Assessing Quality of Life and the Feasibility of a Nutrition and Pharmacological Algorithm for Oncology Patients with Anorexia

CONFIDENTIAL

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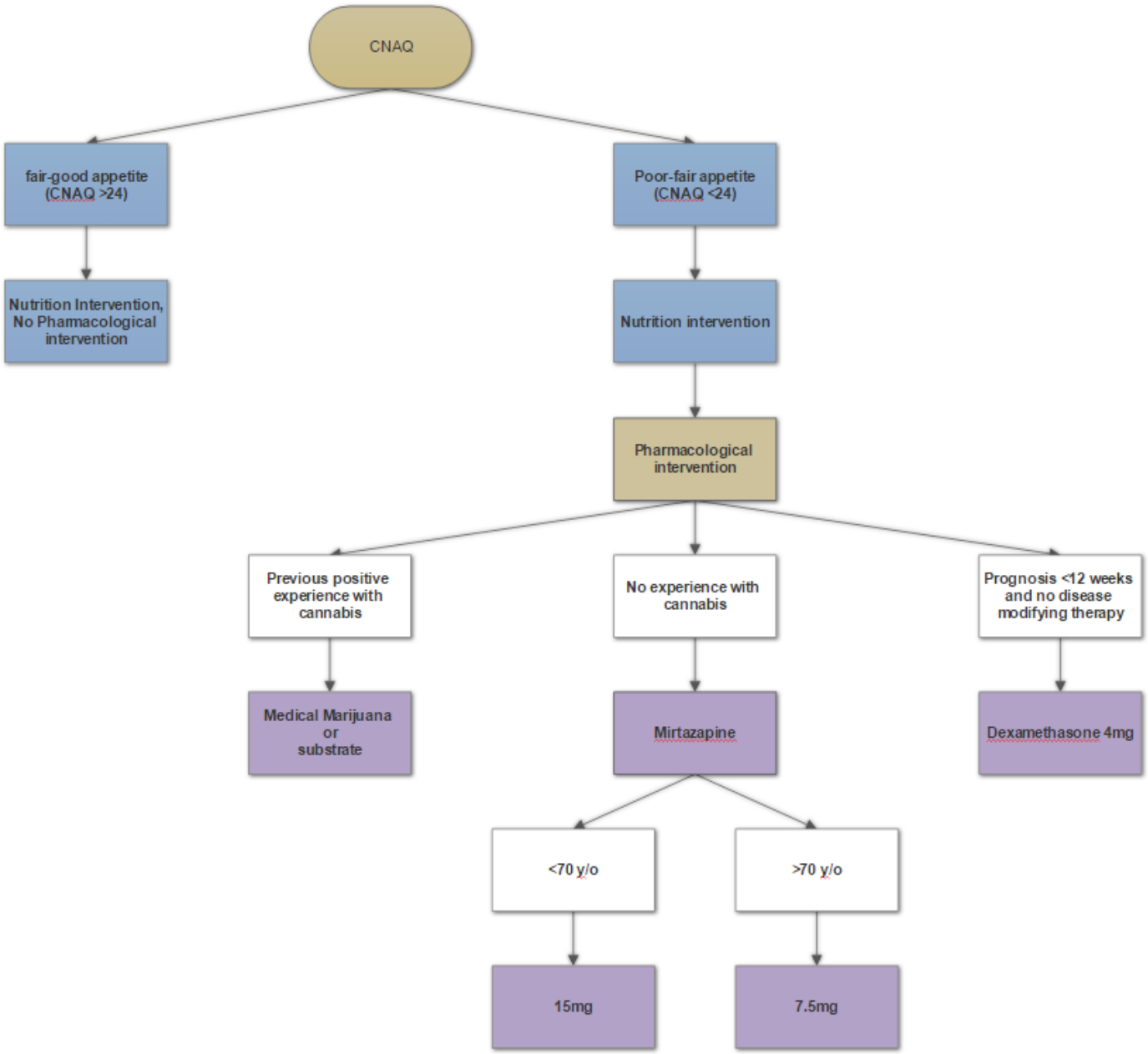

Assessing Quality of Life and the Feasibility of a Nutrition and Pharmacological Algorithm for Oncology Patients With Anorexia

1.0 BACKGROUND

1.1 Background and Significance

Cancer is one of the leading causes of death in the United States, accounting for nearly one out of every four deaths each year. According to the American Cancer Society, the lifetime risk for developing cancer is approximately one in three for women and one in two for men; of those diagnosed, one in four men and one in five women will ultimately die.[1]

Cancer patients are particularly vulnerable to nutritional depletion as a result of the joint impact of the malignant disease process and its treatment.[2] The frequency of weight loss and malnutrition in oncology patients has been estimated to range from 31 to 87 percent.[3] Among most types of cancer, weight loss has been associated with a decreased ability to perform activities of daily living (ADLs), and even a six percent weight loss has been found to predict a diminished response to treatment, survival, and quality of life.[4] Weight change and associated performance status are important, as they can potentially influence decisions about modality, dosage, and timing of treatment(s).

Malnutrition has been given the definition of "a state of nutrition in which a deficiency or excess (or imbalance) of energy, protein, and other nutrients causes measurable adverse effects on tissue/body form (body shape, size and composition) and function and clinical outcome."[5] Many studies examining the consequences of malnutrition in the oncology population have revealed increased morbidity and mortality rates when compared to well-nourished patients.[6] It has been proposed that cancer patients often die from malnutrition and its related complications rather than from the direct effects of the disease itself.[7] Thus, the identification of oncology patients at nutritional risk and implementation of nutritional intervention is critical to ultimately reduce cancer morbidity and mortality.[8]

In addition to malnutrition, the oncology population often suffers from a cachexia syndrome. Cancer cachexia is a term which is given to patients who have ongoing loss of skeletal muscle mass, insulin resistance, along with other nutritional and medical abnormalities. It is characterized by an “ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment”.[9] Typically, cachexia is first seen when a patient experiences anorexia. The consequence of the anorexia can affect the patient and caregivers in many different ways including, physical, psychological, social, and existentially. The patients and caregivers often feel negative emotions with regards to cachexia and malnutrition.[10] Some of these negative emotions are described as “sadness, disappointment, bewilderment, confusion, bother, concern, dissatisfaction, feeling upset, anger, frustration, guilt, desperation, anguish, fear, anxiety, and existential distress”.[11] This stress is not only on the oncology patient but the caregiver as well.

There is no single cause of the symptoms associated with cancer cachexia despite years of research. Along with the causes, there is not one particular treatment plan for this syndrome. Jointly there are three main interventions which are pertinent in treating and managing cancer cachexia. These are antitumor treatment, nutrition intervention, and pharmaceutical intervention.

Nutrition assessment and intervention of patient is one of the most crucial steps in a patient’s care. Nutritional assessment of cancer patients can reveal mild or moderate states of malnutrition before the patient becomes visibly wasted.[12-18] With in-depth nutritional assessment, performed by an RD or medical professional, the presence of symptoms that may adversely affect nutritional status is documented, which enables the planning of appropriately individualized interventions. Early and intensive nutrition intervention provides beneficial outcomes in terms of positive impact on nutrition status, physical function, quality of life, weight maintenance, and overall survival in oncology patients. Poor nutritional status at baseline is associated with worse outcomes that may aggravate from both disease course and its treatments, thus oncology patients at risk for malnutrition should receive early, regular and individualized nutrition intervention and support.[19-23]

Many pharmacological agents have been studied in order to help prevent deterioration of patients. However, many of the results remain variable. Some studies have found there may be a benefit in terms of appetite but limited increase in lean body mass and continued weight loss in patients despite medicine administration. However, overall improved quality of life (QOL) may be possible for these patients. There is not currently one pharmacologic agent which has been proven to be beneficial for the general oncology population.[24]

With anorexia being a major symptom of cancer cachexia and the psychological stress which impacts the patient and caregivers, and limited research showing the benefit of both nutrition intervention and pharmacological agents on overall survival and lean body mass, our goal to is focus on decreasing the suffering and distress associated with eating in our patients.

2.0 AIMS

2.1 Aim 1

- To establish the feasibility of implementing an algorithm for nutrition interventions in our Cancer Center

2.2 Aim 2

- To assess associations between appetite scores and general quality of life measures in cancer patients.

3.0 METHODS/DESIGN

The patients must fulfill the following inclusion criteria prior to entering the study.

3.1 Inclusion Criteria

1. Patients with a diagnosis of head/neck, lung, pancreatic cancer, or metastatic disease of any solid primary malignancy
2. Planned, ongoing, or recently treated patient (within the past 30 days) with radiation therapy, chemotherapy, immunotherapy, and/or intravenous targeted biologic therapy
3. No previous use of appetite stimulants (steroid use for purposes other than appetite stimulant is allowed)
4. All patients must sign study specific informed consent prior to being included in the study
5. No contraindication to appetite stimulants

4.0 METHODS/DESIGN

4.1 Patient Selection

Patients with head/neck, lung, pancreatic cancer or metastatic disease of any solid primary malignancy will be screened for the study using the Oncology Nutrition Assessment which is currently the Standard of Care in the Montefiore Einstein Center for Cancer Care (Appendix 1). The patients will then be informed regarding the study and decide to join or not. The patients who wish not to be included will be asked as to why if open to answer.

4.2 Study Design

Appetite Assessments

This study will utilize the validated Council of Nutrition appetite questionnaire (CNAQ) (Appendix 2) to evaluate the effect of the nutrition intervention and pharmacological agents on patients'

appetite and nutritional intake. The CNAQ has been used in many studies as a validated questionnaire to assess appetite. The patient populations in these studies have ranged from community-dwelling adults and nursing home residents to patients with chronic diseases like ALS.[25-26] It has also been used as a validated analysis of appetite in studies with patients with liver cancer in Taiwan and head and neck cancer. [27-28]

The patients will fill out this questionnaire weekly to assess change. If the patient scores >28 on the CNAQ, then the questionnaire will be administered biweekly, as will the nutrition education.

Quality of Life Assessments

All participants will also be asked to complete a quality of life survey (Functional Assessment of Cancer Therapy-General Population (FACT-GP), Appendix 3) on a weekly or biweekly basis at the same time as the nutrition assessment. If a patient is not present in the Medical Oncology or Radiation Therapy at the time either assessment is due, the assessments will be performed over the phone.

FACT-GP measures quality of life by asking about physical, function, emotional, and social wellbeing. In its creation, the questionnaire was modified to so it can be applicable to the general cancer population. It has been used to assess quality of life in many different sites of cancer. [29-33]

Nutritional Status

Nutritional status will be determined based on the answers to the appetite assessment and quality of life questionnaire, as well as the nutrition assessment provided by the Registered Dietitian. No lab values will be used to assess nutrition status during the course of this study.

Algorithm

The patient care will follow a pathway based on their responses to the CNAQ and clinical judgment of the physician and dietitian. The patients with fair-good appetite (score on CNAQ >24) will not receive any pharmacological agents and will receive nutrition intervention alone. Nutrition intervention will be in accordance with the Academy of Nutrition and Dietetics guidelines. The intervention will involve "purposefully planned action(s) designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition, or aspect of health status" [34].

The patients with poor-fair appetite (score on CNAQ <24) will be provided nutrition intervention by the Registered Dietitian and then put into one of three pharmacological groups. If the patient's prognosis is extremely poor (<12 weeks expected survival, based on discussion with the patient's treating physicians) and there is no additional disease modifying therapy planned, the patient will be prescribed 4mg dexamethasone (which is FDA approved), once daily, to be taken orally in the morning. Dexamethasone is given to patients with a limited expected lifespans because it has been found to be effective on a short-term basis. Also, the long-term usage of steroids has been found to myopathy and other various side effects. [35]

If a patient has a history of marijuana use or has tried it in the past, then he/she will be prescribed medical marijuana based on financial availability due to previous exposure exhibiting better tolerance to the drug. If the marijuana is not feasible, he or she will be prescribed dronabinol (which is FDA approved). Dronabinol is used as a substitute as it is contains synthetic delta-9-tetrahydrocannabinol (THC), a substrate of marijuana and therefore has a similar affect to medical marijuana. Since dronabinol is compounded similarly to medical marijuana, then for this patient population the tolerance to the medication is likely to be good. [36-38]

If the patient does not have any history of marijuana use, mirtazapine will be prescribed. Mirtazapine has been show to improve both appetite and quality of like in cancer patients. [39-41] Dosing mirtazapine was determined by guidelines published by the US Department of Veterans Affairs/Department of Defense. If the patient is under the age of 70, then she/he would be prescribed 15mg of mirtazapine (which is FDA approved), once daily, to be taken orally at bedtime. For geriatric population (if the

patient is over the age of 70), then she/he would be prescribed 7.5mg of mirtazapine, once daily to be taken orally at bedtime.

Refer to the flowchart (Appendix 4) for the sample pathway.

Study Duration

The study period will begin after the initial screening and immediately following study registration and last for three months.

4.3 Primary Study Endpoint

The primary endpoint of this study is assessing the impact on quality of life for the oncology patients by using an algorithm for nutrition intervention and appetite stimulants.

4.4 Exploratory Secondary Study Endpoints

- Hydration administration in the clinics
- Emergency Room visits
- Hospital admissions and days spent in the hospital

5.0 STATISTICAL CONSIDERATIONS

Primary Endpoint:

The primary endpoint of the study is administration of the appropriate nutrition/pharmaceutical intervention, as defined by our algorithm, within 30 days of study enrollment. A secondary and exploratory endpoint is to assess associations between appetite scores and general quality of life measures.

Statistical Analysis:

Descriptive statistics (eg: counts, percentages) will be used to report each of the following measures:

- number of potential subjects screened
- number of potential subjects who met inclusion criteria
- number of subjects consented/enrolled
- study subject demographics
- number of subjects completing baseline assessments
- number of subjects receiving nutritional intervention following the study algorithm
- number dropped out will be presented as frequency counts and percentages along with their 95% confidence intervals

Associations between appetite scores and quality of life will be examined using analysis of variance (for continuous scale variables) and Cochran Mantel Haenzsel testing (for categorical variables). Changes in quality of life scores over time will be examined using covariance pattern models or linear mixed models, as appropriate.

Sample Size Justification:

This is a pilot study to examine the feasibility of implementing our nutritional intervention algorithm in the study population. We have based the sample size on precision in estimating the rate of feasibility. We hypothesize that we will be successful in implementing the algorithm in 85% of the study population. We will recruit a total of 30 participants, which would produce a 95% confidence interval around our point estimate of the feasibility rate whose width is 28% (i.e. 67% to 95%), based on the exact (Clopper-Pearson) formula.

Exploratory Secondary Endpoints:

Descriptive statistics will be utilized to characterize quality of life measures over time for study subjects and to characterize the frequency of outpatient IV fluid hydration episodes, Emergency Room visits, and hospital admissions in study subjects.

6.0 REGULATORY CONSIDERATIONS

6.1 Protection of Human Subjects

The Investigator must ensure that patients or their legally acceptable representatives are clearly and fully informed about the purpose, potential risks and other critical issues regarding clinical trials in which they volunteer to participate. Preparation of the consent form is the responsibility of the Investigator and must include all elements required by CFR 21 Part 50.25 and the local IRB.

6.2 Compliance with the Protocol and Protocol Revisions

The study must be conducted as described in this approved protocol. All revisions to the protocol must be provided to the PI. The PI should not implement any deviation or change to the protocol without prior review and documented approval/favorable opinion from the IRB/IEC of an Amendment, except where necessary to eliminate an immediate hazard(s) to study patients.

The investigator must ensure that patients or their legally acceptable representatives are clearly and fully informed about the purpose, potential risks and other critical issues regarding clinical trials in which they volunteer to participate. Preparation of the consent form is the responsibility of the PI.

6.3 Registration and Enrollment

All patients will be registered through the Clinical Trials Office at Montefiore Medical Center. On Study Form and the signed Patient Consent Form must be emailed to the clinical trials office at Montefiore Medical Center, cpdmuregistration@montefiore.org, at the time of registration and prior to patient treatment. At the same time, patient will be registered into the Velos system at ctms.montefiore.org. Recruitment will occur during standard of care visits by the treating physician. At the time of registration, all eligibility criteria must be checked. Patients must meet all of the eligibility requirements listed in Section 3.1. Data collection must not start prior to registration. It is the study coordinator's responsibility to review all data submitted to Velos and the Clinical Trials Office for accuracy and completeness, and he/she must sign off on the study form.

7.0 DATA HANDLING AND RECORD KEEPING

7.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.
- In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

7.2 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial.

7.3 Data Safety Monitoring

As this is not a therapeutic trial, regular review of study conduct, adverse events, and results by a Data Safety and Monitoring Board is not required.

7.4 Data Recording

An excel spreadsheet will be used to record the CNAQ score, FACT-GP score, date of assessment and medication provided for each visit.

KEY INFORMATION FOR ASSESSING QUALITY OF LIFE AND THE FEASIBILITY OF A NUTRITION AND PHARMACOLOGICAL ALGORITHM FOR ONCOLOGY PATIENTS WITH ANOREXIA

We are asking you to choose whether or not to volunteer for a research study about nutrition education with regards to a low or decreased appetite and its and an appetite's stimulant's effect on your quality of life. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The goal of this study is to decrease the suffering and distress associated with eating during cancer treatment. Loss of appetite is a common symptom and can cause distress which impacts patients and caregivers so this study's goal is to reduce the stresses and improve the quality of life of the patient. There is no one medicine which has been proven to be to help the general cancer population in terms of appetite, so this study has a pathway to potentially help improve the patient's quality of life and appetite. By doing this study, we hope to learn about ways to improve patient's quality of life. Your participation in this research will last 3 months.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You are being asked to participate in this study because you were screened by a nursing assessment, which indicated a need to be seen by a Registered Dietitian. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may not want to participate in this study because you will have to fill out a questionnaire weekly or biweekly while undergoing your treatment and afterwards. *For a complete description of risks, refer to the Consent Document below.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of the study is Rachel Padilla. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is 718-920-6720.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called Assessing Quality of Life and the Feasibility of a Nutrition and Pharmacological Algorithm for Oncology Patients With Anorexia. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Rachel Padilla. You can reach Mrs. Padilla at: **Office Address:** **111 East 210th Street** **Bronx, NY, 10467** **Telephone #: (718) 920-6720** For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.	The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail: Einstein IRB Albert Einstein College of Medicine 1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461

Why is this study being done?

The goal of this study is to decrease the suffering and distress associated with eating during cancer treatment. Loss of appetite is a common symptom and can cause distress which impacts patients and caregivers so this study's goal is to reduce the stresses and improve the quality of life of the patient. There is no one medicine which has been proven to be to help the general cancer population in terms of appetite, so this study has a pathway to potentially help improve the patient's quality of life and appetite.

Why am I being asked to participate?

You are being asked to participate in this study because you were screened by a nursing assessment, which indicated a need to be seen by a Registered Dietitian. Patients with a diagnosis of head/neck, lung, pancreatic cancer, or metastatic disease of any solid primary cancer with planned, ongoing, or were recently treated (within the past 30 days) with radiation therapy, chemotherapy, immunotherapy, and/or intravenous targeted biologic therapy are included in this study. Also, no previous use of appetite stimulants and no contraindication to appetite stimulants are included in this study. Approximately 30 patients are going to be enrolled in this study. This study is only taking place at the Moses Campus of Montefiore Einstein Center for Cancer Care.

All patients must sign study specific informed consent prior to being included in the study and have no contraindication to appetite stimulants.

How many people will take part in the research study?

You will be one of about 30 people who will be participating in this study.

How long will I take part in this research?

It will take you about 3 months to complete this research study. During this time, we will ask you to make at least one visit to Montefiore Medical Center.

What will happen if I participate in the study?

Your appetite will be assessed initially by a validated Council of Nutrition Appetite Questionnaire. After which, you will either receive nutrition counseling alone or nutrition counseling with an appetite stimulant. The questionnaire will be given weekly if your appetite is poor. If it is fair or good, then the questionnaire will be given biweekly, as will the nutrition education. You will also receive quality of life survey on a weekly or biweekly basis at the same time as the nutrition assessment. If your appetite is found to be poor, then you will be given one of four possible appetite stimulants. The possible appetite stimulants are: medical marijuana or marinol, mirtazapine, and dexamethasone.

The study will begin after the initial screening and immediately following study registration and last for three months

As part of this study we will review your medical records and put the information we collect in our research records.

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

If you take part in this study, you or your insurance will pay for the appetite stimulant which is most appropriate for you.

What will happen if I am injured because I took part in this study?

Unfunded Research

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Rachel Padilla, 718-920-6720

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any risks to me?

We do not think there are any physical risks related to participating in this research study.

There are some potential side effects from taking the appetite stimulants. Please alert your doctor, Registered Dietitian, or research coordinator if you are experiencing any of these.
For dronabinol, >10% of the patients experience euphoria. Other not so common side effects can be: facial flushing, dizziness, abnormal thinking, drowsiness, paranoia, stomach pain, nausea, and vomiting.
For mirtazapine, >10% of the patients can experience drowsiness, dry mouth, or constipation. Other not so common side effects can be: swelling of the hands and feel, dizziness, abnormal dreams or thinking, skin rash, weakness, flu-like symptoms, and stomach pain.
For dexamethasone, patients can have irritability, difficult sleeping, swelling in hands and feel, heartburn, muscle weakness, impaired wound healing, and increase blood sugar levels. Other not so common side effects can be dizziness, headaches, mood swings, and cataracts and bone thinning (with long term use).

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the

study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include an improved quality of life and increased appetite. You will also receive frequent one-on-one nutrition counseling with a Registered Dietitian.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time

References:

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43.

Nutrition and Pharmacological Intervention for Oncology Patients With Anorexia
Eligibility Checklist

CONFIDENTIAL

The information contained in this document is regarded as confidential and, except to the extent necessary to obtain informed consent, may not be disclosed to another party unless law or regulations require such disclosure. Persons to whom the information is disclosed must be informed that the information is confidential and may not be further disclosed by them.

Inclusion Criteria (list each criteria)	**Yes** (all must be "yes" for eligibility)	**No**
1. Diagnosis of head/neck, lung, or pancreatic cancer or metastatic cancer of any primary solid malignancy		
2. Planned, ongoing, or recently treated patient (within the past 30 days) with radiation therapy, chemotherapy, immunotherapy, and/or intravenous targeted biologic therapy		
3. No previous use of appetite stimulants (steroid use for purposes other than appetite stimulant is allowed)		
4. Signed study specific informed consent prior to being included in the study		
5. No contraindication to appetite stimulants		

Participant is: Eligible Not Eligible

Completed by: _____ _____

Print Name Signature Date

Investigator: _____ _____

Print Name Signature Date

Appendix 1

Patient Diagnosis:
Patient has been diagnosed with the following:
Height/Weight:
Weight:
Symptoms
Problems eating: Yes/No
No appetite, just did not fell like eating (x1 week): Yes/No
Nausea/vomiting (x3 days): Yes/No
Constipation without BM (x>4 days): Yes/No
Mouth sores, oral mucositis: Yes/No
Problems or painful swallowing: Yes/No
Pain (specify where below): Yes/No
Diarrhea: Yes/No
Feel full quickly: Yes/No
Fatigue: Yes/No
Ostomy: Yes/No
Open wound or ulcer: Yes/No
Visible cachexia/muscle wasting: Yes/No
Trouble buying food: Yes/No
Assessment Completed (Auto-Calculation):
Referral to Nutritionist
Referral:

Appendix 2

Council on Nutrition Appetite Questionnaire

1) My appetite is
    1. Very poor
    2. Poor
    3. Average
    4. Good
    5. Very good

2) When I eat, I feel full after
    1. Eating only a few mouthfuls
    2. Eating about a third of a plate/meal
    3. Eating over half of a plate/meal
    4. Eating most of the food
    5. Hardly ever

3) I feel hungry
    1. Never
    2. Occasionally
    3. Some of the time
    4. Most of the time
    5. All of the time

4) Food tastes
    1. Very bad
    2. Bad
    3. Average
    4. Good
    5. Very good

5) Compared to when I was younger, food tastes
    1. Much worse
    2. Worse
    3. Just as good
    4. Better
    5. Much better

6) Normally, I eat
    1. Less than one regular meal a day
    2. One meal a day
    3. Two meals a day
    4. Three meals a day
    5. More than three meals a day (including snacks)

7) I feel sick or nauseated when I eat
    1. Most times
    2. Often
    3. Sometimes
    4. Rarely
    5. Never

8) Most of the time my mood is
    1. Very sad
    2. Sad
    3. Neither sad nor happy
    4. Happy
    5. Very happy

TOTAL SCORE: _____

Scoring Total the score by adding the numbers associated with the patient's response. A score of less than 28 is cause for concern. If the total is 8-16, the patient is at risk for anorexia and needs nutrition counseling. 17-28, the patient needs frequent reassessment. >28, the patient is not at risk at this time.

Appendix 3:

FACT-GP (Version 4)

Below is a list of statements that other people have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	<u>PHYSICAL WELL-BEING</u>	**Not at all**	**A little bit**	**Some -what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

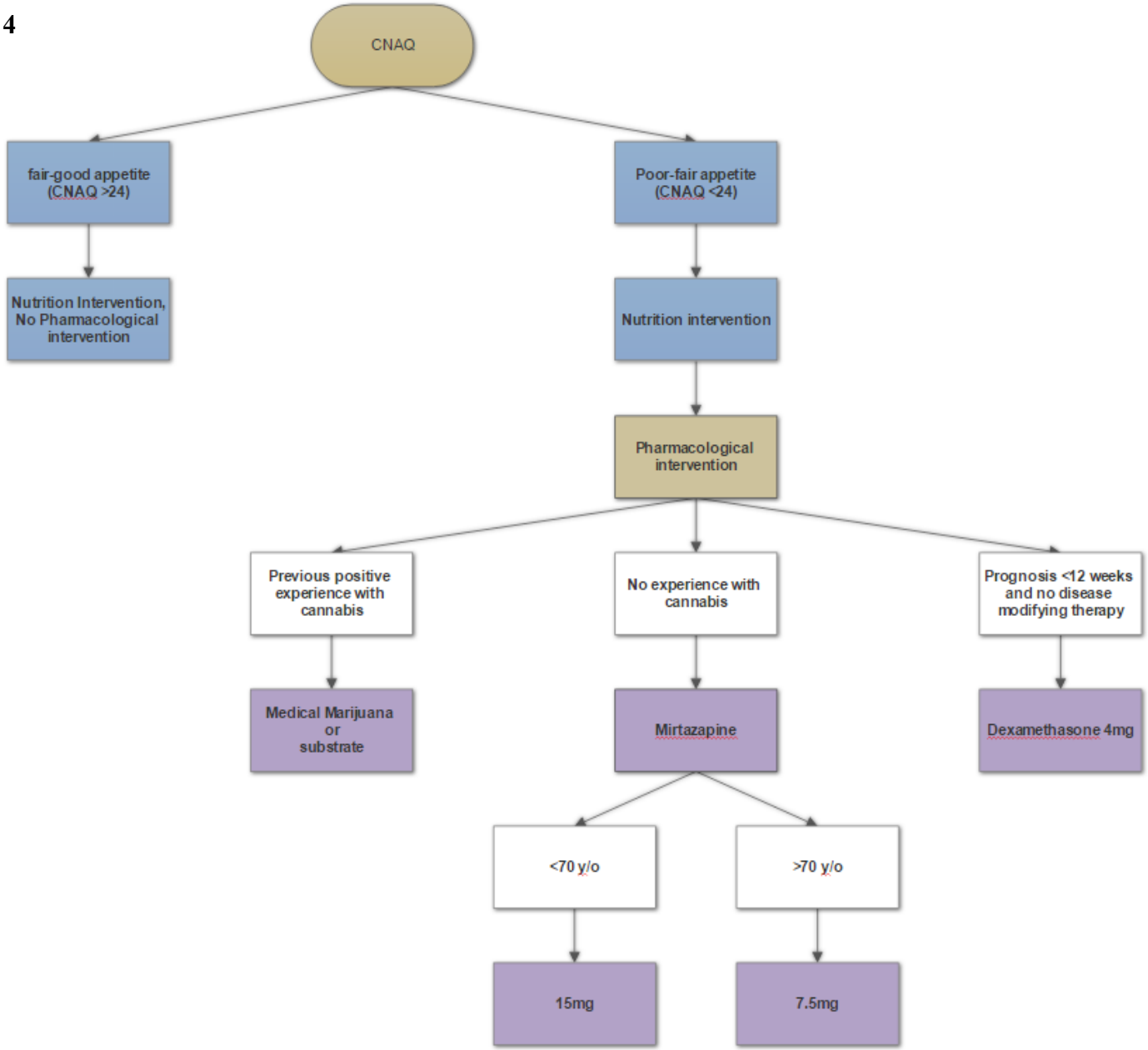
	<u>SOCIAL/FAMILY WELL-BEING</u>	**Not at all**	**A little bit**	**Some -what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4

Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some -what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some -what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF	I am content with the quality of my life right now	0	1	2	3	4

Appendix 4


CNAQ
fair-good appetite (CNAQ >24)
Poor-fair appetite (CNAQ <24)
Nutrition Intervention, No Pharmacological intervention
Nutrition intervention
Pharmacological intervention
Previous positive experience with cannabis
No experience with cannabis
Prognosis <12 weeks and no disease modifying therapy
Medical Marijuana or substrate
Mirtazapine
Dexamethasone 4mg
<70 y/o
>70 y/o
15mg
7.5mg