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

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LAKESHORE CANCER CENTER
SCREENING • TESTING • TREATMENT
We Care

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[Informed Consent Form for patients who are invited to participate in a research project on Financial Navigation on Financial Toxicity and Treatment Adherence for Cancer Care at Lakeshore Cancer Center in Lagos, Nigeria]

Part I: Collaborating Institutions

Lakeshore Cancer Center
Northwestern University

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part II: Information Sheet

Introduction

At Lakeshore Cancer Center we have partnered with Northwestern University in Chicago, Illinois on a study to understand the potential impact a Financial Navigation Program may have in alleviating the cost burden of cancer and improving the quality of life for patients in supporting their access and adherence to cancer care treatment options.

Key Information about this Research Study

This research will involve your participation if you agree to enroll in a new Financial Navigation Program with our research assistant or financial navigator. You are being invited to take part in this project because we feel that your experience with cancer can contribute to our understanding of how the connection to a financial navigation program has the potential to reduce cancer costs and improve treatment adherence and may be important in informing the government on how to give patients better access to cancer care. If you agree to participate in this study, you will be randomly assigned to either the treatment or control groups. If you are in the treatment group, you will receive financial navigation services from a trained financial navigator who will help you with your financial needs and concerns related to your cancer treatment. If you are in the control group, you will receive routine care with a research assistant. As part of the study, we will have access to your medical records, and you will be asked to complete a brief 10-minute survey regarding your social and financial background at different times throughout the study. Participation is voluntary and you will still be entitled to receive all the health care benefits at this hospital if you decide not to participate.

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

We are asking you to take part in this research study because paying for cancer care can mean significant costs for you and your family. We would like to know if the implementation of a financial navigation program has the benefit of helping you and your family by alleviating some of those costs and giving you more access to treatment options.

How many people will be in this study?

We expect about 96 people will be in this research study at Lakeshore Cancer Center.

What should I know about participating in this research study?

We will give you information about the program and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. At any point you have questions or need further explanation, please ask us to stop as we go through the information, and we will take time to address your questions in more detail. If you have questions later, you can ask them of me or another researcher. You can choose not to take part in this research study, that decision will not be held against you. You do not have to answer any question you do not want to answer.

Risks ***(Is there any way being in this research study could be bad for me?)***

We will be asking you to share some information regarding your health and financial status, and you may feel

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uncomfortable talking about some of the topics. You do not have to answer any questions or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.

Benefits *(Will participating in this study help me in any way?)*
There may not be any direct benefit to you, but your participation is likely to help us improve access to cancer care in your community and country. There is no payment or reimbursement for participating in this study. Compensation in the form of phone credit may be possible.

What happens if I do not want to be in this research, or if I change my mind later?
Participation in this study is voluntary. You can decide whether to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship and the care you receive at Lakeshore Cancer Center.

Confidentiality *(How will the researchers protect my information?)*
Your participation is confidential. The information that we collect from this research project will be kept private. Any information about you will have a number instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except outside of the research team. Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who need to review this information.

How might the information collected in this study be shared in the future?
We will keep the information we collect about you during this research study for study recordkeeping and potential use in future research projects. If the study data contains information that directly identifies its participants: Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you. De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data is shared. Despite these measures, we cannot guarantee the anonymity of your data. The Principal Investigator (PI) would like to retain your contact information to contact you for future research participation. This information will not be shared with other researchers but will only be retained for potential interest in research with this PI. We will ask for your consent to do so at the end of this form.

You can be in this current research study without agreeing to future research use of your identifiable information. The results of this study could be shared in articles and presentations but will not include any information that identifies you unless you permit the use of information that identifies you in articles and presentations. Study results will be made available to patients upon request to the PI.

Who can I talk to?
If you have questions, concerns, or complaints, you can contact the Principal Investigator, Dr. Juliet Lumati at juliet.lumati@northwestern.edu or the study's Co-Investigator, Dr. Chineye Iwuji at ciwuji@lakeshorecc.org.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB in the United States by phone at +1 (312) 503-1376 or by email at irbcompliance@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

This research has also been reviewed and approved by the Health Research Ethics Committee (CMUL) within the College of Medicine at the University of Lagos, Research Management Office in Nigeria. For questions, you may contact the Chairman of the CMUL HREC, Prof. S.A. Omilabu by phone at +234 802 864 2463 or by email at hrec@cmul.edu.ng.

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The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may use **video and/or photographs** of me in scholarly presentations or publications when showing my face or hearing my voice might serve to help others understand the research. I may be identifiable as part of this activity.
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator.

Part III: Certificate of Consent

I have been invited to participate in research about the implementation of a Financial Navigation Program at Lakeshore Cancer Center.

This section must be written in the first person. It should include a few brief statements about:
(This section is mandatory)
I have read the previous information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year
If

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **Thumbprint of participant**

Signature of witness _____

Date _____
Day/Month/Year

Statement by the researcher/person taking consent: I confirm that the participant was allowed to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/Month/Year