Childhood Cancer Survivorship Intervention Program in Western Kenya

PROTOCOL VERSION: 01-05-2024

Consent forms

1. Caregivers Educational Program Control Group
2. Caregivers Educational Program Intervention Group
3. Healthcare providers Follow-Up Program

CONSENT FORM – Caregivers Educational Program Control Group

Participants of study:

Caregivers of childhood cancer patients who are in the last two months of their treatment

Study information:

This study assesses the follow-up adherence of childhood cancer survivors in follow-up after completion of treatment. The study also explores the caregivers' knowledge about cancer diagnoses, treatment and late effects risk. The insights obtained through this study will help us to improve follow-up of childhood cancer survivors after completion of treatment. You have the opportunity to read this study information form, or have the form read aloud, and ask questions about the content and goals of the study.

Follow-up adherence will be evaluated at 3, 6, 9, 12, 18 and 24 months after treatment completion. In case of follow-up non-adherence we will make a call to find out reasons for non-adherence and evaluate treatment outcome status.

We will perform two knowledge assessments: the pre-test should be completed during the last two months of cancer treatment. At six months after completion of treatment, you will receive a final knowledge assessment.

If you agree to participate in the study, you will be questioned about your knowledge of your cancer diagnosis, survivorship care and the risks of developing late or long-term treatment effects. All data collected from you will be dealt with confidentially. The research data will only be available to dedicated researchers. Participating in the study is voluntary. Saying no will not affect your rights to health care or any other services. Any additional information about the study results will be shared after concluding the study.

Risk and benefits:

There are no risks involved for participating caregivers. Caregivers will be educated about their cancer diagnosis and survivorship care and their treatment outcome status will be frequently evaluated. There will be no monetary compensation.

Confidentiality:

All reasonable efforts will be made to keep your information private and confidential. Using or sharing of such information will follow National privacy guidelines. By signing the consent form, you are giving permission for the use and disclosure of your study information. Study information cannot be traced back to any individual. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed by paper shredding. You are free to quit the study at any time. If you want to withdraw your permission for use of your personal data, you should contact the investigators. Health information collected before this

withdrawal may continue to be used for the purposes of reporting and research quality.
Information from this research will not be added to your medical record.
You have the right to see and copy your personal information related to the research study for as long as the study team holds this information. You will receive a copy of this form if you decide to sign it.

Consent:

I have read or have had someone read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks, discomfort, and possible benefits of the study. I freely volunteer to take part in this study.

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Name of participant	Name of researcher
……	……
Signature of participant and date	Signature of researcher and date
……	……..
Name of witness	Name of Principal Investigator (PI)
……	……
Signature of witness and date	Signature of PI and date

Contacts for questions about the study:

PI Contact Information: [Dr. Festus Njuguna; muigaifes2000@yahoo.com]

Co-Investigator Contact Information: [Drs. Susan Mageto; susanmageto.mageto@gmail.com]

Questions about your rights as a participant:

You may contact the Institutional Ethics and Research Committee (MTRH//MU-IREC) 0787723677 or email irec@mtrh.go.ke or irecoffice@gmail.com. The MTRH//MU-IREC is a group of people that review studies for safety and to protect the rights of participants.

Address: Moi Teaching and Referral Hospital, Nandi Road, Eldoret, Kenya
Telephone Number: +254 53 2032393

Study Title: Survivorship Intervention Program
Organizations: Moi Teaching Referral Hospital | Moi University | Princess Máxima Center
Sponsors: World Child Cancer NL | AFAS Foundation
PI: Dr. Festus Njuguna | Co-Investigators: Drs. Susan Mageto; Drs. Jesse Lemmen

CONSENT FORM – Caregivers Educational Program Intervention Group

Participants of study:

Caregivers of childhood cancer patients who are in the last two months of their cancer treatment at MTRH

Study information:

This study assesses the follow-up adherence of childhood cancer survivors in follow-up after completion of treatment. The study also explores the caregivers' knowledge about cancer diagnoses, treatment and late effects risk. The insights obtained through this study will help us to improve follow-up of childhood cancer survivors after completion of treatment. You have the opportunity to read this study information form, or have the form read aloud, and ask questions about the content and goals of the study.

Follow-up adherence will be evaluated at 3, 6, 9, 12, 18 and 24 months after treatment completion. In case of follow-up non-adherence we will make a call to find out reasons for non-adherence and evaluate treatment outcome status.

Caregivers will receive a video presentation, an educational booklet and a Survivorship Card addressing the importance of follow-up after completion of treatment, the risks of physical late effects, psychosocial late effects, stigmatization, and social reintegration. We will perform three knowledge assessments: the pre-test should be completed before receiving the educational intervention. After completion of treatment, you will complete another knowledge assessment to investigate knowledge uptake. At six months after completion of treatment, you will receive a final knowledge assessment. Satisfaction of caregivers about the educational intervention, will also be measured after this time point.

If you agree to participate in the study, you will be questioned about your knowledge of your cancer diagnosis, survivorship care and the risks of developing late or long-term treatment effects. You will also be questioned about what you liked about the educational material and how the content could possibly be improved. All data collected from you will be dealt with confidentially. The research data will only be available to dedicated researchers. Participating in the study is voluntary. Saying no will not affect your rights to health care or any other services. Any additional information about the study results will be shared after concluding the study.

Risk and benefits:

There are no risks involved for participating caregivers. Caregivers will be educated about their cancer diagnosis and survivorship care and their treatment outcome status will be frequently evaluated. There will be no monetary compensation.

Confidentiality:

All reasonable efforts will be made to keep your information private and confidential. Using or sharing of such information will follow National privacy guidelines. By signing the consent

form, you are giving permission for the use and disclosure of your study information. Study information cannot be traced back to any individual. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed by paper shredding. You are free to quit the study at any time. If you want to withdraw your permission for use of your personal data, you should contact the investigators. Health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality. Information from this research will not be added to your medical record.
You have the right to see and copy your personal information related to the research study for as long as the study team holds this information. You will receive a copy of this form if you decide to sign it.

Consent:

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CONSENT FORM – HEALTHCARE PROVIDERS Follow-up Program

Participants of study:

Healthcare providers involved in the management of pediatric oncology patients at MTRH

Study information:

This study explores the healthcare providers' experience with survivorship, their knowledge about cancer diagnoses, treatment and late effects risk. We are investigating how a comprehensive presentation about survivorship care, may improve the knowledge of pediatric oncology healthcare providers. The insights obtained through this study will help us to improve follow-up of childhood cancer survivors after completion of treatment. You have the opportunity to read this study information form, or have the form read aloud, and ask questions about the content and goals of the study.

We will perform three knowledge assessments: one should be completed before the beginning of the presentation. After finishing the training, you will complete another knowledge assessment to investigate knowledge uptake. At six months after completion of the training, you will be subjected to a final knowledge assessment. Satisfaction of healthcare providers who have been using the follow-up form in clinic, will also be measured after this time point.

If you agree to participate in the study, you will be questioned about your clinical experience with survivorship, and about the risks of developing late or long-term treatment effects. All data collected from you will be dealt with confidentially. The questionnaire data will only be available to dedicated researchers. Participating in the study is voluntary. Saying no will not affect your rights to health care or any other services. Any additional information about the study results will be provided after concluding the study.

Risk and benefits:

There are no risks involved for participating healthcare providers. Healthcare providers will be educated about survivorship care, positively impacting patient and survivorship services. The training on survivorship care will be accompanied by a lunch. There will be no monetary compensation.

Confidentiality:

All reasonable efforts will be made to keep your information private and confidential. Using or sharing of such information will follow National privacy guidelines. By signing the consent form, you are giving permission for the use and disclosure of your study information. Study information cannot be traced back to any individual. We may need to share your protected information with the community advisory board, MTRH//MU-IREC, NACOSTI or the healthcare team. We will retain your research records for at least six years after the study is completed. At that time, the research information is destroyed by paper shredding. You are free to quit the study at any time. If you want to withdraw your permission for use of your personal data, you should contact the investigators. Health information collected before this

withdrawal may continue to be used for the purposes of reporting and research quality.
Information from this research will not be added to your medical record.
You have the right to see and copy your personal information related to the research study for as long as the study team holds this information. You will receive a copy of this form if you decide to sign it.

Consent:

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