Adolescent Wellness Visits in Tanzania

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MUHIMBILI UNIVERSITY OF HEALTH & ALLIED SCIENCES (MUHAS)

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL (UNC-CH)

Informed Consent Form for Parents/Guardians of Adolescent Research Participant (Intervention).

Consent Form Version Date: 27 October 2021

Title of Study: Adolescent Wellness Visits to Reduce Health Risks

MUHAS IRB Study #: MUHAS-REC-11-2021-904
UNC IRB Study #: 21-1198

Site Principal Investigator: Dr. Sylvia Kaaya, MUHAS
Principal Investigator: Dr. Joy Noel Baumgartner, UNC-CH

Funding Source and/or Sponsor: U.S. National Institute of Child Health and Development

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Concise Summary

This is a research study to find out if an intervention called VITAA helps improve adolescent health outcomes in the community.

If your child enrolls in this study they will meet with a researcher 5 different times for an interview: at the beginning of the study, then about 6 months, 12 months, 18 months, and 24 months after leaving Standard 7. Your child's school has been randomly assigned to take part in the VITAA intervention.

There is a chance that your child may feel uncomfortable discussing some of the topics such as puberty and reproductive health during the survey and/or the intervention.

If you are interested in learning more about this study, let us continue.

What are some general things you and you child should know about research studies?
You are being asked to allow your child to take part in a research study. To join the study is voluntary. You may decide to not allow your child to participate, or you may withdraw your permission for your child to be in the study, for any reason, without penalty. Even if you give your permission, your child can decide not to be in the study or to leave the study early. Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect you or your child's relationship with the researcher, health care provider, or school. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care. Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study. You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
Muhimbili University of Health and Allied Sciences (MUHAS) in collaboration with the University of North Carolina at Chapel Hill (UNC-CH) and Duke University in the United States is conducting a study to understand how and when adolescents check their health. The study is called VITAA, short for **Vi**jana **Ta**mbua **A**fya (*Youth Check Health*). The study is conducted in Tanzania, but investigators at UNC-CH and Duke University will collaborate with the Tanzanian investigators to review and analyze the data.

This study is taking place in Dar es Salaam region and the Coastal region. Both the regional health and education offices have given permission for the study to take place.

Your child has been invited to participate in this study because they are a Standard 7 student in a primary school that agreed to participate in the study.

Adolescence is a time of transition and change. It is an important time to set a foundation of general health and wellness. Having an opportunity at adolescence to obtain comprehensive health services can help youth become familiar with what health services are available to them and can help provide important health information and screenings at a time in their life when their bodies and relationships to their own health are changing. The VITAA intervention is a free comprehensive wellness visit at a clinic.

The VITAA intervention will provide health information and screenings for:

- Vision
- Dental Pain
- Nutrition
- Mental Health
- Puberty

- Reproductive Health
    - This may include contraception, screening for sexually transmitted infection (STI) symptoms and treatment if needed per the standard of care in Tanzania, and HIV testing and counseling.

The study will not be providing free treatment for vision, dental, nutrition or mental health-related problems. Your child may choose to take part in none of the offered services, or may choose to take part in only some of the services. If your child screens as needing any follow-up health service, they will be given a referral form, which we will encourage them to share with their parents. There could be additional costs for any referred services (example, without health insurance, a specialist visit costs ~10,000 Tsh [USD $4]), but following-up on a referral is up to you and your child. Please note that per Ministry of Health, Community Development, Gender, Elderly, and Children (MoHCDGEC) Guidelines, reproductive health counseling, services, and results are confidential and will not be shared with parents although we will encourage adolescents to talk to you about their needs and concerns. Nurses will visit the school before the wellness visits to discuss health topics, and school counselors will be available after the wellness visits to assist with questions and to help communicate with the clinic.

We are conducting the study because we do not know yet if the VITAA intervention will be beneficial to adolescents. There will be only one wellness visit but the overall study of how well adolescents are doing will last about 3 years. The researchers are studying how adolescents who participate in the VITAA intervention compare to a group of adolescents who do not receive the VITAA intervention.

What will happen if your child takes part in the study?
Your child will be asked questions about his/her health and use of health services. Similar questions will be asked at each interview. The first interview will be done in person at the clinic and the following interviews can be done by phone or in-person at a neutral community-based location such as a school, government building, or the child's home if confidentiality is ensured. A select number of clinic visits will be observed for quality checks and improvement. If your child's visit is observed, the same principles of confidentiality will apply to the observing team member.

Your child will not miss any school-related educational activities if they participate in this study. We are working with your child's school to ensure that participation in the adolescent wellness visits and participation in any interviews will not affect their academic preparation.

A member of the research staff may be in contact with your child to maintain contact and remind them of the study.

If you agree to participate in this study, the research team also will have access to your child's health records from the VITAA clinic visit.

How many people will take part in this study?
Approximately 1500 adolescents will take part in this study.

How long will your part in this study last?
As part of the study, a researcher will meet with your child for a survey five times; after they participate in the VITAA clinic visit, then about 6 months, 12 months, 18 months, and 24 months after leaving Standard 7.

What are the possible risks or discomforts involved from being in this study?
There is a chance that your child may feel uncomfortable discussing some of the topics during the survey, such as puberty, sexual activity, abuse and drug use. If a child is sexually active and/or has been coerced or abused in any way, he/she may feel emotional during the visit. If anemia tests are available, your child may receive a finger prick which could cause minor physical pain. Your child may choose to get an HIV test, in which case they will receive testing, results, and counseling per the Tanzanian government standards. If positive and your child would like to receive additional counseling, they will be encouraged to disclose their status to a close guardian, and will receive a facilitated referral to care and treatment. The providers at the clinic and the school counselors are trained to support students in various situations in this case. All studies also have a risk of breach of confidentiality; however, to lower this risk we will ensure that any data collected on paper will be stored in locked rooms and any electronic data will be password-protected on secure computer.

What are the possible benefits from being in this study?
There are no specific benefits for people who choose to participate in the study, though you and your child may appreciate the opportunity to contribute to research that will inform future adolescent health programming. Because your child is participating in the VITAA intervention he/she may receive additional health services that could support his/her overall health.

How will your child's information be protected?
If your child is participating in the research, other students in the school will know your child is taking part in the study. His/her answers in the survey and the content of his/her visit are strictly confidential. Individual information from your child's interviews will not be shared with you and study staff will protect your child's individual information closely so no one without proper authorization will be able to connect your child's responses to any other information that identifies them. But, if your child tells us about an intention to harm themselves or others, or they tell us about experiencing current abuse during the interview or during the wellness visit, we need to follow Tanzanian guidelines and may need to break confidentiality so we can immediately link them to mental health support or social services.

The findings of the research will be reported with all of the students' answers combined, which means that your child's individual information will NOT be identifiable. De-identified information collected in this study may be made public (data repository/archive) or used for future research purposes if approved by our ethical review boards.

Will your child receive anything for being in this study?
After completing each interview your child will receive either 7,500 Tsh (~USD 3.50) or a token worth up to 7,500 tsh.

Does your child have to participate in this study?
NO. Taking part in this study is completely voluntary. If your child does not take part in the study, there will be no negative consequences. You may decide at any time that you do not what your child to participate. Your child may also decide at any time not to participate, or choose not to answer certain questions or have certain services during the visit.

What if you have questions about this study or want to withdraw from the study?
If you have any questions about the study, please contact:
Dr. Sylvia Kaaya; Department of Psychiatry and Mental Health,
Muhimbili University of Health and Allied Sciences,
PO Box 65001 Dar es Salaam, Tanzania
Tel. 0713 262 756

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.

Who is sponsoring this study?
This study is funded by U.S. National Institute of Child Health and Development.

What if you have questions about your child's rights as a research participant?
All research on human volunteers is reviewed by committees that work to protect your child's rights and welfare. If you have questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact:

Dr. Bruno Sunguya; Director of Research and Publications
Muhimbili University of Health and Allied Sciences,
PO Box 65001 Dar es Salaam, Tanzania
Tel. +225 22 215 2489
--Or--
Chairperson, National Research Ethics Committee, National Institute of Medical Research, 2448 Ocean Road, P.O. Box 9653, Dar es Salaam, Tanzania
Tel: +255 22 2121400; Fax: 255 22 2121360
Website: www.nimr.or.tz
--Or—
University of North Carolina at Chapel Hill Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw consent at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

If participant cannot read the form, a witness must sign below:

I was present while the informed consent form was presented to the parent/guardian. All his/her questions were answered.

_____
Printed Name of Witness

_____
Signature of Witness

_____
Date

Thumb print of participant

Administrative:

Child Participant ID: _____

Child Name:

Parent Phone Number(s):