Long Protocol Title:
Culturally Adapted Cognitive Behavioral Stress and Self-Management (C-CBSM) Intervention for Prostate Cancer
Short Protocol Title: Encuentros de Salud – Por tu Salud Después del Cáncer

NCT#03344757

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Informed Consent

Health Gatherings – For Your Health After Cancer
(Encuentros de Salud – Por su Salud Después del Cáncer)

Purpose of this study:

Almost 2.8 million men are living with Prostate Cancer (PC). About 80% of PC cases are diagnosed with cancer that has not spread and have a 5-year relative survival rate of 100%.

Living after having PC often means dealing with long term side effects such as sexual and urinary problems, pain and fatigue. Side effects may lead to other issues such as distress, problems with intimate relationships, and the way you see yourself (for instance, body image and masculinity worries).

This study is sponsored by the National Cancer Institute (NCI). It is being done to look at the effects of a 10-week stress management in-person group program.

The program will study emotions, stress, and stress management techniques (such as relaxation and coping techniques) on quality of life, distress, depression, and physical health in Spanish-speaking, Hispanic/Latino men diagnosed with PC.

Why am I being asked to take part in this research study?

Based on your answers during a recent phone interview you seem to be a good participant for our study.

How long will the research last?

We expect that you will be in this study for about twelve (12) months.

How many people will be in the study?

We expect to enroll about 190 men in Miami and 10 in Chicago, for a total of 200 participants in the study.

What happens if I say, "Yes, I want to be in this research study?

If you agree to be in this study, you will be asked to take part in a 10-week in-person or remote group program via the telephone or video-conference. You will also complete four (4) in-person or remote interviews over the course of about 12 months. You will:

- Be asked to complete your first interview after signing the consent form. Someone from our study team will help you complete it.

- Be placed in a group (Group A or Group B) by random assignment, like flipping a coin. You have an equal chance of being put into either of these 2 groups. The 2 groups vary *only* in the way the information is talked about during sessions.

- Take part in a 10-week in-person or remote stress management program with other men like you. Trained group leaders will run both groups.

Each session will last about 90 minutes, with a small break in between.

During the meetings, you will be given facts on:

- stress
- coping with difficult events
- managing anger
- social support
- stress reactions
- how we make sense of events in our lives and how they can cause stress

You will also get information on how to practice the relaxation exercises on your own. We will give you an audio copy of our relaxation exercises you learned during the meetings.

You will be asked to complete 3 follow-up interviews with the help of one of our team members. The follow-up interviews will occur in-person or remotely via a phone call with a member of our team or via a conference platform like Zoom.

- The first follow-up interview will take place 3-months (plus or minus two month) from the first interview.
- The second interview within 6-months (plus or minus a month) from the first interview.
- The last interview is about 12-months (plus or minus a month) from the first interview.

You will be called 2 times after you finish the group meetings.

- The first call will be after your second follow-up interview.
- The second call will take place after the third follow up interview.

The reason for the phone calls is for us to answer any questions you might have about the materials given to you, your participation in the study, concerns, or any comments you may wish to express.

What do these in-person interviews look like?

Each study interview can take up to 2.5 hours to complete. This will depend on how much time you need to answer each question. You will be given breaks in-between if you wish.

The interviews look at different aspects of your life such as current life events and how you are coping with those events. These include your points of view and thoughts, social relationships and how anxious or depressed you are.

There will be interview questions on:

- what you think about yourself as a person
- what issues worry you most about your condition and its treatment
- how you keep yourself healthy
- mental and physical health
- alcohol and drug use/abuse
- COVID-19 impact

The in-person interviews can be done at one of our office locations, or at a place of your choice. The remote interviews can be done via phone or through a teleconference platform, like Zoom at a time that is convenient to you.

Following each interview, you will be asked to provide blood samples either via an intravenous blood draw (about 2 tablespoons) or remotely via blood spot collection. For the in-person intravenous blood draws we will make arrangements with one of our labs to schedule your blood draw.

We will also collect other health information such as:

- blood pressure
- height
- weight
- waist circumference

A trained person will collect this information at the time of your lab visit.

Remote dried blood spot (DBS) sample collection will be done by using a protein saver card to collect a total of 5 drops of blood. You will be mailed a blood spot packet consisting of a set of 2 protein saver cards, lancets, a desiccant, plastic bags, alcohol swabs, and gloves. You will also receive hard copy instructions on how to collect and ship samples. You will be asked to provide us with your current height and weight.

We are also interested in looking at your electronic medical record during the time you are in our study. If you agree to take part in this study, you are also letting us access your health records and collect data to use in our study. This may include:

- Information since your diagnosis like your Gleason Score, Prostate Specific Antigen (PSA) results, staging (i.e. TNM staging)
- Time since diagnosis
- Types of treatments
- HIV/AIDS status
- Sexually transmitted diseases (STD's)
- Mental health treatment records (i.e. involuntary or voluntary mental health treatment)
- Substance abuse (drug or alcohol) and treatment records
- Sexual assault information
- Information regarding hospitalizations (reason, number of days) during your participation in the study
- Cardiovascular Conditions (i.e. Congestive Heart Failure, Hypertension, Myocardial Infarction)
- Gastrointestinal Conditions (i.e. Crohn's Disease, Diverticulitis, Acute Esophagitis, Gastroenteritis, Intestinal Infections, Pancreatitis, Ulcerative Colitis, Hepatitis C)
- Behavioral & Cerebrovascular Conditions (i.e. AD, Delirium, Dementia with Delirium, Schizophrenia, Suicide Ideation, TIA, Withdrawal – Alcohol)
- Hematology & Oncology (i.e. Lymphoma & Leukemia, Malignant Neoplasm)
- Nephrology and Genitourinary Conditions (i.e. Chronic Kidney Disease, Nephrotic Syndrome)
- Respiratory Conditions (i.e. Asthma, COPD)
- Rheumatology Conditions (i.e. Graves's Disease, Rheumatoid Arthritis, CFS)
- Other Conditions (i.e. Bacteremia, Lupus, Sjogren's Syndrome)

This information is reviewed to see if any changes in your condition will have an impact on your quality of life while participating in the study. Study staff will collect this data from your health chart after each in-person interview.

You will also be asked if you agree to be audio or video recorded during the group sessions. This is voluntary and will not affect your participation in the study. The recordings are only to look at how the group therapist runs the 10-week group sessions.

Tapes are only seen by the supervisor and study team. The recording of the group sessions will occur only if all men in the session agree to be recorded. If any member of the group asks that no recording be made, it will not be recorded.

What are my rights as a participant in this study?

Participation in this study is voluntary. You can stop participating at any time and it will not be held against you. Whether or not you take part in this study, this will not affect the availability of any other treatment for you.

It will not affect your relations with Sylvester or UHealth, your doctors, or other personnel. Also, you will not lose any of the benefits to which you have the right to receive.

If you choose to take part in this study, you are still free to seek out any other forms of care in which you may be interested.

If you decide to leave the study, please contact the study team first. If you withdraw, no more data will be collected from you.

Is there any way being in this study could be bad for me?

Agreeing to this study involves some risks. For instance, there are certain risks associated with blood draws, like possible pain, discomfort and/or bruise at the site of blood draw that may last 1 or 2 days.

There is also a small risk of feeling lightheaded or fainting during or after the drawing of blood, and a small chance of infection at the site of the blood draw.

Some people may find that answering some questions in the survey can be upsetting, as they will ask you to recall stressful situations and your emotional responses to these situations. If at any time, you do not feel comfortable answering a question you can always choose to not answer such questions and/or stop the survey.

The group session experience may also cause you to think about stressful issues more closely than you would otherwise. These discomforts are generally temporary.

Every attempt will be made to provide relief and to remedy the source of discomfort. If you wish, we can refer you to a source of assistance for any distress that you may be experiencing.

Payment for Injury:

Injury is not likely and treatment will be available in most cases if harm occurs.

If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay.

Funds for pain, expenses, lost wages, and other damages caused by injury are not usually available.

Are there benefits to being in the study?

We cannot promise any benefits to you or others from your taking part in this study. Yet, the results of this study may help you and your medical team have a better understanding of how your disease and treatment affect your life. They can then aid in making decisions about emotional support for you and other people with the same condition.

The major benefit resulting from your participation in this study is to help us learn about the effects of stress management on quality of life, health behaviors, and physical health in men with PC.

Is there a cost to participating in the study?

This study involves completing surveys and blood collections. All expenses of these activities are paid by the study. Being in this study will involve no expense to you.

Will there be a reimbursement for participating in this study?

You will be paid $75.00 for each completed in-person interview and blood collection for a possible total of $300. Individuals who are not able to complete the blood collection or the entire in-person interview will be paid $50.00 and may earn $25.00 upon completion of the incomplete part of the in-person interview.

What happens to the information collected for the search?

All the information about you (survey responses, blood samples, and data from health records) will be coded by a special study ID code, not your name. A list will link the ID codes to names, but it will be kept separate from all the rest of the data. Your name will be used only when addressing you personally (for instance, in a phone conversation or during actual group sessions).

The information you give us once encoded and stripped of all personal data will be entered into a secured database linked to University of Miami, the main research site for this study.
We will use a program called RedCap to collect and store all the information you give us.

All your data will be secured by passwords so that only authorized persons can see them. Study personnel who will have access to your data will include: Northwestern University (NU) and University of Miami (UM) faculty, graduate students and the project manager.

Results from this project will be reported in professional journals as a group, not your specific results. Your records and data will not be identified as pertaining to you in any publication without your expressed permission.

We consider your data private to the full extent allowed by law, therefore we cannot promise complete privacy. Other groups that may request and review copies of your record include:

- The National Institutes of Health (funding agency),
- National Cancer Institute (NCI),
- Representatives from the Office for Human Research Protections (OHRP),
- Researchers taking part in this study at Northwestern Memorial Hospital, and NU Robert H. Lurie Comprehensive Cancer Center.

Your records may also be reviewed by UM officials or other personnel who will follow the same strict rules of confidentiality.

Information shared with people outside of UM and NU will not contain your direct personal data unless the law requires release of the information. The information may be viewed by the study sponsor and its partners or contractors at the office of the doctor in charge of the study in certain cases.

Group sessions are generally video or audio-recorded. The videos or audio tapes will be stored on a secure, in a locked room and cabinet. They may be used for up to 7 years after recording them for training.

Our study team will store your blood samples at our research laboratory space at Rosenstiel Medical Science Building, 1600 NW 10th Ave. # 3146A, Miami, FL 33136, until shipped to the University of California, Los Angeles (UCLA) for further analysis.

Your samples will be stored only for the length of our study (about 4 years) and will then be destroyed.

Only the laboratory staff and the supervising doctor will have access to your samples. Your samples will not be used for future research and will not be shared with other researchers.

Your samples will be labeled with a code that does not have any personal or identifying data. All your lab results are kept completely private and under no circumstances will the data gained from your samples be shared with anyone outside of our study team.

All data is kept in coded and password protected files on a locked network. Your name and any other identifying data are kept in a separate, locked and private location to ensure your identity cannot be linked to your samples. To ensure the security of your information, we will be *unable to give you with the medical results to your samples*.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding. For example, the information collected in this research cannot be used as evidence in a proceeding unless you consent to this use. Information, documents, or biospecimens protected by this CoC cannot be disclosed to anyone else who is not connected with the research, except:

- To a federal agency sponsoring this research when information is needed for auditing or program evaluations;
- To meet the requirements of the U.S. FDA;
- If a federal, state or local law requires disclosure such as a requirement to report a communicable disease;
- If information about you must be disclosed to prevent serious harm to yourself or others such as
- If you consent to the disclosure, including for your medical treatment, to an insurer or employer to obtain information about you; or
- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.
- To University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations.

This CoC also does not prevent you or a family member from voluntarily releasing information about yourself and your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

Can I be removed from the research without giving my OK?

The doctor in charge of the research study or the sponsor can remove you from the study without your approval. You may be removed from the study if there are possible risks to your overall health.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the study.

Who do I call if I have questions?

You are encouraged to ask any question related to the study at any time of your participation in this study. Our staff will be happy to answer any questions you may have.

Any new information found during the study that may affect your participation in this study will be given to you.

You may contact the person who leads the study if you have any questions about being a part of this study:
Dolores Perdomo, PhD.
Phone: 305-431-2574

You may also contact the doctor in charge of the study:

Frank Penedo, Ph.D.	Michael Antoni, Ph.D.
Frank.penedo@miami.edu	mantoni@miami.edu

If you have any questions regarding your rights as a research participant, you may contact the UM's Human Subjects Research Office at 305-243-3195.

Other Important Information

Dr. Frank Penedo is an inventor of the intellectual property used in the study. Dr. Penedo is also a compensated consultant for Blue Note Therapeutics.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

The results of this study may also be used for teaching, or presentations at scientific meetings. They may also be published. Data presented will not contain any information that could identify you. Although you may withdraw consent to be in this study at any time, you must withdraw authorization for use or disclosure of your health information in writing. To withdraw your authorization, write to:

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University of Miami
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Optional Elements:

The research activities below are optional, meaning that you do not have to agree to them to take part in the study. Please indicate if you would like to take part in these optional activities by placing *your initials* next to each activity.

I agree	I disagree	
_____	_____	The study team may audio or video record my sessions to aid with quality control and data evaluation. The study team will not share these recordings with anyone outside of the study team.
_____	_____	The study team may contact me in the future to see if I would be interested in taking part in other studies by the doctor in charge of this study.

Your signature documents your permission to take part in this study. Participant

Signature:

_____ _____
Signature of participant Date

_____
Printed name of participant

Study Personnel Signature:

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent

_____

Witness (if applicable)

_____

Printed name of witness