

LONDON
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MEDICINE



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

ADOLESCENTS 10-15Y WHO DID NOT RECEIVE CHECK-UP

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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 and what they know about the Y-Check service that was recently delivered in your community. In total, approximately 10-20 young people aged 10-19 years will take part in this part of the Y-Check study. Your child is being invited to take part in the study because check-up visits have recently been delivered in your child's school or community, and our records show that your child did not receive a check-up.

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 for your child to take part in the study, we will ask your child to take part in individual, paired or group discussions with other participants to answer questions about their health and well-being. Interviews will take around 60 minutes. We will also ask them about their opinion of the check-up visit to help us to understand the service better. We will audio record these discussions and take notes, but your child's name will not be recorded. We may quote what your child says when reporting results, but no one will be able to link what your child says back to them.

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.

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. There is a risk that 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. During group discussion sessions, information shared by your child may be shared outside the group by other participants. However, the group discussion facilitator will remind all participants to avoid sharing group discussion information with outsiders. Your child can refuse to answer any questions 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. 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 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 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 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.

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.

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 take part in group discussions or an interview
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

Name of Parent/Guardian (print) Signature of Parent or legally authorized representative
(or Thumb Print*) Date
□ □ / □ □ / 20 □ □

Relationship to the Participant

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

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

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 children 10 to 15 years old

Hello my friend. We are kindly asking if we can talk to you about your health and how well you feel. We are doing a research study to create a health check-up visit for young people. We want to know if it is possible to have check-up visits for young people in Zimbabwe. We want to know if young people and their families like the check-up visits. We are asking about 20 young people who did not get a check-up to take part in discussions and interviews. 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.

If you agree to talk to us, 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.

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 a healthcare provider then we will tell your parent/guardian so that they can support you.

Name of Participant		Signature
Assent given:	Yes	No