed with cancer. There is a significant gap between national guidelines that recommend exercise to benefit quality of life, mitigate treatment related symptoms and improve survival and, access to resources to facilitate this. This is a significant unmet health-related need impacting all our cancer patients in San Francisco, including our patients seen and treated at our Mt. Zion location and patients seen in our Integrative Oncology practice at the Osher Center for Integrative Health.

Both our patients and providers want access to these resources as well! Our preliminary needs assessment, consisting of qualitative interviews and surveys with patients and multidisciplinary team members, including physicians, indicated that 100% of providers and patients reported that exercise is Important to Very Important for patients' lifestyle. Most providers (92%) reported that exercise was Important for patients' lifestyle and 80% felt it should be integrated into the treatment of patients with cancer. Ninety-six percent felt that exercise improved quality of life, decreased fatigue (100%) and reduced treatment-related side effects (92%). While patients and providers were motivated to refer and support patients' participation in a customized exercise program, there is very limited availability of exercise counselors. Additionally, patient feedback indicated a preference to be part of a more structured program with more frequent visits, to assess progress and modify exercises if needed.

This project embodies many of the MZHF values, including Social Justice, as we seek to create inclusive exercise programing by including patients with physical limitations and patients who do not speak English as a primary language; Innovation, as we seek to be one of the first cancer centers in the United States to implement clinical access, research, as we measure the impact of formal exercise programing; and Compassion, by creating programs that do not exclude participation based on physical ability, ability to pay, or language barriers.

4.Type and duration of campus-community partnership, if applicable:

Plan for sustainability:

Pilot data from this grant will be critical to determining both need for services, guidance for widespread implementation and outcomes in cancer patients including demonstration of exercise on cost savings. Specifically, there is growing evidence that exercise oncology, when properly performed, improves functional outcomes, quality of life, survival and serves as a cost savings event by reducing unplanned visits to the emergency room and decreasing the number of hospitalizations needed to manage the complications that can occur during and after treatment.

Despite evidence that exercise can be beneficial to patients' quality of life and survival, in addition to providing cost saving, widespread incorporation of exercise into the treatment plan of

newly diagnosed cancer patients has been severely limited by the absence of many of the conventional methods for clinical activity reimbursement.

Our overall goal is to ensure this service is available to all cancer patients. We are actively working to obtain Category III CPT codes for exercise interventions. These codes are temporary codes for new and emerging therapies that allow data collection and assessment of new services to substantiate widespread usage of new and emerging interventions to justify the establishment of a permanent Category I CPT code.

We believe pilot data from this program would be integral to this effort and to UCSF through the Mt. Zion Health Fund, which would be leading this effort to obtain reimbursement for exercise nationally and to create a national model for exercise counseling.

Pilot data from this program will also be presented to the Cancer Center leadership and be critical for ongoing infrastructure, dissemination, and support.

5.How the community partner's experience and expertise was integrated into proposal development:

The exercise program will be offered through a partnership with Maple Tree Cancer Alliance, a 501(c)(3) non-profit organization that has developed a unique, evidence-based model of exercise programming that has gained national attention. Maple Tree Cancer Alliance is dedicated to improving the quality of life of individuals who battle cancer that creates program of supervised, individualized exercise training. In other types of cancers, they have demonstrated improved patient outcomes in terms of increased fitness parameters, decreased symptom severity, and decreased health care utilization.

Program Outcomes: The following charts represent the outcomes data Maple Tree has measured on the patients who have completed their programs showing improvement in domains including quality of life, multiple fitness parameters and health care utilization. (n=11,328).