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

RESEARCH COHORT – ADOLESCENTS 15-19Y - SCHOOLS

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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 your child. 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 allow your child to take part, or to agree for your child to take part now but to change your mind later.
- Whatever you decide, it will not affect your child's regular care
- Please review this consent form carefully. Ask any questions before you make a decision.
- Your choice to allow your child to participate is voluntary.

PURPOSE

You are being asked to allow your child 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 they know about staying healthy, whether the check-up visit has made a difference to their health and well-being, and whether they liked the service. We also want to find out if the services caused them any problems. In total approximately 2200 young people aged 10-19 years will take part in this study. Your child is being invited to take part in the study because check-up visits have been or will soon be delivered in their school.

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 allow the child to take part in the study, and they also agree, we will ask your child questions about their health and well-being. We will also ask them about their experiences and opinions of the check-up visit to help us to understand the service better. They will answer questions directly on a tablet computer and the interviewer will not be able to see their answers, but their answers will be available to the nurse and counsellor who will provide care. The questions will be asked in school 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.

Your child will be asked to return for two follow-up visits over the next 12 months. If they cannot make it to the school or Y-Check centre for a follow-up visit, we may ask if we can visit them at your home. At the follow-up visits, we will ask them to answer some questions about their health and well-being. We may offer them the check-up visit again (questionnaire, examination and measurement, and blood test for anaemia, urine test for Schistosomiasis (Bilharzia)). Each follow-up visit should take 30-90 minutes. If your adolescent is identified as needing any treatment or further assessment, they will receive on-the-spot treatment or counselling and/or they will be referred to a specialist service. We will inform you of the results and may request your help to escort the adolescent to the specialist. In addition, counselling will be available for the adolescent and family members if the adolescent tests positive for an important health condition.

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

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

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 will look at your child's school records to collect data on their performance and attendance to help us to understand if improving health and well-being also helps to improve educational outcomes. We may invite your child 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 your child to participate in the Digital Health Club we will ask you to sign another consent form at a later date.

RISKS AND DISCOMFORTS

Even if you agree to your child's participation, we will only ask your child to take part if they want to. The risks of participating in this study are minimal. Your child may feel uncomfortable or embarrassed by some of the questions they are asked in which case they 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 result could lead to stigma and anxiety. However, the Y-Check team will provide counselling for you and your child if they test positive for any of the conditions. The needle for the blood test could cause discomfort or a small bruise, as with any other blood test. Your child 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 through the public health system for a newly discovered condition 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 your child to take part in the study. However, we will provide your child with a drink and snack during follow-up interviews and we will reimburse their bus fare, up to a value of US\$5, if they have come to the clinic or another venue for follow-up visits/discussions.

CONFIDENTIALITY

If you agree that your child can 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 child's 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 your child 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 allow your child to take part in this study. However, your child does not have to take part in this study if you do not want them to. If you decide that they should not participate in this study, that decision will not affect your and their daily life or regular care or schooling in any way. If you decide that they should take part but then change your mind you may withdraw your child at any time without having to give a reason. Participation in this study is completely voluntary. If you decide that you do not want your child to participate, your decision will not affect their future relations with check-up visits or any associated school, clinics, hospitals, and its personnel. The services that they 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 your child is able to receive the services part of the Y-Check project?
- If you decide for your child to receive the services but not the research part of the project, will they still receive the services?
- Can you tell me if you remember the number of times that your child 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 your child should experience pain after the check-up visit?
- Can you tell me if you have understood correctly the benefits that your child will have if you take part in the study?
- Do you know if the study will pay for your child's travel costs?
- Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about your child 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 their parent/guardian, and to the best of my ability made sure that the parent/guardian 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 parent/guardian 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 parent/guardian.

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

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AUTHORIZATION

You are making a decision whether or not your child should 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 let your child take part.

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

I agree for my child to take part in this study YES/NO

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

I agree for my child 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 my child says may be included in reports and papers as anonymous quotes YES/NO

I agree for my child's school records to be used in this research YES/NO

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

Name of Parent/Guardian (print) Signature of Parent or legally authorized representative
(or Thumb Print*)

Date

Relationship to the Participant

Name of Staff obtaining consent Signature of Staff

Date

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

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.

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Assent for adolescents 15 to 19 years old

Hello my friend. We are kindly asking if we can talk to you about your health and how well you feel. There are two parts to our work.

The first part is the Check-up visit during which the Y-Check health workers will check how healthy you are and offer you treatment or further help if needed. During this visit, we will ask you questions about your general health and wellbeing such as your home environment, education, social activities, diet and exercise, mental health, alcohol, tobacco and drug use, and adolescent immunisation history. We will give you some information on how to stay healthy. We will also measure your height, weight, and blood pressure, test how well your body moves, and look at your mouth, eyes and ears. We will test your blood using a finger prick and ask you to provide a urine sample so we can check for schistosomiasis (Bilharzia). You will get a chance to ask a nurse any questions that you have about your health.

The second part is a research study to find out whether the Check-up visits were acceptable and to see if they helped young people to stay healthy. This form is about the research. If you take part in the research then we will ask you some extra questions and ask for ideas on how to make Y-Check better. We are talking to 2200 young people. What these young people are going to tell us will be used to come up with programs to help young people stay healthy and well. We will also invite you to have another check-up visit which includes a blood test using a finger prick, a urine test, and other examinations. However, you can choose to talk to us only and not to have these tests. A researcher may observe your visit so that we can check that the staff are doing their jobs well. We might ask you to join a Digital health club where you can find out more about staying healthy. If you agree to talk to us and have tests, you will not necessarily get anything but what you are going to tell us will help us improve programs for young people in the future. Some of the questions or tests may make you feel sad or worried. The Y-Check team will be able to help you with these feelings.

You are not forced to talk to us if you do not want and nothing will happen to you if you refuse to talk to us. Again, your refusal will not affect the way you are treated health-wise, in school, or your daily life. You can also tell us that you no longer want to talk to us whenever you want and no one will ask you why. We will not tell your parent/guardian any of your answers. If we find that you need treatment or need to see another healthcare provider then we will tell your parent/guardian so that they can support you. The information that we collect from you will be kept secret and will have a number on it instead of a name. Only the Y-Check researchers will know what your number is and we will lock that information up safely. Other researchers may use the data in the future but they will see only your number and will not be given your name. You can choose not to talk to us even if your parents want you to join the study.

Name of Participant

Signature

Assent given:

Yes

No