

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



Y-Check: Evaluating the effectiveness of adolescent health check-ups

RESEARCH COHORT – ADOLESCENTS 16-19Y - COMMUNITY

Principal Investigator: Associate Professor Aoife Doyle [BSc, MPhil, PhD]
Phone: +263 771164415

What you should know about this research study:

- We give you this information sheet and consent and assent form so that you may read about the purpose, risks, and benefits of this research study.
- We cannot promise that this research will benefit you. The main goal of research studies is to gain knowledge that may help other people in the future.
- You have the right to refuse to take part, or to agree to take part now but to change your mind later.
- Whatever you decide, it will not affect your regular care
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your choice to participate is voluntary.

PURPOSE

You are being asked to agree to participate in a research study to find out whether a check-up visit can improve the health of adolescents in Zimbabwe. We want to find out what you know about staying healthy, whether the check-up visit has made a difference to your health and well-being, and whether you liked the service. We also want to find out if the services caused you any problems. In total approximately 2200 young people aged 10-19 years will take part in this study. You are being invited to take part in the study because check-up visits have been or will soon be delivered in your school or community.

The research team is made up of scientists from the Biomedical Research and Training Institute (BRTI), Harare and the London School of Hygiene and Tropical Medicine. The study is supported by the Ministry of Health and Child Care and the Ministry of Primary and Secondary Education of Zimbabwe.

PROCEDURES AND DURATION

If you agree to take part in the study, we will ask you questions about your health and well-being. We will also ask you about your experience and opinion of the check-up visit to help us to understand the service better. You can answer questions directly into a tablet computer and the interviewer will not be able to see your answers, but your answers will be available to the nurse and counsellor who will provide care. The questions will be asked on the day of the check-up visit and/or in the week or two before the visits and will take about 15-30 minutes.

You will be asked to return for two follow-up visits over the next 12 months. If you cannot make it to the Y-Check centre for a follow-up visit, we may ask if we can visit you at your home. At the follow-up visits, we will ask you to answer some questions about your health and well-being and we may offer you the check-up visit again (questionnaire, examination and measurement, blood test for anaemia, urine test for Schistosomiasis (Bilharzia), oral fluid test for HIV with confirmatory blood test if required, urine test for STIs, vaginal swab test for STIs (females only)). Each follow-up visit should take 30-90 minutes. If you are identified as needing any treatment or further assessment, you will receive on-the-spot treatment or counselling and/or you will be referred to a specialist service. We will inform your trusted adult of the results and may request their help to escort you to the specialist. Counselling will be available for you and your family members if you test positive for HIV or another important health condition.

We will have to keep your contact information so that we can contact you again, but we will not write your name on any form that contains your answers or test results. We will also offer regular motivating health messages that we can send via SMS or WhatsApp to your phone. We will delete all contact information after your last study visit.

A member of the research team may also observe your check-up visits and/or referral visits to take notes on how the service is being provided and received. We may ask you to take part in individual, paired or group discussions with other participants to talk about your experiences using the check-up services and whether you were able to follow the health and well-being advice provided at the visits. We may audio record these discussions and take notes but your name will not be recorded. We may quote what you say when reporting results but no one will be able to link what you say back to you.

For telephone interviews: If restrictions are in place to address COVID-19 infection in Zimbabwe, some interviews may take place over the telephone and should take no longer than one hour. If you have an email address or WhatsApp on your telephone, this information sheet and consent form can be forwarded to you for your review.

We may invite you to participate in a digital health club where they will have the opportunity to receive additional health information and advice via an online platform. If you would like to participate in the Digital Health Club we will ask you to sign another consent form at a later date.

RISKS AND DISCOMFORTS

The risks of participating in this study are minimal. You may feel uncomfortable or embarrassed by some of the questions you are asked in which case you do not need to answer them. As for any health

care, the check-up services can have side-effects that can be serious or minor. The tests and any positive results could lead to stigma and anxiety. The needle for the anaemia and HIV blood tests could cause discomfort or a small bruise, as with any other blood test. Additionally, the vaginal swab may cause you slight discomfort. However, the Y-Check team will also provide counselling for you and your family if you test positive for any of these conditions. If the need arises, we may refer you to counselling services. You can refuse to undergo any of the testing and/or withdraw from the study at any time.

BENEFITS AND/OR COMPENSATION

There are no direct benefits to participants when they take part in this study. Taking part in this study will cost you nothing. There will be no cost for the check-up visit. Within the four months after the visit, there will be no costs for any further treatment or care obtained through the public health system for a condition that is newly discovered during the check-up visit. The study will help us understand the challenges adolescents face staying healthy, and what they need and want in terms of services, education, and support. We will not pay you to take part in the study. However, we will provide you with a drink and snack during follow-up interviews and we will reimburse your bus fare, up to a value of US\$5, if you have come to the clinic or another venue for follow-up visits/discussions.

CONFIDENTIALITY

If you agree to participate in this study by signing this document, all information obtained will be kept secret. It will be stored using a unique study number (instead of your name), in safe paper and computer files. No one will be able to access the information about you except members of the study team and no one will be able to identify you from the information and samples collected. Data without any names but only a number may be made available to other researchers. Under some circumstances, the Medical Research Council of Zimbabwe and the Research Council of Zimbabwe may review research records to check for any problems with the way that the study is being carried out.

DATA ARCHIVING

At the end of the project, data that can be anonymised fully to protect participants' identities will be archived through the LSHTM Data Compass, a curated UK digital repository of research outputs. Details of how to access the data will be published with each study publication, and access will be granted to bona fide research users and beneficiaries based on a case-by-case request and approval process.

VOLUNTARY PARTICIPATION

We hope that you will agree to take part in this study. However, you do not have to take part in this study if you do not want to. If you decide that you will not participate in this study, that decision will not affect your daily life or regular care or schooling in any way. If you decide that you will take part but then change your mind you may withdraw at any time without having to give a reason. Participation in this study is completely voluntary. If you decide that you do not want to participate, your decision will not affect your future relations with check-up visits or any associated school, clinics, hospitals, and its personnel. The services that you receive through the check-up visit will not be affected if you decide not to participate in the research study.

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over. If you have any questions, please contact the Study Coordinator Dr Farirai Nzvere on 0774692698.

RESEARCHER PAGE- QUESTIONS TO ELUCIDATE UNDERSTANDING

- Do you understand that you can choose whether or not to receive the services part of the Y-Check project?
- If you decide to receive the services but not the research part of the project, will you still receive the services?
- Can you tell me if you remember the number of times that you will undertake the screening? Over how many months?
- Do you understand that some minor discomfort may occur during the check-up?
- Do you understand that, even though unlikely, some side effects may occur?
- Do you know who to reach out to in the unlikely event that you should experience pain after the check-up visit?
- Can you tell me if you have understood correctly the benefits that you will have if you take part in the study?
- Do you know if the study will pay for your travel costs?
- Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential?
- Do you want me to go through the procedures again?
- Do you have any questions?

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant and to the best of my ability made sure that he/she understands that the following will be done:

1. Y-Check screening services will be provided
2. Y-Check educational and health promotion information will be provided
3. Referral services will be provided if needed.

I confirm that the potential participant was given an opportunity 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 consent form has been given to the participant.

Print name of the Researcher/person taking the consent _____

Signature of Researcher/person taking the consent _____

Date (Day/month/year) _____

SIGNATURE PAGE Protocol Version 1.3 dated 15 July 2022

Y-Check: Evaluating the effectiveness of adolescent health check-ups

AUTHORIZATION

You are making a decision whether or not to take part in this study. Your signature shows that you have read and understood the information provided above, have had all your questions answered, and have decided to agree to take part.

- I have read the information concerning this study [or have understood the verbal explanation] and I understand what will be required of me
- I understand that I may withdraw from this study without giving a reason

I agree to take part in this study YES/NO

I agree to be contacted again for two follow-up interviews and repeat check-up visits in the 12 months following the first check-up visit YES/NO

I agree for my check-up visit to be observed by a researcher YES/NO

I agree to take part in group discussions or an interview if asked and for the discussion/interview to be audio recorded YES/NO

I agree that what I say may be included in reports and papers as anonymous quotes YES/NO

I understand that the research data, which will be anonymised (not linked to me) may be shared with others YES/NO

Name of Participant (print) Signature of Participant (or Thumb Print*) / /20
Date

Name of Staff obtaining consent Signature of Staff / /20
Date

*Name of Witness (required only if participant is illiterate) *Signature of Witness / /20
Date

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research participant or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the Medical Research Council of Zimbabwe (MRCZ) on telephone (242)791792 or (242)791193 and cell phone lines 0784 956 128. The MRCZ Offices are located at 20 Cambridge Road, Avondale in Harare.