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

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List of Abbreviations and Acronyms

ART	Anti-Retroviral Therapy
BMI	Body Mass Index
BRTI	Biomedical Research and Training Institute
BVI	Body Volume Index
CBO	Community-Based Organisation
CHW	Community Health Worker
CT	Chlamydia Trachomatis
GC	Neisseria gonorrhoeae
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HTC	HIV Testing and Counselling
IEC	Information, Education and Counselling
IPC	Infection Prevention and Control
IPV	Intimate Partner Violence
IRB	Institutional Review Board
LARC	Long Acting Reversible Contraception
LSHTM	London School of Hygiene and Tropical Medicine
mHealth	Mobile Health
MHH	Menstrual Health and Hygiene
MOHCC	(Zimbabwe) Ministry of Health and Child Care
MOPSE	(Zimbabwe) Ministry of Primary and Secondary Education
MRCZ	Medical Research Council of Zimbabwe
MUAC	Mid-upper arm circumference
NGO	Non-Governmental Organisation
OMT	Oral Mucosal Test
PITC	Provider-initiated HIV testing and counselling
PLHIV	People Living With HIV
PrEP	Pre-Exposure Prophylaxis
RCT	Randomised Controlled Trial
RCZ	Research Council of Zimbabwe
RDT	Rapid Diagnostic Test
SAC	Scientific Advisory Commitee
SDF	Silver Diamine Fluoride
SMS	Short Messaging Service
SRH	Sexual and Reproductive Health
SSA	Sub-Saharan Africa
STI	Sexually Transmitted Infection
UK	United Kingdom
UNAIDS	United Nations Programme on HIV/AIDS

VMMC	Voluntary Male Medical Circumcision
WHO	World Health Organization
YAG	Youth Advisory Group
YFHS	Youth Friendly Health Services
YP	Young People

Executive Summary

In adolescence, health-related behaviours are adopted that will have substantial positive or negative impacts on the individual's short- and long-term health, educational attainment, and employment prospects. However, few adolescents have any contact with health services, especially for health promotion and disease prevention, and services are not always appropriate for their needs.

Aim: To develop, implement and evaluate the acceptability, feasibility, effectiveness, and cost-effectiveness of a potentially sustainable adolescent health and well-being check-up programme in Zimbabwe to improve health and well-being.

Design:
The study comprises: Phase 1: Development and piloting; Phase 2: Implementation and evidence generation; Phase 3: Knowledge dissemination and translation. Outputs will be (i) a novel intervention to improve adolescent health and well-being, (ii) evidence in urban settings in Zimbabwe on the interventions feasibility and cost-effectiveness, (iii) guidelines for implementation and evaluation in Zimbabwe and in other LMICs, and (iv) proposals for follow-on studies in Zimbabwe and other LMICs.

Intervention: The Y-Check strategy will involve the screening and treatment/referral of adolescents for important conditions through health check-up visits at two key time points during adolescence: early adolescence (10-14y) and mid/late adolescence (15-19y). Adolescents will only be screened for conditions with an accurate and acceptable screening test and a locally-accessible effective intervention e.g. mental health, HIV, vision, hearing, and anaemia. The package of services will include risk reduction counselling and general health information and counselling.

Study Outcomes: In this hybrid effectiveness-implementation study, both implementation process and adolescent outcomes will be captured. The primary outcome will be the proportion of those screening positive for at least one condition who receive appropriate on-the-spot care or complete appropriate referral within 4 months. Secondary outcomes will include yield of previously undiagnosed and un-referred conditions; intervention acceptability, adoption, appropriateness, feasibility, fidelity, and cost; reported health-related risk and protective behaviours; engagement with health services; well-being; clinical and educational outcomes.

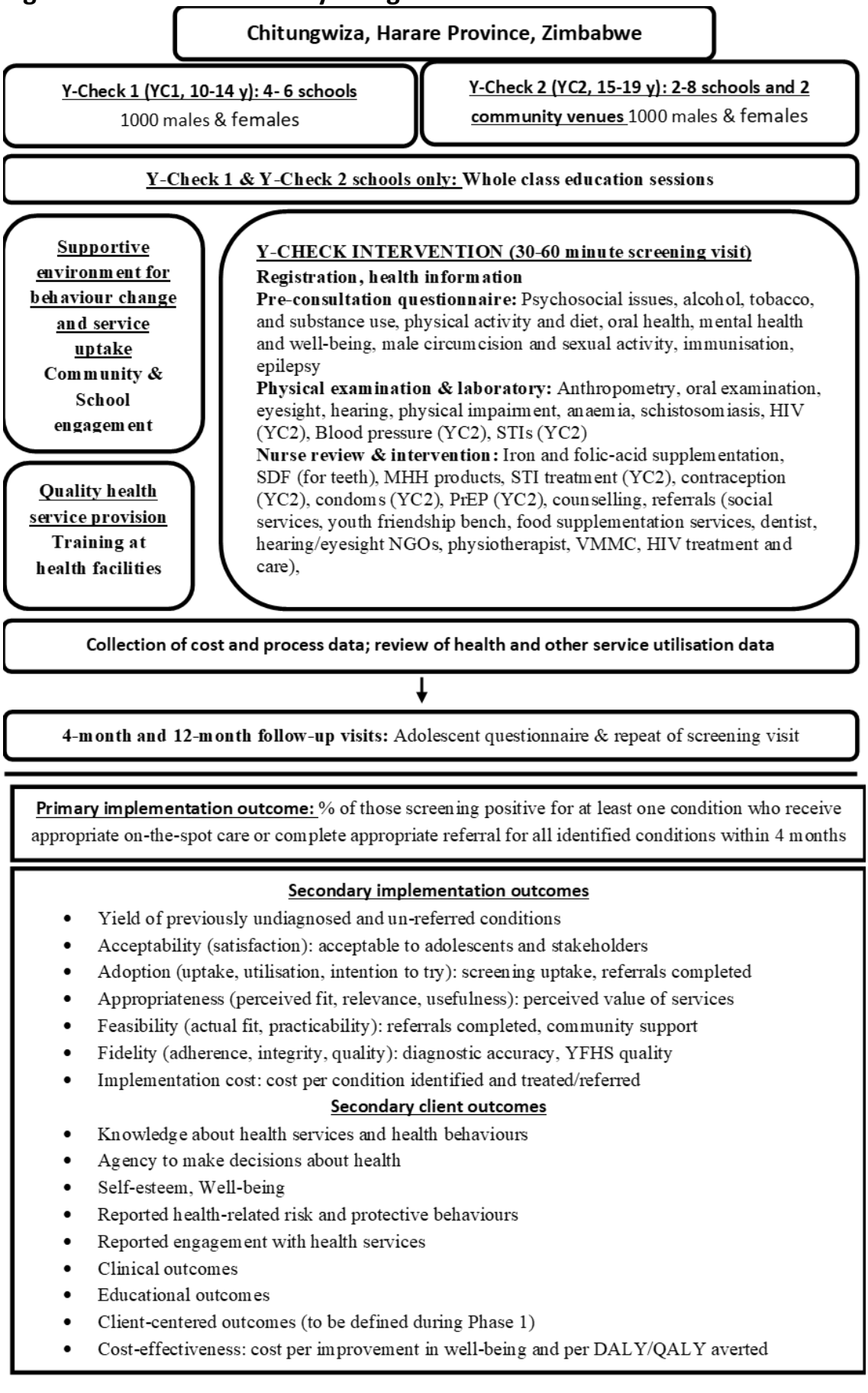
Study population: The intervention will be delivered to 1000 10-14 year old males and females and 1000 15-19 year old males and females. An initial pilot study of around 200 participants will be conducted before the main intervention, taking the total number of participants to 2200. Parents, carers and other stakeholders (teachers, service providers, community leaders etc.) will participate in study development and evaluation workshops and interviews.

Study duration and sites: The planned duration of the entire study will be 4 years. The two age cohorts will be recruited in year 2 and followed for approximately 12 months. The study will be conducted in 4 communities, up to 8 secondary schools, and up to 6 primary schools in Chitungwiza, Harare Province, Zimbabwe.

Risk-benefit assessment: The risks and benefits of the Y-Check intervention will be described to participants and their parents/guardians during the consent process. Y-Check participants

will benefit from early detection of health problems, health promotion, and the development of health-seeking behaviours. However, some conditions such as HIV and sexually transmitted infections (STIs), which will be screened for, are associated with stigma and anxiety. The Y-Check team will be trained in good clinical practice, data protection and confidentiality, and will provide counselling for participants testing positive for any conditions. Furthermore, the protocols and procedures for communicating with adolescents and their families will be carefully developed in collaboration with the Youth Advisory Group (YAG) and community stakeholders.

Figure 1. Overview of Study Design



1. Introduction

To unlock human potential and accelerate progress towards achieving the Sustainable Development Goals (SDGs), it is essential to improve the health and well-being of adolescents (10-19 years).[1] Health is an essential component of human capital,[2] yet adolescent investments have focused primarily on education with little attention to synergies between health and education.[1] Research investments in the first 1000 days of life have dramatically outweighed investments in the subsequent 7000 days, leaving an evidence-gap on how to develop and sustain human potential through adolescence and early adulthood.[3]

Among adolescents in African low and middle-income countries (LMICs), HIV and iron-deficiency anaemia are among the top five causes of adolescent disability-adjusted life years (DALYs) lost, with poor mental health, poor diet, low physical activity, and alcohol use among the leading risk factors for death.[4] Adolescents with disabilities are particularly vulnerable and face a range of challenges in achieving their full capabilities.[5] Identifying adolescents with risky conditions and behaviours or undiagnosed disability is important given (i) the growing number of adolescents (ii) the increasing proportion of the total burden of disease that occurs in adolescence and (iii) the fact that many key health conditions (e.g. mental health disorders) and behaviours (e.g. tobacco and alcohol use, unhealthy diet, low physical activity, risky sexual behaviours) that predispose to serious conditions in later life start in adolescence[4] (iv) the negative impact of poor health on educational attainment.

Systematic reviews have identified individual interventions that are effective at improving various aspects of adolescent health,[4] however, most adolescents only come in contact with health services when they are ill, and services are not always appropriate for their needs.[6] This represents a missed opportunity for early detection of health problems, health promotion, and the development of healthy health-seeking behaviours. Early and sustained engagement with health services could reap a triple dividend for human development by improving the health of adolescents, their health in adulthood and the health of their future offspring. [2,4]

Routine health check-up visits for adolescents which screen for multiple conditions and risk behaviours, could provide an entry point into services and be highly cost-effective,[7] [8] but there is little empirical evidence for their feasibility, acceptability and effectiveness. Many high-income countries have national recommendations related to adolescent health check-ups (largely based on expert opinion).[9-11] In low and middle income settings, preventative health services for adolescents are largely provided in schools, are usually limited to deworming and vaccination campaigns, and do not address other important conditions and risk factors such as nutrition, mental health, and disability.[12] Obtaining evidence on check-ups is a top World Health Organization (WHO) priority for adolescent health research so that they can develop recommendations for preventive and promotive contacts with the health system for adolescents.

The 2018 Zimbabwean School Health Policy, jointly authored by the Ministry of Health and Child Care (MoHCC) and the Ministry of Primary and Secondary Education (MoPSE), provides a policy framework for the provision of comprehensive school health programming.[13] This policy provides a framework for the implementation of health education and promotion including screening for communicable and non-communicable diseases, immunization campaigns, mass drug administration (e.g. for bilharzia and soil-transmitted helminths), growth monitoring and assessments, and nutritional services. In this policy the government confirms their commitment to providing school health services

in order to optimise educational outcomes and contribute towards the broader National development objectives.

The programme (Y-Check) will therefore, address a critical gap in the field of adolescent health and will provide policy relevant evidence on check-up visits and the implementation of school health services. Y-Check will screen and treat/refer adolescents for common conditions through health check-up visits in younger (10-13y) and older (16-19y) adolescents. Adolescents will only be screened for conditions that have an accurate and acceptable screening test and a locally accessible effective intervention e.g. mental health, HIV, vision and hearing impairments, anaemia. Human-centred design will be used to develop the intervention, including the content and mode of delivery of the intervention, to address the supply and demand barriers to services.

The conceptualisation of an adolescent health check-up programme was the focus of a WHO-convened, DFID-funded multi-country workshop in Zimbabwe in 2018. WHO, London School of Hygiene & Tropical Medicine (LSHTM), Biomedical Research and Training Institute (BRTI) and collaborators subsequently obtained funding from Fondation Botnar for formative work (August 19-October 20, PI: David Ross (WHO)) to develop the content and format of a programme in Zimbabwe, Ghana, and Tanzania. The Zimbabwean situation analysis involved a document review, and in-depth interviews and participatory workshops in Chitungwiza. The document review showed the lack of any routine health check-ups and the absence of age-disaggregated prevalence data for many health conditions.[14]

In-depth interviews and participatory workshops with adolescents, parents of adolescents and key stakeholders (MoHCC, MoPSE, Community Based Organisations (CBOs), healthcare workers and specialists) found that there was overall support for the introduction of routine health check-ups. To navigate potential barriers, stakeholders suggested clear messaging, awareness building, and sensitisation campaigns to overcome disinterest in preventative healthcare and religious messaging against healthcare engagement.[14]

2. Study Aim, Objectives and Design

2.1 Aim

To develop and implement a potentially sustainable adolescent health check-up programme in Zimbabwe and evaluate the acceptability, feasibility, effectiveness, and cost-effectiveness of the programme to improve health and well-being.

2.2 Objectives

1. To develop and pilot test a check-up programme for adolescents that screens for important health conditions using accurate and acceptable screening tests and provides locally-accessible effective interventions (**Phase 1**)

1a To develop and pilot test a Digital Health and Well-being Club for adolescents as a basis for longer-term contacts with the adolescents (**Phase 1**)

2. Through a prospective intervention study in selected schools and communities in Chitungwiza, Zimbabawe to (**Phase 2**):
    i. Evaluate the **implementation of the programme** by measuring key implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, and cost.

ii. Describe the programme **context** and **mechanisms of action**.
iii. Estimate **short-term programme impact on adolescent outcomes**: health-related knowledge; intentions, agency, and perceived social support for behaviour change; engagement with health services; health-related behaviours; well-being, improvements in previously-diagnosed health and well-being conditions.
iv. Estimate the **cost-effectiveness** of the programme in reducing overall disease burden and improving adolescent well-being
v. **Obtain information on key parameters needed for the planning of a next phase larger evaluation study**: prevalence of health conditions and behaviours, acceptability of referral, feasibility of following-up programme participants, initial estimates of the impact of the programme on longer-term health, educational and well-being outcomes, and optimal implementation of the Y-Check intervention.

3. To refine the programme and its theory of change, and finalise optimal methods for the measurement of impact of the programme in future studies (**Phase 3**).

2.3 Study design

During **Phase 1 (Intervention development and piloting)** we will use a variety of processes and methodologies including community engagement, participatory co-design, qualitative interviews and discussions, health register and school register review, and validation and pre-testing of screening tools, procedures and referral protocols. Locally accessible services will be identified and pre-tested to confirm that they are acceptable and accessible from multiple perspectives, including adolescents themselves. An extended period of piloting will involve the piloting of the screening tools and procedures for each of the target conditions and behaviours with revisions and repeat piloting where required. Up to 200 participants will be involved in the piloting of screening tools and procedures. There will be an opportunity for young people and stakeholders to suggest additional relevant outcomes that may reflect some of their priority concerns/intentions that should be captured (Client-centered outcomes).

During **Phase 2 (Implementation and evidence generation)** we will conduct a prospective intervention study (cohort study) in Chitungwiza, Zimbabwe to assess the feasibility of the intervention and to evaluate the short-term impact of the intervention.[15,16] The intervention will be implemented for 10-14 year olds in 4-6 primary schools (N=1000, Y-Check 1), 15-19 year olds at 2-8 secondary schools, and 16-19 year olds at 2-4 community venues (N=1000, Y-Check 2). The intervention does not intend to target all adolescents but instead to focus on two time points during the adolescent period: early adolescence (10-14) years at or just before the onset of puberty, and middle/late adolescence (15-19 years) when many adolescents become or are soon to become sexually active. The exact target school grades and age-ranges will be agreed in consultation with MoPSE, MoHCC and other stakeholders during Phase 1 of the study.

In this hybrid effectiveness-implementation study, both data on implementation process, and adolescent outcomes will be captured.[17] A mixed-methods process evaluation will describe the programme implementation, context, and mechanisms of action. The study cohort will be followed up for approximately 12 months with adolescent process and outcome data collected at screening, 4-month and 12-month follow-up visits **(Figure 2)**. An economic evaluation will estimate unit costs per adolescent screened, condition identified and case treated, and estimate the cost-effectiveness of the intervention in improving adolescent well-being. Where data are available, we will estimate the impact

of the intervention on DALYs averted. We will gather information to develop methodologies for a potential larger future study to measure the longer-term health, well-being and educational impact of the programme. We will assess the scale up and financial sustainability of the programme.

The prospective intervention study design is more appropriate than a randomised controlled trial (RCT) for answering the research question because i) it is impossible to measure the adolescent outcomes in the absence of the screening which is an integral part of the Y-Check intervention; ii) the intervention components are known to be effective for identifying conditions for which known effective interventions exist (e.g. Provision of spectacles for adolescents with myopia; provision of psychological interventions by trained lay mental health providers through the "Friendship Bench" approach for adolescents with symptoms of significant common mental health disorders), so a control arm in which adolescents were screened, found to have these conditions but not offered care would be unethical; and iii) the great majority of conditions being screened for are chronic, so the prevalence of previously undiagnosed and untreated conditions or risky behaviours provides its own counterfactual reflecting a lack of prior appropriate diagnosis and effective treatment.

COVID-19, which the WHO declared a pandemic on 11 March 2020, has had significant effects on research activities worldwide. Over the past 18 months, adaptations to procedures have allowed research activities to continue in a safe environment for research staff and participants.

All Y-Check procedures will be conducted in well-aerated tents or outdoors to minimise risk during screening tests, physical examinations, and blood tests. Standard infection prevention and control (IPC) protocols will be implemented with all staff and participants wearing appropriate surgical or cloth masks. If a participant does not have a suitable mask, the research team will provide a new surgical mask. In addition, all staff and participants will wash their hands before interacting. Finally, all working surfaces and instruments will be sanitised between each participant. If standard COVID-19 IPC protocols cannot be implemented in school settings, the Y-Check service will be temporarily delivered in the community until a suitable solution is found.

If there is a suspected COVID case, we will follow the national guidelines that are current at the time. Y-Check will use opportunity to advocate for all adolescents who are eligible for Covid-19 vaccination locally who attend the Y-Check-Up to avail themselves of this opportunity and will provide information on where they might go to get vaccinated.

Social distancing, handwashing, and sanitisation of surfaces will also be implemented during all interviews and focus group discussions.

Phase 3 (Knowledge dissemination and translation) will involve statistical analysis, mathematical modelling, refinement of programme guidelines, report writing, dissemination of study findings to young people and other stakeholders, and the development of research proposals.

Figure 2: Timeline of Study

	2021				2022				2023				2024			
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Inception	*	*														
Intervention development and pilot testing			*	*	*	*										
Implementation of Y-Check							*	*	*	*						
Research cohort recruitment							*	*	*	*						
Follow-up at 4 & 12 months								*	*	*	*	*	*	*		
Process and economic evaluation							*	*	*	*	*	*	*	*		
Analysis & reporting													*	*	*	*

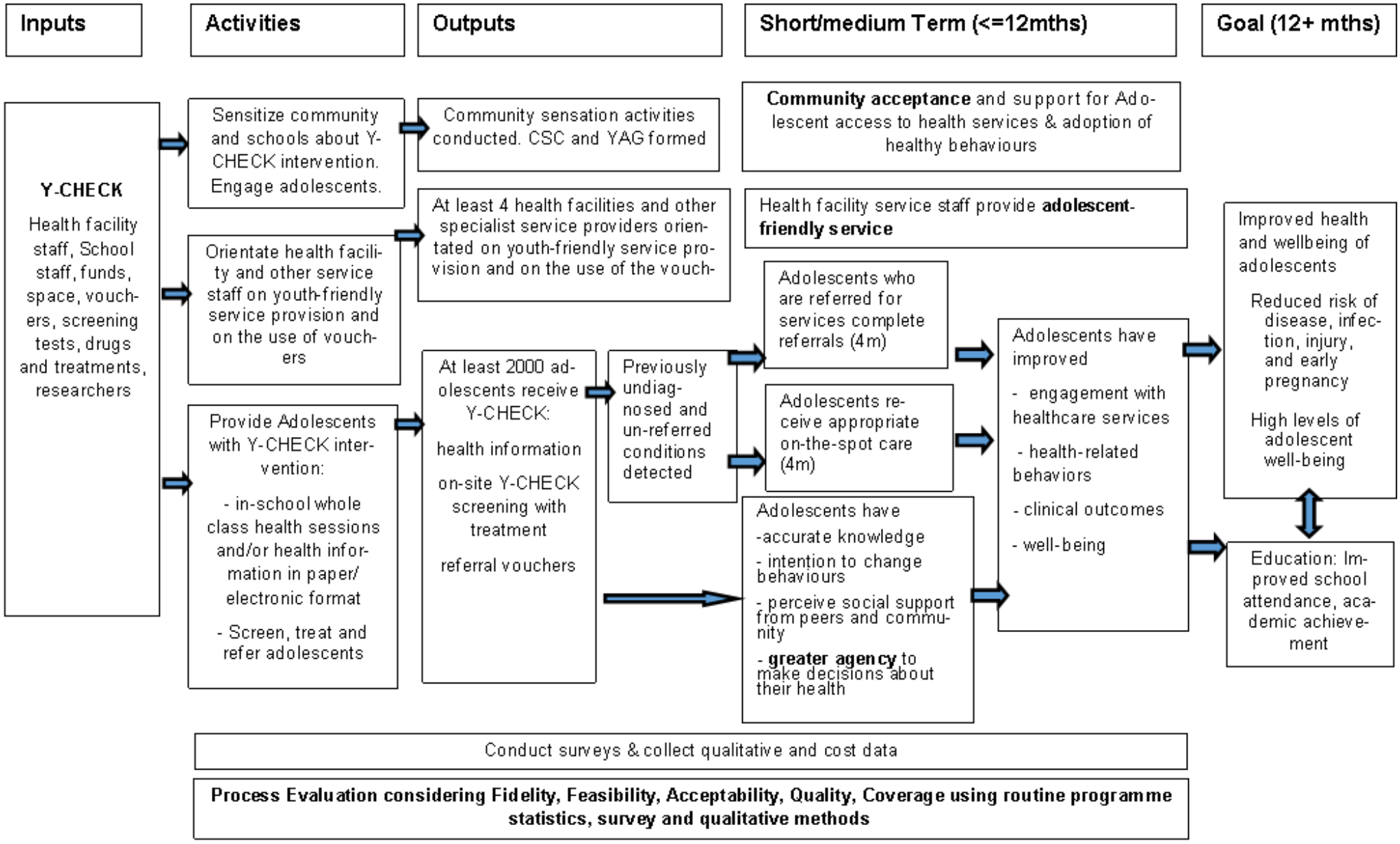


Figure 3: Y-CHECK logic model

3. Y-Check Programme

The Y-Check programme comprises of health and well-being education classes in schools and check-up visits at two time points during the adolescent period (early and middle/late adolescence) delivered at both school and community venues. In addition, the programme will include community mobilisation, and school and health facility staff training and orientation. The programme will be co-created with adolescents, their caregivers, policy-makers, teachers, and healthcare providers, ensuring that it aligns with national priorities, and is accessible and acceptable to users**.**

3.1 Target conditions and behaviours

Informed by a scoping literature review and expert consultation during the 2019/20 formative work, conditions and behaviours were selected based on their prevalence, and the ability to diagnose and treat. The conditions and behaviours to be screened for and the rationale for their choice is summarised in **Table 1**. The target health conditions and behaviours will be finalised towards the end of Phase 1 following additional stakeholder engagement and pre-testing of screening tools and referral pathways (s**ee section 5.1**).

Table 1: Rationale for choice of conditions and behaviours included in check-up visit.

	Rationale
Psychosocial issues (difficult home environment, challenges with education or employment, participation in social activities, and safety and security)	The quality of an adolescent's home and working/school life, and their relationship with their peers can impact on their mental health. Identifying and helping adolescents who are living in difficult situations will improve their health and well-being.
Drug, alcohol and tobacco use	Risk behaviours often start in adolescence and contribute to morbidity and mortality in adolescence as well as increasing later risk of NCDs
Mental Health	Identified as a leading cause of morbidity among adolescents and is associated with suicide and increased risk behaviours.
Growth, nutrition, and physical activity	Poor nutrition in adolescence can affect health and well-being, adult body size, and may also affect the nutritional status of children born to women who were malnourished in adolescence. Obesity and lack of exercise in adolescence are risk factors for NCDs in adulthood.
Anaemia	Anaemia is a leading cause of morbidity among adolescents.
Oral health	Untreated dental cavities can cause severe pain, infection, and problems with eating, speaking, and learning in children and adolescents. [18]
SRH & HIV prevention	Risk reduction counselling is insufficient without the availability of commodities. Provision of MHM and other SRH products enhances acceptability by community and adolescents.

	Testing for STI's important as syndromic management not very effective.
Immunisation	Completing immunisation schedules will protect adolescents against preventable diseases in addition to contributing towards the development of herd immunity in the community.
Eyesight	Untreated eyesight problems can impact on educational attainment, and physical and mental health.
Hearing	Untreated hearing problems can impact on educational attainment, and physical and mental health.
Physical impairment	Untreated physical impairment can impact on an adolescent's ability to perform everyday tasks, and impact on their educational and work prospects.
Epilepsy	Epilepsy is one of the most common neurological conditions which carries a high burden of disease when left untreated. A large treatment gap exists in LMICs.[19]
Blood pressure (Y-Check 2)	Prehypertension and hypertension in adolescence are predictors for developing manifest hypertension as adults.[20]
Schistosomiasis	In the short term, schistosomiasis during adolescence can cause anaemia, stunting and a reduced ability to learn (WHO). In the long-term it can cause considerable disability and reduce the individual's work productivity and even death (WHO).

3.2 Setting

Chitungwiza is the third largest city in Zimbabwe, located approximately 25km south of the capital city, Harare, and has a population of about 456 000. The houses are mostly high-density, single story, detached units with small yards that are generally used for growing vegetables. Most of the people work in Harare, as there is little industry in Chitungwiza. There is one tertiary hospital, 4 public primary healthcare facilities, 20 private medical facilities, and 34 government primary schools (all mixed sex).

Four communities and four schools were chosen by Chitungwiza stakeholders to take part in Y-Check formative work in 2019/20 (High schools: Seke High 6, Zengeza High 1; Primary schools: Dungwiza Primary, Chinembiri Primary). Communities and schools were selected to represent the diversity of wards in the town and taking into account the economic disparities. The selection of the schools and communities for this study will be conducted in collaboration with stakeholders including MoPSE, MoHCC, and the study Youth Advisory Group (YAG) taking into consideration previous participation in the formative work and the location of other ongoing projects. We will aim to work in four distinct communities which are representative of the urban, peri-urban and rural populations of Chitungwiza.
Potentially eligible schools must meet the following criteria:

- Student population of at least 200 learners in Grade 5, 6, or 7 (Y-Check 1 target intervention year) or at least 75 learners in Form 3, 4 or 5 (Y-Check 2 target intervention year).
- Located in or close to one of the selected study communities

3.3 Community engagement

This study will build on the community engagement established during the 2019/20 formative work. Briefly, this comprised a detailed stakeholder analysis (meetings and discussions with stakeholders including health services, CBOs, non-governmental organisations (NGOs)), and interviews and discussions with youth, family members and other community gatekeepers. Workshops were held with youth selected from study communities to inform the design, content and delivery of the intervention and to ensure they are equitable partners in the research process.[14]

In Year 1 a **Community Steering Committee (CSC)** comprising key community leaders and stakeholders will be set up to facilitate input from, and feedback to, participating communities. Strong community engagement will allow the establishment of a partnership between communities, participants and researchers to ensure the latter discharge their responsibilities ethically in the study communities**.** A **Youth Advisory Group (YAG)** will provide a forum for adolescents to input into the programme. The YAG will meet with research staff a minimum of 4 times a year, be active participants in programme design and dissemination workshops, and help to ensure that the programme meets the needs of adolescents. Community engagement will be an ongoing process through regular contacts with stakeholders and the YAG.

In addition, a key aspect of building confidence within communities is the knowledge that the study has the support and partnership of the government. Partnership with the MoHCC and MoPSE was sought at the inception of the study and input on this protocol was provided by Dr. Nyamayaro and Mr. Aveneni Mangome (MoHCC) and Ms. Nyanungo and Ms. Patience Manhiwi (MoPSE). Support and permission to conduct the study will be sought from the Harare Provincial Medical Directorate, Chitungwiza City Health Director, Local Authorities, and Health Services Director. At community level, permission will be sought from the Provincial and District Administrators for the use of community centres.

3.4 School orientation and training

Study schools will be contacted the term before the team are due to arrive in the school. The study team will agree with the school principals on the most appropriate days, times, and location for the service delivery. They will also agree on the best timing for the delivery of whole-class education sessions in line with the School Health Policy. School staff will receive information on the programme including an overview of adolescent health and well-being, the conditions to be screened for and the referral pathways available.

3.5 Health service provider orientation and training

The local health services (e.g. the primary health care clinics) are the custodian of health of the community and collaboration with them is essential for ensuring both care of Y-Check clients beyond the intervention and to facilitate scalability. The intervention team will work with the nurses at the clinics to ensure that HIV and other services provided by Y-Check are integrated with routine services e.g. ensuring that all youth diagnosed with HIV through Y-Check are registered into the National antiretroviral therapy (ART) programme. Regular meetings will be held between the intervention team and health service staff to ensure that strong relations are maintained.

Social service, food supplementation and CBOs/NGOs providing specialist services will also be engaged. The Y-Check programme staff will hold detailed discussions with potential referral services and review the appropriateness and quality of services that they are able to offer, and where necessary to agree a fee for services provided. Additional training and support will be provided to referral services to support their provision of youth-friendly health services. Service providers who are likely to receive

referrals from Y-Check will be orientated on the use of referral vouchers. Adolescents will be given referral vouchers during the check-up visit so that they do not need to pay for the referral. The Y-Check team will then reimburse the service provider for any vouchers that are redeemed. The referral protocols will be co-designed with service providers during Phase 1 including pre-testing and piloting.

3.6 Whole school sessions

Whole-class education sessions will be delivered in line with the School Health Policy on nutrition, exercise and oral health; mental health, and alcohol, tobacco, and drug use, puberty, menstrual health, sexual health, and early marriage[4]. The content will be age appropriate and may vary between Y-Check 1 (primary schools) and Y-Check 2 (secondary schools).

3.7 Check-up visits

The target school grades and age-ranges will be agreed in consultation with MoPSE, MoHCC and other stakeholders during Phase 1 of the study and will align with existing or planned school services. The timing of the check-up visit will be agreed with teaching staff, students, and community stakeholders. Y-Check will target two age cohorts, Y-Check 1 (10-14 year olds) and Y-Check 2 (15-19 year olds).

Y-Check 1

The first visit, Y-Check 1, will target the 10-14 year old age cohort and will be delivered exclusively in primary schools as a very high proportion of the target population are attending primary schools (90.5% (MICS 2019).[21,22] The intervention is likely to target adolescents in Grade 5 where the majority of students are aged 10 years (45% aged 10 years in MICS 2019) or 11 years (21% aged 11 years in MICS 2019). However, as a result of starting school late or repeating years there are a proportion of students who are over age for their grade (10% were aged 12 and 4% were aged 13 years).[22]

Y-Check 2

The second check-up visit, Y-Check 2, will target the 15-19 year old age cohort and will take place both in secondary schools and at community venues (16-19 years only in the community). In schools, Y-Check 2 is likely to target adolescents in Form 3 where most learners are aged 15 or 16. School attendance drops off in secondary schools and an estimated 50% of 16 and 17 year olds are out of school.[22] We are therefore proposing to also deliver Y-Check 2 at community venues to adolescents aged 16-17 years who are not attending school. Community venues will be multi-purpose use locations, such as a community centre. Using methods developed to deliver sexual and reproductive health services in the ongoing CHIEDZA trial (www.chiedza.co.zw) we will create bespoke 'hubs' in existing community centres to deliver Y-Check 2. This will be accompanied by mobile outreach at locations frequented by adolescents (e.g. shopping centres, workplaces, bars, sports venues) to advertise the check-up visits and achieve high coverage.

Information about Y-Check services will be shared with parents/guardians and community members before the intervention team visit the school/community venue. Consent procedures will differ for those recruited in schools (Y-Check 1 and Y-Check 2) and those recruited in the community.

- School recruitment (Y-Check 1 (10-14y) & Y-Check 2 (15-19y)): All students in the Y-Check target classes/forms will be eligible to participate if their parent/guardian has signed a consent form and the student has provided written assent.

- Community recruitment (Y-Check 2 (16-19y)): Participants receiving Y-Check 2 services in the community will provide their own verbal consent. Parent/guardian consent will not be required for adolescents receiving services in the community, but participants will be encouraged to share information and results with their parents/guardians or another trusted adult.

Parents/guardians/students can choose to participate in the full screening visit or part of the screening visit e.g. the pre-consultation questionnaire and nurse review only.

3.7.1 Information, education and communication (IEC)

During check-up visits in all settings, IEC materials about mental health, diet and exercise, oral health, drugs and alcohol, sexual and reproductive health (SRH), HIV, safety, and general health will be available in the form of video clips, games, information leaflets and social media postings. IEC materials will be appropriate for various age and literacy levels. Materials will also be provided to help adolescents to navigate the health system and find a trusted provider if they have an urgent issue. The Y-Check team will provide details on how clients can get tailored advice or further information from the Y-Check team following the check-up visit, for example, if they can't access the trusted provider. The format of this support will be designed with young people during Phase 1 and may take the form of a live chat option on a Y-Check webpage, a phone number that can be messaged (via SMS or WhatsApp), or a hotline phone number that can be called free of charge. All IEC materials to be shared in schools will be submitted to the Curriculum Development and Technical Services Department for confirmation of curriculum alignment.

3.7.2 Screening tests and treatment/referral protocols

Screening tests and detailed treatment/referral protocols will be developed and implemented in line with national guidelines and best practice. As the screening of adolescents in Zimbabwe for many of the conditions listed below has not been implemented before, identifying locally accessible care pathways will involve working with existing services and potentially developing novel opportunities and pathways to address current gaps in service provision. During Phase 1 we will form a working group comprised of study investigators, health and social care, and disability stakeholders to decide on the final screening and referral strategies. Draft protocols are described here and in **Appendix 1.**

Psychosocial issues and alcohol, tobacco and substance use
Participants will respond to questions about their home, school/work, social activities, and exposure to violence and other risky situations using questions adapted from multi-domain psychosocial screening tools such as HEEADDSSS (Home, Education and Employment, Eating, peer activities, Drugs, Sexuality, Suicide/Depression, Safety and Security, Screens and Strengths) and other validated substance abuse questionnaires such as CRAFFT and Alcohol, Smoking and Substance Involvement Screening Test - Youth (ASSIST-Y)[23]

Adolescents who are identified as high-risk including those who report experiencing or perpetrating violence, addiction to drugs or alcohol, or being suicidal will be referred to health, social and/or police services. The Y-Check team have a legal obligation to report certain findings such as domestic violence/abuse of children (<18 years of age) to the relevant authorities (e.g. the relevant department of the police, and the social welfare department for domestic violence or abuse). Decisions around referral will take place in consultation with school staff, parents/guardians and/or trusted adults who have been nominated by older adolescents (see section 7.6).

Mental Health

Mental health will be measured in a stepped screening process using validated tools for depression and anxiety e.g. the Shona Symptom Questionnaire (SSQ), Patients´ Health Questionnaire – Adolescent (PHQ-A), Generalised Anxiety Disorder (GAD-7), Pediatric Symptom Checklist (PSC-Y),or Hospital Anxiety and Depression Scale (HADS). [24] Those with a score indicating risk of common mental disorders (CMD) will be referred to the nurse or counsellor for additional assessment and counselling. The nurse will then refer those with moderate anxiety or depression to the Friendship Bench for Youth (YouthFB) intervention or other youth-friendly counselling services. Participants who indicate severe mental health disorders that require more urgent care will be referred immediately as a 'red flag' case to the nearest health facility or youth-friendly counselling services.

Growth and nutrition

Participants will report on their diet and exercise in the pre-consultation questionnaire. All participants will have their waist circumference, mid-arm circumference (MUAC), Body Mass Index (BMI), and Body Volume Index(BVI) or Bioelectrical impedance analysis (BIA) measured to assess nutritional status. MUAC measurements will be compared to age and gender specific standards.[25,26] Adolescents who are overweight or obese will receive counselling and information on diet and exercise. Adolescents who are severely underweight will be referred to food supplementation services.

All participants will be screened for anaemia by taking a finger-prick sample of blood which will be tested during the check-up visit using HemoCue. If anaemic (children <11 years Hgb <11.5g/dL, 12-14 years <12g/dl, females >15 years <12g/dl, males > 15 years <13 g/dL): Iron and folic acid-supplementation (3 months supply) will be provided. If severely anaemic (<8g/dl) the participant will be referred to health facility for investigation.

Oral health

Participants' teeth will be visually inspected to identify dental caries, pits or fissures in the enamel, abscesses, swelling or oral lesions. Untreated caries, pits or fissures will have an application of silver diamine fluoride (SDF). If the adolescent has also reported pain or swelling they would also be referred to a dentist. For all participants, a fluoride varnish will be applied to all their teeth (irrespective of condition). A gift of a tube of toothpaste and a toothbrush with be provided to allow participants to practice the oral health guidance that they will have received from the research team. A demonstration of how to brush teeth correctly will be included in the IEC materials (see section 3.6.1).

Voluntary male circumcision (VMMC) (Y-Check 2 in the community hubs only)

During the background assessment males accessing services in the community will be asked if they are circumcised. If necessary, they will also undergo a visual inspection, respecting their privacy. Privacy will be respected during any visual inspection by the inspection happening in a closed room or tent where only the participant and the health worker are present. If they are not circumcised and request VMMC then expedited referral will be arranged.

HIV Testing and Counselling (Y-Check 2 in the community hubs only)

All participants will be offered standard provider-initiated HIV testing and counselling (PITC) using national guidelines. Clients will be offered a self-test for HIV on-site using an oral mucosal test (OMT). The staff member will provide a demonstration on the use of the OMT. All positive HIV test results will require a second confirmatory test with a blood-based rapid diagnostic test (RDT). Discordant or

inconclusive results will be further evaluated according to national guidelines. For 16-19 year olds who test positive, the counsellor/nurse will suggest that the adolescents' trusted adult be contacted so that they can join the discussion of the results and next steps. The study team will facilitate referral of those who test positive to a local health facility to register for HIV care. HIV+ adolescents will be encouraged to join adherence support groups run by local NGOs/CBOs. If HIV positive and sexually active, adolescents will be asked to refer their partners to government health clinics for HIV testing.

Sexual and reproductive health (Y-Check 2 in the community hubs only)

- All participants will be offered male **condoms** regardless of reported levels of risk behaviour. Those reporting high risk sexual behaviour (sexual intercourse without a condom, multiple sexual partners) in the pre-consultation questionnaire will be offered **risk-reduction counselling**.

- **HIV pre-exposure prophylaxis (PrEP)**, which confers significant protection against HIV acquisition, is being rolled-out in Zimbabwe for populations at high risk of HIV acquisition including men who have sex with men and girls aged 15-24 years who report high risk sexual behaviours.[27] Participants who report high risk sexual behaviour and who test negative for HIV will be referred to a local health facility to assess their eligibility to receive PrEP according to national guidelines.

- Participants will be offered screening tests **for sexually transmitted infections (STIs).** Urine samples will be screened for infection with Gonorrhea (GC) and Chlamydia Trachomatis (CT) using the closed GeneXpert system. This is a near point of care test which provides results in 90 minutes. Females will also take their own vaginal swabs which will be tested for trichomonas *vaginalis* (TV) using a point of care lateral flow assay. There will be a private space available for girls to self-administer the vaginal swabs. This will either be in a bathroom or a private room they can access on their own. They will be provided gowns and drapes should they wish to use these. They will place the swab into a container and return the container to Y-Check staff after leaving the private space.

  Syndromic management and treatment of STIs will be provided according to national guidelines. Participants who test positive for an STI and who had not already been treated following syndromic management will be followed up and treated according to national guidelines. Partner notification slips will be provided to those who are treated for STIs.

- For females, **Pregnancy testing and contraception** (emergency contraception, Depo injections and the oral contraceptive pill) will be provided upon request and participants will be referred to the local health facility for longer-term contraception care.

Menstrual health and hygiene (MHH)

Females will receive guidance on MHH[28] including advice on pain management along with the provision of a choice of reusable MHH products (e.g. reusable pads, reusable period underwear) and analgesia.

Immunisation

The Human Papillomavirus vaccine was introduced for adolescents in 2018 targeting Grade 5 learners (age 10-14 y) or out of schoolgirls aged 10y. Participants will be asked to show their immunisation

record (when available) or verbally report whether they have had the HPV vaccination. Where vaccination cards show that the participant has not completed the recommended schedule, the nurse will either link the girls to the National HPV programme or provide the first dose of the vaccine and refer for subsequent doses, if necessary. Eye health

Visual acuity problems will be identified using the Peek Acuity smartphone app.[29-32]The Snellen Tumbling-E card will be available as a back-up screening tool. Those who are identified as having problems with their distance vision (worse than or equal to 6/12 in either eye)) will be referred to specialist services for further examination and to identify the cause of sub-optimal acuity. Treatments such as eye drops and and glasses will be provided free of charge by the Y-Check programme. Participants with visual impairment will be given a printout of a smartphone simulation of what they are able to see vs. what someone with normal vision would see with the referral letter to present to their parent or guardian.[30]

Hearing

Hearing problems will be identified using the HearScreen or HearWHO smartphone app.[33] Participants who fail the HearScreen or HearWHO test may have the threshold of their hearing loss measured using HearTest and the nurse will check for the presence of wax using an otoscope or the smartphone app. If wax is present, then the nurse will attempt to remove the wax and then repeat the hearing test. For those who still fail the hearing test and/or where wax was not present, the participant will be referred to specialist services for further examination and potential treatment with antibiotics for chronic middle ear infection, wax removal, or hearing aid fitting.

Physical impairment

We will include questions from The Washington Group/UNICEF Child Functioning Module child screening tool[34] in the pre-consultation questionnaire to identify adolescents who might have a physical impairment. All adolescents will be asked to undergo a short non-invasive test for lower limb impairment such as a jump or squat test. Upper limb impairment and fine motor skills will be assessed using existing tools e.g. grip strength test, functional reach test, or through the development of new context specific tools. Adolescents with significant untreated physical impairment will be referred to a physiotherapist.

Epilepsy

We will screen adolescents for convulsive seizures using questions adapted from existing tools. [35] There is limited epidemiological data on epilepsy in the African Region and the prevalence is estimated to be anything from 2.2 to 58 per 1000 with the second highest incidence in the age group 10-19 years.[36,37] Participants who screen positive will be referred for diagnosis, counselling and treatment.[19]

Blood pressure (Y-Check 2)

The blood pressure of participants will be measured using a digital sphygmomanometer. Two or three measurements will be taken at set intervals during the check-up visit.. Participants with suspected prehypertension will receive counselling to identify modifiable risk factors e.g. obesity, lack of physical exercise, smoking, and will be advised to attend a health facility to repeat their BP measurement after 6 months. Those with suspected hypertension will be given advice on diet and exercise and referred to the local health facility for further assessment. [38]

Schistosomiasis

A national study of schistosomiasis in Zimbabwe published in 2014 showed a prevalence of 5.2%

(95%CI 2.9,8.6%) for the combination of S. haematobium and S. mansoni in primary schools in Chitungwiza and of 9.6% (95%CI 8.0,11.5%) in Harare (Midzi et al., 2014). In Chitungwiza, the estimated prevalence of S. haematobium was almost 10 times higher than that of S. mansoni. We will therefore test initially only for S. haematobium using a urine filtration lab test to detect the parasites in the urine. Considered the 'gold' standard, this test shows high sensitivity and specificity. We will review the screening procedure after the first 200 adolescents have been screened. If the prevalence of S. haematobium is 15% or higher (n=200 will allow 5% margin of error on prevalence estimate) then we will additionally test urine samples for S. mansoni using the commercially available urine-based Point of Care test, based on detection of circulating cathodic antigen (CCA). In this situation, the initial 200 adolescents will be revisited so that they can also be tested for S. mansoni. Detection of schistosomiasis will require collecting urine specimens which will be tested in the lab or on-site as stated above. National protocols for treatment will be provided as needed for those who test positive."

3.7.3 Configuration of Services

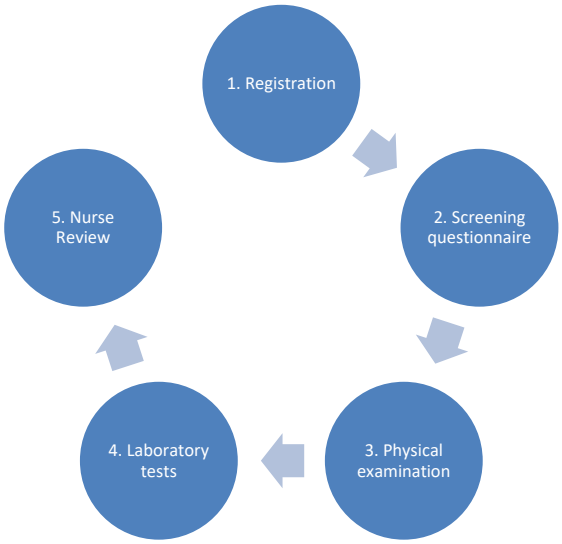
On the first day of the screening visit, the intervention team will arrive at the school or community location and set up the intervention room/tent. Clients at school settings (Y-Check 1 and 2) will provide written assent and provide completed parental consent forms before proceeding through the check-up visit stations. Clients at community settings (Y-Check 2) will provide verbal consent before proceeding through the check-up visit stations.

Y-Check will be configured to be "youth-friendly" i.e. able to effectively attract adolescents, meet their needs comfortably, and responsively and retain them in care. Visual and auditory privacy will be prioritised, services will be appropriate and affordable, staff will have received training in youth-friendly service delivery, and adolescents will be involved in the design of the intervention content and delivery (see section 4.2.1). Visits will involve a five staged-process, consisting of: i) registration; ii) completion of a screening questionnaire; iii) a physical examination; iv) laboratory tests; and v) a review with a nurse.

STATION 1: Registration

During registration, a trained research assistant will welcome adolescents, record their date of birth and sex, and national ID number. Research cohort participants will also be provided with a personal identifying number (PID). They will also record their ID numbers, name, address and mobile phone numbers on a separate locator log. While clients are waiting to proceed to the next station they will have access to health and well-being information (see section 3.6.1).

Figure 4. Y-Check configuration of services



STATION 2: Pre-consultation screening questionnaire

The adolescent client will then be given an audio computer-assisted self-interviewing (ACASI) questionnaire on a tablet computer and respond to questions on home environment, education and employment, social activities, physical activity, diet, mental health, alcohol, tobacco and drug use, sexual health, male circumcision, oral health, adolescent immunisation history, and general health questions (see Section 3.6.2). The questionnaire, developed and validated during Phase 1, will be based on the WHO Global School-based Student Health Survey tool, HEEADSSS[23] and other existing pre-visit screening tools for adolescents.[39] The research assistant will assist with any challenges or questions during completion of the questionnaire or when using other tablet features. Completion of all sections of the questionnaire will be incentivised by a rewards system e.g. where clients get to customise their electronic avatar on the tablet as they proceed through the questionnaire or gather points that can be used to retrieve health and well-being products at the end e.g. soap, extra sanitary pads, deodorant etc. Incentives will be decided on in collaboration with adolescents and other stakeholders during Phase 1. In case of technical difficulties, a paper and pen back-up questionnaire will be available. If a client does not want or is unable to self-complete the questionnaire, then a member of staff will interview them and complete the questionnaire.

STATION 3: Physical examination

The physical examination will be conducted by a trained community health worker, and will include the following:

- Oral health, with visual inspection for dental caries, pits or fissures in the enamel, abscesses, swelling or oral lesions;
- Physical impairment assessment, examining lower and upper limb function
- Anthropometry to measure waist circumference, mid-upper arm circumference, body mass index (BMI), and Body Volume Index(BVI) or Bioelectrical impedance analysis (BIA). BVI and BIA measure body fat volume and distribution providing additional information on an individual's nutritional status and risk for NCDs.
- Visual impairment assessment, using portable eye examination kit (PEEK) mobile app
- Hearing impairment assessment, using HearScreen or HearWHO smartphone app
- Blood pressure measurement, using a digital sphygmomanometer.

The physical examination will not include a full standard clinical physical examination (eg. examination of the heart, lungs, abdomen, pelvis, etc).

STATION 4: Laboratory test

The laboratory tests will be conducted by a trained research assistant and/or a laboratory technician and will include:

- Anaemia, using haemoglobin measurement
- Participants will be asked to provide a urine specimen that will be tested for Schistosoma haemotobium and Schistosoma mansoni.
- HIV testing for older adolescents using a HIV oral mucosal transudate test with confirmatory blood testing using RDTs (Y-Check 2 community hubs only)
- STI testing for the older adolescents using GeneXpert for CT/NG and a lateral flow assay for TV. (Y-Check 2 community hubs only)
-

STATION 5: Nurse review

Lastly the clinical assessment will be conducted by a nurse, who will review all results and provide on-the spot treatment and care, or referral as needed. For each domain of the pre-screening questionnaire, an automated score report will be generated with cut-offs. The nurse will be directed to ask additional questions, and where appropriate refer the client to social services, health services and/or specialist NGOs/ organisations. The nurse may also refer the client to the Y-Check counsellor for counselling and/or brief interventions. The nurse will also take the opportunity to provide advice and anticipatory guidance.[40] Referral pathways will be established during Phase 1 to ensure prompt referral.

3.7.4 Intervention team

There will be two intervention teams, each comprising of a two nurses, a counsellor, and three or four research assistants. The team will consist of a mix of male and female providers. The Y-Check team(s) will spend approximately 2-3 weeks in each school for the check-up visit. The Y-Check 2 teams(s) will spend 3-5 weeks delivering the check-up visit in each community hub.

Although the intervention teams are affiliated with this research project (and this will be made clear to all those who interact with them), their primary role will be to deliver what is recognized by the WHO as 'best practice' public health interventions. Hence for this project we regard the intervention teams as separate from the 'research teams' and believe that the norms and standards governing their activities should largely be those accepted for the implementation of public health interventions rather than those applied to conventional clinical research projects. Regarding the services being delivered by the intervention team as research activities would make this public health research project logistically impossible to implement.

The intervention team will be selected on the basis of prior experience in working in communities and with adolescents. In addition, the intervention team will undergo a training programme on provision of youth friendly services as well as on each of the intervention components. Training will particularly focus on the following aspects:

- Adolescent physiology and development

- Knowledge and skill on delivery of each intervention component according to age and maturity of client
- Skills on counselling and communication with adolescents
- Skills to bring myths to surface, and to discuss and dispel them
- Interpersonal skills
- Adolescent rights
- Attitudinal training (respect, confidentiality, non-judgement, relatability)
- Referral pathways
- Gendered vulnerabilities and gender responsive health services

4. Research Procedures and Activities

4.1 Stakeholder involvement in the research

In Year 1 a Community Steering Committee comprising key community leaders and stakeholders will be set up to facilitate input from, and feedback to, participating communities. A Youth Advisory Group (YAG) will be established with members selected through a participatory process in collaboration with the study communities and local stakeholders. The YAG will provide a forum for adolescents to input into the programme. The YAG will meet a minimum of 4 times a year with research staff, be active participants in programme design and dissemination workshops, and help to ensure that the programme meets the needs of adolescents.

In Year 2, pilot study results will be discussed at a co-design workshop with local stakeholders including young people, and agreement reached on any revisions that need to be made to the intervention. In Year 3, a meeting will be held to update stakeholders on progress with the study and to give stakeholders an opportunity to raise any issues related to the programme that they would like to discuss further. In Year 4, a participatory dissemination workshop with local and national stakeholders will discuss the findings, implications for future programmes, and next steps for the programme of research.

The Y-Check school research team will collaborate with the MoPSE Centre for Educational Research and Innovation Development (CERID) on the development and evaluation of the intervention including development of educational materials and the screening questionnaire, evaluation tool design, and interpretation and dissemination of the evaluation findings. The Y-Check school research team will collaborate with multi-disciplinary District and Provincial MoPSE teams including Learner Welfare, Schools Psychological Services and Special Needs Education (LEPS) staff, and Child Protection Committees on the implementation and monitoring of the intervention.

4.2 Intervention development and pilot testing (Phase 1)

MRC guidance on developing and evaluating complex interventions[12] and WHO recommendations on digital interventions for health system strengthening[13] will underpin the development and implementation of the intervention. Clear messaging, awareness building, and sensitisation campaigns will be developed to overcome the potential barriers that were identified during Y-Check formative work conducted in Chitungwiza in 2020 (Section 1).[14] This phase comprises 3 distinct research development activities followed by a pilot study.

Intervention acceptability and relevance

Through BRTI's Youth Research Academy[14], we will recruit and train two Youth Researchers (aged 18-24) who will be full-time members of the Y-Check team and co-lead ongoing youth engagement activities. In order to maximise the acceptability and relevance of the Y-Check intervention to adolescents, the programme branding and messaging, the visit environment/experience, and support structures for onward referral and care will be co-developed with adolescents in Year 1. Client-centered outcomes will also be identified.

A crowdsourcing challenge contest in Year 1 will involve an open call to solicit new ideas, images, or strategies from adolescents (10-19 years) on how to brand and promote Y-Check[15]. Crowdsourcing, where a group of people design a solution to a problem and share it with the public, is an innovative participatory method to intervention development.[41,42]

BRTI staff, the YAG, and Youth Researchers will form a steering committee who will develop the call, solicit entries, promote the contest and judge entries. Shortlisted entries will be invited to co-design the Y-Check brand and messaging in a two-day hackathon with a marketing agency. Winners will get a prize (e.g. recording of a song, short film, internship). The crowdsourcing contest will be evaluated through a descriptive summary of number and quality of entries, along with in-depth interviews with adolescent participants and their parents, adolescents who expressed an interest but did not participate and organisers. The winning entries and evaluation findings will be disseminated to stakeholders.

A review of epidemiological data including analysis of routine DHIS data on service uptake will allow us to identify sub-groups of adolescent health service users (population segments). Intervention messaging and the Y-Check visit experience will be tailored to maximise potential relevance for different population segments. Analysis of Y-Check pilot data will allow further refinement of our understanding of population segments and tailoring of the intervention.

The intervention will be co-designed with young people and service providers through the following series of activities:

- **Co-design workshop 1**: A participatory workshop will be held to discuss format and content of digital platform, and the referral pathways (see below)
- Development of a demo platform and referral pathway by the Y-Check study team
- **Co-design workshop 2:** The demo will be pre-tested among adolescents and service providers
- Pre-testing and ongoing refinement to develop minimum viable product (MVP)
- **Co-design workshop 3:** The MVP will be pre-tested among adolescents and service providers

Clinical characteristics of intervention including screening tools and referral pathways

Update of situation analysis and prioritisation of Y-Check content

We will update the 2020 situation analysis to identify best practices (Section 1). In particular, we will review the literature on screening tools and effective interventions for the conditions to be included in Y-Check. In collaboration with the Community Steering Committee and the Youth Advisory Group, we will define priorities in terms of screening and referral protocols, agree on clinical setting and cadre

of staff to deliver check-up visits. Through consultation with service providers we will agree on clinical treatment and referral protocols.

Screening tool validation

The review of the literature will identify potential items, questions, and tests to measure the conditions and behaviours of interest. An expert panel comprising study investigators and local healthcare professionals will review the tools and make recommendations for tools to be taken forward for pre-testing and will indicate where tool validation is required. The self-completed pre-consultation questionnaire will comprise of questions from existing validated tools e.g. HEADSS and the Shona Symptoms Questionnaire, and some new questions which have not been validated in Zimbabwe or other similar contexts e.g. physical impairment, epilepsy, question to assess if HPV vaccination was received. We will develop or adapt a measure of adolescent well-being that can be used to understand the impact of the intervention on overall well-being, defined as 'Adolescents thrive and are able to achieve their full potential'.[43] We will review existing measures of adolescent well-being and select a measure to be pre-tested and included in the Y-Check pre-consultation questionnaire.

Our aim will be to keep the pre-consultation questionnaire as short as possible while still accurately identifying those who require further investigation.

Validation studies will take place during the co-design workshops, during pre-test or during the pilot or intervention study. Validation study participants will be identified from the target study schools and communities. Depending on the tool, validation may involve the following:

- Repeat completion of the pre-consultation questionnaire one week after the initial completion to measure test-retest reliability.
- Where a series of questions are used to measure an overall construct e.g. mental health, chronbach's alpha will be calculated to assess internal consistency and construct validity will be assessed using Principle components analysis and/or confirmatory factor analysis.
- Clinical confirmation of the condition/risk factor to assess sensitivity and specificity of the questions

Finalisation of screening and referral protocols

We will liaise with MoHCC and other service providers to establish referral pathways for the conditions listed in Table 1. Potential referral institutions will be visited by the study team to understand the services that they offer, the services that they could potentially offer with additional resources, and to assess the quality of the services provided by comparing against national guidelines and standards. Referral pathways will be pre-tested to assess their local acceptability. Referred clients will be given a voucher to allow them to access referral services for free. Redeemed vouchers will be retrieved by the study team and used to measure referral uptake and organise payment to the providers. Additional support for the completion of referrals and access to care will be developed in collaboration with the YAG and CSC. One potential mechanism of providing advice and support to adolescents and their parents/guardians is through a free hotline number, similar to the one currently used in the CHIEDZA trial.

<u>The output will be finalised screening and referral protocols to be used in the pilot study.</u>

Digital platform development and design of a "Digital Health and Well-being Club"

In order to increase visit/referral efficiency we will develop a **Y-Check digital platform**. The platform will be used during face-to-face data collection by the registration personnel and the nurse. Adolescents will be able to self-screen using electronic pre-consultation questionnaires and pre-existing apps, and if they provide a phone number they will receive reminders about referral appointments. A reward system incorporated in the digital platform with adolescents gaining points when they complete screening will encourage sustained engagement. The digital platform will be developed in Open Data Kit (ODK) or other suitable platforms and will follow the Principles for Digital Development.[44]

The output will be a minimum viable product (MVP) to be used in the pilot study.

In addition, we would like to develop a **Digital Health Club** where Y-Check participants can receive periodic online advice, encouragement, reminders, quizzes, competitions and rewards through an online platform. We envisage that this will lead to long-term improvements in adolescents´ health and well-being. This will provide a safe space where adolescents can feel accepted, free from stigma, maltreatment and violence, and in which they can access youth-friendly information about health concerns and health services. Adolescents attending Y-Check will be invited to sign up to join a "Digital Health Club". Our current idea is that participants who opt to join the club will receive a password-protected personal login which allows them to access their "personal space" in the web platform from any internet-enabled device. They will be able to develop their own profile, choose the information they display, as well as select an avatar. The personal space will include the results of the Y-Check screening and any referrals if they were referred. In this space, they will receive reminders and alerts, as well as relevant health information. At the site, they will also be able to receive details of all the accredited referral facilities, health-related quizzes, games, stories, news, encouraging messages. These will be tailored for their age, gender and stated interests (eg. fashion, beauty, sports, education, business etc). By completing quizzes or other activities they will be awarded points that they can cash in for vouchers to do brief training courses run by local NGOs/CBOs on business skills (eg. cv writing, basic accounting, how to make a spreadsheet using EXCEL, etc). The service will provide a moderated chat function, where adolescents can chat with others who have signed up, and share their experiences with others in an online safe space.

The digital health club component was not explored in any detail during the Y-Check formative phase. During this phase of the research, we will conduct formative research, including desk based research, a photovoice study, and co-design workshops, to design a digital adolescent health and well-being club, and to explore its likely feasibility and acceptability.

Through the photovoice study we will gather information on the contextualised factors that contribute to or impede adolescent health and well-being using photographic evidence. Photovoice is an innovative qualitative research method that falls under participatory action research strategies[45,46] The technique requires participants in the study to take visual images that reflect the topic. These photographs are then used to support dialogue around the topic of adolescent health issues (such as nutrition) and well-being. The photovoice method follows a sequence of steps or procedures which are as follows. The process begins with recruitment of participants. A total of 20-30 Y-Check participants will be purposively recruited based on gender, age, health status, household assets/income and catchment area in order to maximise representativeness of the adolescents in the Chitungwiza community. Participants aged 16-19 years will be asked to provide their own informed consent (16+years) **(YC_A14).** Participants aged

10-15 years, and those aged 16-19 years who cannot provide their own consent, will be asked to provide informed assent with parent/guardian informed consent (10-19 years) **(YC_A13).** The consented participants are then invited to attend a series of up to six meetings, that include two training sessions, three focus group discussions and one credibility meeting. For the first meeting, participants will familiarize with other peers, the study, the study team, and the topic. During the second meeting, participants will undergo training on the use of cameras, practice taking photos; subject matter; ethics of photography; as well as the potential risks of photovoice and how to minimize these risks. After the adolescents have successfully been trained, the Y-Check team will then distribute cameras and film to each participant who will be tasked with taking creative pictures that document their experiences and perspectives of issues relating to their health and well-being. After a week or two, participants will then return the camera and film to the facilitators. Participants younger than 16 years will be accompanied by a member of the Y-Check Study Team to ensure their safety and adherence to the photovoice guidelines.

After the photographs have been developed, the facilitators and adolescents will once again meet for focus group discussions. During these audio-taped meetings, participants will have the opportunity to reflect, discuss and tell the story behind between 3-5 of their own pictures. Recurring themes and issues will be reported in the findings. Discussions will be terminated once data saturation has been reached. For this research we anticipate that a maximum of three of focus group discussions will be needed. Once all data has been compiled, facilitators and participants will meet again to verify and ensure the adolescents' views have been recorded correctly and are a true representation of their thoughts. This last meeting is known as the credibility meeting.

During this final meeting, facilitators together with participants will plan and decide the platform and manner in which to publicly display or share the photos taken during the study. The purpose of this, is to give participants an opportunity where they can share their photos with an audience of policymakers and community leaders to raise awareness around adolescent health and wellbeing. Permission will be sought from the participants and their guardians before using their pictures **(YC_A16).**

The desk-based research along with findings from the photovoice study and co-design workshops will inform plans for the digital health club. When the digital health club is ready to be pretested and piloted we will submit a protocol amendment with new or modified consent forms specifying the details of the club, the risks and benefits of participation, and how the data will be managed.

The output of this part of the research will be a prototype 'Digital Health Club for Adolescents and Youth' and preliminary information on its feasibility and acceptability as a way to initiate longer term contact with the adolescents.

4.2.4 Pilot study

The intervention will be pilot-tested in one or more of the selected primary schools, secondary schools, and community settings with 50-100 adolescents participating per age group (10-14;15-19 years). The aim of the pilot study will be to test the relevance, acceptability and feasibility of the intervention components, and to test and refine study procedures. Pilot work will take place over a six-month period to allow for refinement and improvements to intervention procedures.

A mixed-methods evaluation will be used to refine the intervention procedures during the pilot phase. Programme data will be described. Targeted in-depth interviews (IDIs) will be conducted with a sub-

sample of students, out of school adolescents, teachers, caregivers and staff delivering the intervention, to assess the interventions relevance, acceptability, and feasibility.

A participatory workshop (Co-design workshop 4) will be held with key stakeholders to review the findings of the pilot study and agree on further improvements to the intervention/digital platform. Following that workshop, the Y-Check study team will further refine the digital platform and intervention including clinical referral pathways and brand/messaging.

The output will be an Operation, Training and Supervision Manual, and an evaluation study protocol.

4.3 Prospective Intervention study (Phase 2)

In a prospective intervention study, Y-Check will be implemented for 10-14 year olds in up to 6 government primary schools (N=1000), and for 15-19 year olds at up to 8 secondary schools and up to 4 community hubs (N=1000). The Y-Check programme is described in section 3.

4.3.1 Cohort recruitment and follow-up

Prior to the Y-Check visit, programme participants will be invited to join the research cohort and agree to the following additional activities:

- Self-completion of an additional module of the pre-consultation questionnaire (to measure baseline outcomes not captured for programme participants e.g. knowledge, intention, agency, educational outcomes)
- Observation of check-up visit and referral visit procedures by a Y-Check team member.
- Exit interviews
- Follow up visits at 4-months and 12-months (questionnaire and screening tests)
- Potential participation in qualitative interviews or group activities

Y-Check 1: The information sheet distributed by the school about the check-up visits (section 3.7) will include information about the Y-Check research cohort and the need for separate consent to participate in the research study. Eligible students will be asked to return completed informed parental consent and individual assent forms either before or on the day of the check-up visit.

Eligibility criteria will be:

- Currently enrolled in Grade 5, 6 or 7 in one of the study primary schools
- Adolescent and their parent/guardian have consented/assented to participate in the check-up visit
- Written informed parental/guardian consent and client assent to participate in the research study

Y-Check 2: The information sheet distributed by the school about the check-up visits (section 3.7) will include information about the Y-Check research cohort and the need for separate consent to participate in the research study. Eligible students will be asked to return their completed informed consent form either before or on the day of the check-up visit.

In the community, mobilisation and advertisement will encourage adolescents to attend the community hubs for check-up visits and will describe the accompanying research study. At the community hubs,

following confirmation of eligibility, clients will be asked to provide written informed consent to participate in the research study.

Eligibility criteria will be:

Schools:

- Currently enrolled in Form 3, 4 or 5 in one of the study secondary schools
- Adolescent and their parent/guardian have consented/assented to participate in the check-up visit
- Written informed parental/guardian consent and client assent to participate in the research study

Community hub:

- Currently aged 16 to 19 years & resident in the study community
- Adolescent has consented to participate in some or all components of the check-up visit
- Written informed consent from client to participate in the research study

Cohort follow-up visits will be at schools for Y-Check 1 participants, and at the school and/or community hubs for Y-Check 2 participants, using SMS reminders and active follow-up. Follow-up of Y-Check 1 clients may also be done using the contact details provided by parents/carers. Y-Check 2 clients will be asked to provide mobile phone numbers so that they can receive reminders about referrals and a monthly health message during the 12-month follow-up period. USD5 will be given to each participant to cover any transport costs that they might have incurred to attend follow-up visits.

4.3.2 Outcome evaluation

Adolescent outcomes (see **Figure 1, section 6.1**) will be ascertained during the check-up screening visit, through 4-month and 12-month follow-up visits and through review of school and health service registers and/or collection of referral vouchers. The primary outcome will be measured at the initial check-up visit and through recovery of referral vouchers within the 4-month follow-up period. The 12-month follow-up will provide preliminary data on longer-term health, well-being and education outcomes, and will inform the feasibility of longer-term follow-up in future planned phases of the research.

The primary outcome will be the proportion of those screening positive for at least one condition who receive appropriate on-the-spot care or complete appropriate referral for all identified conditions within 4 months. Completed referral is defined as attending at least the first referral appointment. We expect referral/treatment to have occurred within 4 months **(Figure 1**). Monitoring of completed referral will be facilitated by recovering vouchers given to participants to allow them to access referral services for free and through a review of health records and registers. At follow-up visits, clients will also be asked to report on their attendance at health services in the previous 4 or 12 months.

Secondary implementation outcomes will be yield of previously undiagnosed and un-referred conditions clinical outcomes among those who screen positive, and intervention acceptability, adoption, appropriateness, feasibility, fidelity and cost (**Figure 1, section 4.3.3 Process evaluation**).

Secondary client outcomes will be knowledge about health services and health behaviours, agency to make decisions about health, reported health-related risk and protective behaviours, reported engagement with health services, well-being, self-esteem and quality of life, clinical outcomes,

educational outcomes, client-centered outcomes (see section 2.3) and cost-effectiveness of the intervention (**Figure 1**).
Following the initial check-up screening visit, and during 4-month and 12-month follow-up visits, clients will be asked to self-complete a tablet questionnaire, and undergo clinical screening tests. The content of the follow-up visits will be decided on during Phase 1 following piloting and costing of the screening and referral protocols for each condition. The follow-up visits may offer a reduced number of clinical screening tests.

4.3.3 Process Evaluation

We will conduct a mixed-methods process evaluation based on the MRC Process Evaluation framework[47]. Several research questions and key areas of investigation will be addressed related to each of the 3 core process evaluation functions: implementation, mechanisms of impact and context. We will draw on implementation and evaluation frameworks (RE-AIM[48], CFIR[49], PRISM[50]) to guide the selection of implementation outcomes and contextual factors, develop interview guides, and guide the coding and analysis of barriers and facilitators to programme implementation. Implementation outcomes of interest are acceptability, adoption, appropriateness, feasibility, and fidelity (**Figure 1**).

Across the pilot and intervention studies, data collection will include observations and real-time feedback, quantitative process data, focus group discussions and in-depth interviews with adolescents, those involved in intervention delivery, and other stakeholders. Data will be collected at multiple time points, using multiple methods and sources and triangulated with outcome data. To help interpret the results of the study, existing adolescent services will be mapped in the study communities. The process evaluation findings will provide guidance for the next stage of the programme and potential future sustainable and scalable implementation by local health authorities should it prove successful.

The research questions and key areas of investigation, along with the related data collection methods and sources are outlined in detail in **Table 2**.

Quantitative data

There will be several sources of quantitative process data. Routine Y-Check programme data will be collected from all intervention sites. To the degree possible, the study team will obtain data from routine records in health facilities and other community based organisations (CBOs). This will take the form of de-identified, aggregate routinely-reported health facility data on the uptake of health services by adolescents before, during and after the Y-Check implementation period. The data will be requested from the specific clinics who are providing the referral services for Y-Check participants. As mentioned, it will be aggregate, routinely-reported data and as such it will be number of adolescents seen. It will allow us to to estimate how much the Y-Check referrals increase the number of adolescents attending these clinics, to better understand service use, the number of Y-Check service attendances and uptake of specific service components will be recorded. Outputs of interest include the proportion attending, yield of new cases, diagnostic accuracy of screening tests, screening uptake, and prevalence of conditions. Data on reported uptake of and acceptability of services will be obtained after the initial check-up visit and during the 4- and 12- month client follow-up visits.

Table 2: Process Evaluation Summary

Research Domain		Research Questions / Key Areas of Investigation	Data Collection Methods and Sources
Implementation *What is implemented and how?*	**Coverage & Uptake**	What proportion of adolescents accessed various components of the intervention? How equitable was this coverage? What were the barriers and facilitators to coverage and uptake?	Programme monitoring data Follow-up questionnaires with clients Structured / unstructured observations , workshops, informal interviews IDIs, paired/group interviews and / or FGDs with adolescents , providers, family members of adolescents, community members and other key stakeholders
	Fidelity	How did a) training, and b) actual implementation of each intervention component and delivery-mode vary from what was planned? What were the barriers and facilitators to implementation fidelity? What adaptations were made?	
Mechanism of Impact *How does intervention lead to change?*	**Responses to and interactions with the intervention**	Which components of the intervention were best accepted and adopted by adolescents, parents, teachers, healthcare providers, and other stakeholders? What were the barriers and facilitators to acceptability?	Follow-up questionnaires with clients Structured / unstructured observations Field notes IDIs, paired/group interviews and / or FGDs with adolescents providers, family members of adolescents, community members and other key stakeholders
	Interactions and Consequences	How did various components of the intervention interact? What happened after the initial screening and referral? Were clients satisfied with the overall experience? Were there any unanticipated pathways or consequences?	
Context *How context affects implementation and shape outcomes?"*	**Proximal and Distal**	What social, cultural, political, and logistical factors impede or facilitate (or were affected by) how the intervention was implemented, and how adolescents and other stakeholders engaged with it? What were contextual reasons for adaptations to the intervention and its delivery?	Structured / unstructured observations Field notes IDIs, paired/group interviews and / or FGDs with adolescents, providers, family members of adolescents, community members and other key stakeholders

Qualitative data

The methods for qualitative data collection will include observations, and IDIs, group/paired interviews, informal interviews, workshops and FGDs with adolescents, providers, teachers and other key stakeholders. To reduce the volume of data collection, and burden on research participants, one data collection method may provide data for several research questions simultaneously. Purposive and theoretically informed sampling will be used to determine the sampling frame for other data collection methods, with consideration of study community and provider and participant characteristics (e.g. age, gender, degree of engagement with the intervention). It is anticipated that up to 80 individual in-depth interviews with Y-Check service attendees from the 4 study communities, and up to 16 focus group discussions will be conducted. Up to 40 in-depth interviews with school and intervention staff, up to 40 in-depth interviews and focus group discussions with family members of adolescents, and up to 50 in-

depth interviews and FGDs with key informants including community members and adolescents who did not attend the intervention will be conducted. Semi-structured observations of various components of the Y-Check intervention will be conducted. Throughout the study, the process evaluation will remain flexible and dynamic to be responsive and adapt to emerging study and process findings.

4.3.4 Economic evaluation

Aims and Objectives

Primary objectives:

- To estimate the total cost of developing, setting up and running the Y-Check intervention
- To estimate the cost per improvement of well-being from implementing the Y-Check intervention
- To estimate the cost per DALY averted from implementing the Y-Check intervention

Secondary objectives:

- To estimate the cost of screening for each individual health condition or risk factor
- To estimate the cost per condition detected
- To estimate the cost of providing prevention and promotive advice
- To estimate the cost of providing on the spot healthcare for each health condition
- To estimate the cost of referral for each health condition

A costing study will be conducted to estimate the total costs of developing, setting up, and running the Y-Check package. A combination of top-down and ingredients-based costing approaches will be used to generate cost estimates for the whole package, and for each component/activity. All costs will be estimated from the societal perspective (the adolescents, the schools/community and implementing partners). Financial and economic costs will be calculated for all inputs. Costs will be collected from accounting records, through staff time survey, and process evaluation data including interviews with participants. Capital costs and those costs with a lifespan greater than the project life will be annualised over their useful life. Costs will be inputted into an Excel-based costing tool. The cost analysis will describe the distribution of costs across different forms of inputs, and will estimate the unit cost per adolescent reached, screened, and treated, cost per unit of measure for selected intervention outcomes such as cost per condition detected and cost per condition appropriately treated/referred within 4 months.

A well-being measure developed and adapted during phase 1 will be used to estimate the cost-effectiveness of the intervention measure as cost per improvement in adolescent well-being. Where data are available, we will estimate the cost per DALYs averted.

The cost and cost-effectiveness estimates will be compared to similar programmes in the region and will inform programme replication, scalability, and financial sustainability for different implementing partners.

4.4 Knowledge dissemination and translation (Phase 3)

Throughout the study, the Y-Check team will collaborate with MoHCC and MoPSE on the development of the intervention, including development of educational materials and the screening questionnaire. Study teams will provide routine assessment of progress and interpretation and dissemination of the findings to Ministries as well as other key stakeholders including school officials and community leaders. WHO will facilitate policy engagement and dialogue in countries with key country and regional office staff including Y-Check as part of their regular country dialogues with national counterparts.

During the final phase of the project, the study findings will be disseminated to all stakeholders via dissemination meetings and other engagement opportunities. Using the findings of the study, we will develop a set of methodological guidelines for the adaptation, implementation and evaluation of Y-Check in other LMICs settings. We will develop study protocols for additional larger scale implementation and/or rigorous evaluation studies with the aim of providing evidence on the impact of the programme on both educational and health outcomes.

5. Data management

5.1 Types of primary data

The different forms and uses of data within the study are summarised in Table 3 along with the proposed consent procedures.

5.2 Secondary data analysis

We will conduct secondary data analysis of de-identified routine health facility and other service use data to get a better understanding of adolescent's current use of health services. Routine health facility data includes data on screening and testing, and on services received e.g. family planning, HIV care. Data will be aggregated by service setting and we will request a waiver of consent to use the data.

We will conduct secondary data analysis of school register data to understand overall school attendance using aggregated de-identified data for all students in the target age-range/school years. For individual cohort members, we will also review their school attendance and performance records as part of outcome measurement.

5.3 Data quality and standards

Data collection

The data collection and entry processes will be as detailed in Standard Operating Procedures. We will use Open Data Kit (ODK) for electronic capture of quantitative data into custom-designed forms with built-in range, consistency and discrepancy checks. Sensitive questions will be input by adolescents themselves to prevent social desirability bias. Tablets will be password protected and personal identifiers will be stored in an encrypted format. Service use will also be captured in paper log books and registers designed for the specific care and prevention services provided. In each case a log will be kept of the number of people reached, products used, tests performed etc. Log books will be entered onto computer on a weekly basis on pre-designed forms.

De-identified field notes, team debrief summaries, and outputs from Participatory Action Research (i.e. pictures from mapping, scoring and ranking activities, photographs from photovoice and pictures drawn

during focus group discussions) will be stored electronically. Audio recordings of discussions and interviews will be transcribed verbatim or summarised in detail and then translated (if applicable) into English for analysis by a fieldworker and stored electronically. Each transcript will also have an accompanying summary form capturing details of the data collection and basic demographic details of the interviewee, as well as any pertinent issues related to the data collection session worth noting. Verbatim quotes may be included in reports or publications, but will only identify the category of participant, their sex and age. De-identified routine health facility data on uptake of health services by adolescents before, during and after the Y-Check implementation period will be collected.

Storage and access to data

Data collected off-line on tablets will later be synchronised over our local wi-fi network to the ODK server. Any data transfer over wireless or mobile networks will use Virtual Private Networks or router protected dedicated internet protocol addresses. Data will be fully encrypted to comply with GDPR regulations, using a public and private key for encryption and decryption respectively. All electronic data will be stored in password protected database systems, with access granted to authorised

Table 3 Primary data collection and consent procedures

Time-point	Data collected	Consent procedure
	Intervention development	
Throughout Year 1	<u>Crowdsourcing contest:</u> Short questionnaires from participants (socio-demographics); contest metrics (number and type of entries etc.); contest entries including images, videos or written documents; <u>Evaluation of crowdsourcing:</u> In-depth interviews with participants and organisers	Crowdsourcing contest participants will agree to standard contest terms and conditions including the use of their sociodemographic details and entries. Contest participants and organisers will provide written informed consent/assent prior to interview. Parent/guardian written consent for 10-15y olds.
	<u>Validation and Intervention design activities:</u> Questionnaire and clinical data from validation studies of screening tools. Qualitative data on acceptability of referral pathways. Findings from the co-creation of the intervention package through participatory workshops with adolescents, the Youth Advisory Group, investigators and stakeholders. Annonymised meeting/workshop attendance registers (affiliation, sex, age)	Client written informed consent/assent. Parent/guardian written consent for Y-Check 1 and Y-Check 2 (schools) only.
	Y-Check check-up visits (services)	
Registration	Sex, date of birth. Contact details (name, phone number, address) linked to ID number recorded in a separate file	Client verbal consent (Y-Check 2 at community hubs) Parent/guardian written consent and participant written assent for Y-Check 1 and Y-Check 2 (school-recruitment) only.
Self-completed questionnaire and provider recorded treatment/counselling services	Age, sex, school/hub, screening test data, screening results, treatments received, and referrals provided for a range of conditions and behaviours. HIV oral mucosal transudate and STI test results from a maximum of 1100 adolescents aged 16-19 years.	Client verbal consent for use of de-identified data for programme monitoring and improvement purposes. (Y-Check 2 at community hubs) Parent/guardian written consent and participant written assent for Y-

	Backend digital platform data: information viewed, games played, data from screening apps, rewards provided/used etc.	Check 1 and Y-Check 2 (school-recruitment).
Y-CHECK referral & referral service attendance	Referral voucher with ID number, sex, age and reason for referral Timing of uptake of service within 0-4 months post check-up visit linked to ID	Client verbal consent for information to be shared with service providers (Y-Check 2 at community hubs) Parent/guardian written consent and participant written assent for Y-Check 1 and Y-Check 2 (school-recruitment).
Additional programme monitoring data	Cost data	None
	Outcomes and evaluation	
Pilot study & Cohort study	Self-reported questionnaire data (demographics, location data, contact details, study outcomes not captured in programme data including knowledge, reported behaviour, well-being and self-esteem, acceptability and reported uptake of services)	Client written informed consent. (Y-Check 2 at community hubs) Parent/guardian written consent and participant written assent for Y-Check 1 and Y-Check 2 (school-recruitment).
Adolescents and stakeholders (adolescents providers, family members of adolescents, community members)	Sociodemographic data, audio-taped interviews, transcripts of IDIs, paired/group interviews and / or FGDs Process evaluation data on the implementation, mechanisms of impact and context of the intervention Notes from structured / unstructured observations Annonymised meeting/workshop attendance registers (affiliation, sex, age)	Participant written informed consent. Parent/guardian written consent and participant written assent for Y-Check 1 and Y-Check 2 (school-recruitment) only.

staff only. When necessary, subsets of the redacted database or other data files may be stored on the PI's or senior staff's laptop to permit analyses during visits or travel. Laptop storage will be encrypted and password protected to protect data from unauthorised access. Data transferred to LSHTM will be held on the LSHTM Secure Server, an NHS-IGT compliant storage system that provides access controls, integrity verification, encryption, automated daily backup and other functionality to ensure data authenticity and security.

Data management and analysis

The data management team will regularly report on data completeness and quality to the study team throughout the period of data collection. All analyses of the source data will follow standard good

practice, with consistency checks of the final analysis files against the original versions of the data base to ensure numbers of participants, number of events and person-time at risk are consistent after processing of data. Y-Check data will be analysed and stored in accordance with ethical and legal conditions established during that study. Data redaction will be performed to ensure that the files that will be used for analyses in this study do not contain any participant-identifiable or other non-required fields.

Data documentation, sharing and archiving

New documentation will be written for the purpose of enabling research reproducibility. We will write a codebook including a description of all data collection instruments used. Summary results will be made openly available. Data will be suitable for sharing. The study team will have exclusive use of the data for one year following the end of data collection. The data sharing plan is described in the participant information and consent forms, and participants will be asked for their consent to future sharing. Participants will have the right to exclude their data from further use, as an option on the consent form. If they choose this option, their data will be deleted from the reposited dataset. After study completion, data will be stored in the LSHTM-curated digital repository 'Data Compass' following GDPR guidelines. Data and code registered in LSHTM Data Compass will be made available following deposit. The Biomedical Research and Training Institute has an Information Management and Security policy which ensures that data generated during any study under BRTI will be held with confidentiality and integrity as covered in the ISO15189 standards.

6. Statistical considerations and Data analysis

6.1 Outcomes

Outcomes (see Section 4.3.2) will be assessed using:

- Programme data collected during the check-up visit and at the referral services
- Research data collected through the pre-consultation questionnaire, exit interview, and during follow-up visits in the subsequent 12 months.
- School register data for the 12 months before and after Y-Check school visits

The primary outcome will be the proportion of those screening positive for at least one condition who receive appropriate on-the-spot care or complete appropriate referral for all identified conditions within 4 months.

- Completed referral is defined as attending at least the first referral appointment. We expect referral/treatment to have occurred within 4 months.
- Where a client has been diagnosed with more than one condition they must have had completed care or referral for each of those conditions in order to be included in the numerator for the primary outcome.

Secondary implementation outcomes:

- The proportion of those who screen positive for individual conditions that have had their condition correctly managed within 4 months
- Yield of previously undiagnosed and un-referred conditions
- Intervention acceptability, adoption, appropriateness, feasibility, fidelity and cost (see Process Evaluation Section 4.3.3 for further details)

Secondary client outcomes:

- Knowledge about health services and health behaviours
- Agency to make decisions about health
- Self-esteem
- Well-being

Knowledge, agency and self-esteem will be measured using questions from existing tools or using new locally-specific questions that will be developed and validated during Phase 1.

The following definition of adolescent well-being has been proposed 'Adolescents thrive and are able to achieve their full potential'.[43] In Phase 1, the development of a tool to measure wellbeing will build on extensive previous work led by study team member Giulia Greco on adapting, developing and testing wellbeing measures for use in economic evaluations of complex interventions in Malawi, Mozambique and Uganda.[51,52]

- Reported health-related risk and protective behaviours (see Appendix 1)
- Reported engagement with health services

Reported use of health services will be measured in the past 4 months and in the past 12 months. Use of health services in the past 12 months by 10-24 year olds is proposed as an indicator for monitoring adolescent health worldwide.[53]

- Clinical outcomes (see Appendix 1)
- Educational outcomes

School attendance and attainment in the year prior to and after the initial Y-Check visit will be captured through a review of school registers and/or self-reported by participants during visits. In Phase 1 we will explore the feasibility of measuring cognitive skills and ability, for example through a standardised reading test or computer based tasks of verbal and visuo-spatial working memory.[54]

- Client-centered outcomes (to be defined during Phase 1- see section 2.3)

6.2 Sample size calculations

The package will be delivered to 2000 adolescents (500 per gender in each age group), however, the primary outcome is only measured among those who screen positive for at least one condition. Within one age group and gender, if 150 (30%) of 500 participants screen positive for at least one condition, and 75% of those who screen positive are correctly managed (n=112; primary outcome), the 95%CI for correct management will be +/- 7%.

The sample size also allows us to describe prevalence of individual conditions, and proportion with corrective action taken (secondary outcomes). For example, if 50 of 1000 participants in one age group

(5%) screen positive for a given condition, and 75% of these have complete referral, the 95%CI will be 62%-87%, or a 95%CI of 35%-65% if 50% complete referral.

6.3 Statistical analysis

Crowdsourcing contest

Contest metrics (e.g. number and type of entries) will be described according to the socio-demographic characteristic of participants.

Validation study

Data will be analysed using appropriate statistics to calculate the following measures (dependant on method of validation used): sensitivity, specificity, positive predictive value, negative predictive value.

Programmatic data

Quantitative programmatic data including screening tests results, services delivered, and referrals made will be described according to age, sex, and location.

Prospective Intervention study

We will follow the STROBE guidelines for the reporting of cohort studies. We will create a flowchart showing the number of communities and schools and the number of participants per community and school at each contact point in the cohort study. We will use descriptive analysis to compare the community-level and school-level characteristics of the four study communities and schools.

The primary outcome is a single proportion which will be presented with a 95% confidence interval for each of the 4 target populations: 10-13y male, 10-13y female, 16-19y male, 16-19y female. Secondary outcomes which are measured at a single time point will be presented in a similar way. For outcomes which are measured at two or more time-points, a before-after analysis will be conducted comparing differences in measures between the two time-points. The unit of analysis will be the individual. For clinical outcomes which are measured at two or more time-points, the initial check-up visit (baseline) will give the prevalence of undiagnosed and untreated chronic conditions which will represent the counterfactual. The proportion of undiagnosed and untreated chronic conditions at the 4-month follow-up visit will be formally compared to this counterfactual to estimate the effectiveness of the intervention in improving these clinical outcomes. We will assess health service and client determinants of correct management of conditions at 4 months using multivariable regression.

Digital platform data De-identified data on information viewed, games played, rewards provided/used along with programmatic data on behaviours and clinical conditions etc. will be analysed using machine learning approaches to understand the sub-groups/segments of adolescents who participate in Y-Check. This analysis will help us to define, develop, and pilot test targeted messaging for different sub-groups of young people who attend Y-Check follow-up visits. We will also analyse this data to develop algorithms which could potentially be used in the future phases of the Y-Check programme to further personalise the Y-Check user experience to maximise relevance, uptake and retention.

Mathematical Modelling Using data from the intervention study, the cost-effectiveness of various check-up visit screening and treatment/referral scenarios will be modelled taking into account the underlying epidemiology, sensitivity and specificity of screening tests, and effectiveness of condition-specific interventions.

7. Ethical Considerations

7.1 Collaborative partnerships

Community representatives will be involved in the design of the intervention and will engage with the research team to shape the intervention. Participatory co-design will be conducted with several stakeholders including adolescents, family members of adolescents, health care providers in schools and at health facilities, including those involved in clinical care, and counselling / outreach, CHWs, representatives or key informants from CBOs that are engaged in providing adolescent health services and community members and other gatekeepers. The formative research completed in 2020 is described in a separate protocol that was approved by local and international ethics committees (Protocol numbers as follows- MRCZ: MRCZ/A/2560; WHO Ethics Review Committee (ERC.0003284); London School of Hygiene & Tropical Medicine LSHTM/A/18058).

The research teams will continue to actively engage with the study communities at various levels (for example with government structures, healthcare facilities at management and worker level, existing NGOs and CBOs providing community-based services and other stakeholder groups). As discussed in Section 4.2, a YAG will be established and will provide guidance and feedback to the study team.

7.2 Social value

Adolescents have relatively poor access to promotive, preventative and curative healthcare. If this study is able to show that the intervention is effective and cost-effective, it could contribute to meeting the Universal Health Coverage goals along with SDG 3. In addition, the inclusion of HIV-testing and referral for treatment will contribute to achievement of the UNAIDS goals which have been laid out as a means to ending the HIV epidemic. The multifaceted approach of the intervention offers value to adolescents in the community even if the intervention does not impact immediately on clinical or educational outcomes.

7.3 Scientific validity

Adolescents stand out as a group that have not benefitted from the numerous interventions to reduce the burden of communicable and non-communicable diseases and studies have consistently shown that this age-group are less likely to access health services especially when they have no symptoms of illness. This study will determine if providing check-up visits at two time-points during adolescence improves the detection of undiagnosed and untreated conditions and in doing so improves health and well-being. Furthermore, the study addresses the broader issue of access to services by adolescents. It is well-recognised that adolescents face substantial barriers to accessing health services in facilities and health services in many countries give low priority to this age-group which has contributed to their poorer health gains compared with young children or adults over recent decades.[1,55] Therefore if school and community-based provision of services does result in high uptake (particularly of sensitive services

such as SRH and HIV services), this may provide a model for delivery of other health services to adolescents.

The study will be conducted according to the most rigorous standards of research and will provide an understanding about the process of implementing the intervention as well as the impact of such an intervention. Study procedures, the analysis, interpretation and dissemination of findings, and the formulation of policy and programmatic recommendations will be guided by local and international experts in adolescent health (see **Section 9 Collaborators and Scientific Advisors**). The study results will be shared throughout the study with national and international policy-makers to ensure that the findings are understood and that lessons from the study are implemented.

7.4 Risk-benefit assessment

The risks and benefits of the Y-Check intervention will be described to participants and their parents/guardians during the consent process. Y-Check participants will benefit from early detection of health problems, health promotion, and the development of health-seeking behaviours. Those who choose to participate can opt out of responding to questions or completing examinations/procedures. HIV and STIs are conditions, which are associated with stigma and anxiety. The Y-Check team will provide counselling to those participants testing positive for HIV or STIs. There is also a risk of negative consequences of a parent or guardian finding out that an adolescent has a drug or alcohol problem. However, if needed, participants and their parents or guardian will have access to on-the-spot initial Y-Check counselling services and assisted referral to longer-term services. . The protocols and procedures for communicating with adolescents and their families will be carefully developed in collaboration with the YAG and community stakeholders.

As for any health care, the tests and treatment provided can have side-effects that can be serious or minor. The tests could cause anxiety. The blood test could cause discomfort or a small bruise, as with any other blood test. While the possibility of this happening is low, the informed consent and assent forms will specify these risks clearly to make sure that participants are aware of the possibility. In the unlikely case of an adverse event, the team will be trained to provide care and support, as well as notify the relevant school authorities (for those seen in schools). If urgent care is required, they will be supported to attend a local health facility.

Risks will be minimized by explaining the procedures in detail to adolescents during the school sessions, as well as during the process of obtaining informed consent in schools and community venues. Staff will be trained to detect adverse events and a protocol will be in place to ensure action in the rare case that such an event occurs.

The use of a digital questionnaire is convenient and has the advantage of providing anonymity; however, adolescents may have fears over unauthorised access and trust. There is also a risk to participants of a breach of confidentiality and possible rejection and discrimination by friends and family if they test positive for any of these conditions. The study team will put in place procedures to mitigate these fears. The Y-Check team will be trained in good clinical practice, data protection and confidentiality, and counselling for participants testing positive for any previously mentioned conditions. Adolescents who have low literacy or low digital literacy skills may find completing the tablet self-screening challenging, and the option of a face-to-face interview will be available.

7.5 Consent procedures

Information on the Y-Check programme (both check-up visit and research cohort) will be distributed to parents/guardians through the schools and to community members through an active communication campaign in collaboration with the Community Steering Committee and the YAG. A series of school and community meetings will be held to allow the opportunity for parents and community members to ask questions about the programme and give their feedback.

The consent procedures for younger (Y-Check 1, 10-14y) and older (Y-Check 2, 15-19y) adolescents will be different reflecting their differing information needs and level of autonomy. Consent for the check-up visit (Y-Check services) will be separate to consent for the Y-Check research cohort (additional interviews and follow-up). Consent forms for the check-up visit will include parental consent for on the spot treatment or referral to specialist services. Adolescents will be able to participate in only the check-up visit or both the check-up visit and the research cohort.

Participants and, if required, their parents/guardians, will sign a paper or electronic consent (e-consent) form on an electronic tablet. Participants/Parents/guardians signing an e-consent form will also sign a paper version for their own records, which contains the contact details of the study team and the MRCZ, in case they have issues or complaints about the study or choose to withdraw in the future. The e-consent form and the paper consent form would be linked through an ID number.

For **Y-Check 1 (10-14y),** parents/guardians who would like their adolescent to receive the check-up will be asked to provide written parent/guardian consent. In the weeks before or on the day of the check-up visit, the adolescent will provide written assent. For enrolment into the research cohort, both written consent from parents/guardians and written assent from the adolescent will be required.

For **Y-Check 2 (15-19y) in schools,** parents/guardians who would like their adolescent to receive the check-up will be asked to provide written parent/guardian consent. In the weeks before on the day of the check-up visit, the adolescent will provide written assent. For enrolment into the research cohort, both written consent from parents/guardians and written assent from the adolescent will be required. Emancipated minors (i.e. participants who are married, have children or are the main care-givers for their younger siblings) who are enrolled in school are also required to provide guardian consent and Y-Check will work with the school to identify the minor's guardian.

For **Y-Check 2 (16-19y) at community hubs,** adolescents in the target age ranges who would like to receive the check-up will provide verbal consent on the day of the check-up visit. For enrolment into the research cohort, adolescents will provide written consent.

Adolescents will be asked to provide the contact details of an adult (18+y) whom they want us to contact if the need arises. This 'trusted adult' could be a parent or another adult who they can confide in.

During registration at the community hubs, the research team member will explain the purpose of the trusted adult to the adolescent (16-19 years) and will ask the adolescent to nominate an adult. In many cases, the trusted adult is likely to be their parent, guardian or another adult relative. When necessary, the identity of the nominated trusted adult will be verified by the research team through a phone call or in-person visit prior to the sharing of any confidential information. If the research team are concerned that the nominated trusted adult is not someone who has an interest in the adolescent's

well-being, then they will discuss again with the adolescent and make further attempts to identify an appropriate trusted adult.

Guidelines stipulate that minors defined as those aged under 18 years should have parental consent. However, in this study we request a waiver of the need for consent from a parent/guardian for those aged 16-17 years who are receiving Y-Check services at the community hubs. Following a review of existing practices within African settings and consultation with our independent scientific advisory committee, the consensus is that a waiver for consent is acceptable if the following conditions are met:

1. Research cannot be practically or adequately conducted without a waiver: The main concern in this study is that participants will not be able to be open about their concerns if they worry that their guardians will ask questions and will sanction them for being open. This is a particular concern in relation to sexual and reproductive health services and HIV testing and care. Experts working in the area have found that the very participants whose guardians are likely to refuse consent for them to participate are the very ones who face the most barriers to accessing services. We therefore believe that the requirement for consent will jeopardise meeting the aims of this work
2. Risks are minimal, and rights and welfare are not affected: We will have appropriate support services in place for participants and encourage adolescents to involve their 'trusted adult' in any health or well-being discussions or decisions.
3. Protection of privacy and confidentiality: Interviews will take place in a private location. All information will be maintained strictly confidentially in password-controlled databases with all identifiers stripped. Participants will be reassured that their information will not be disclosed unless holding back the information will result in harm to the participant.

A guardian will be defined as someone who is over the age of 18 years who is responsible for the daily care, welfare and management of the rights of a minor (someone aged <16 years). The guardian does not necessarily have to be related to the child. If the biological parent is alive but absent (not providing daily care for the child), the individual responsible for the daily welfare of the child will be eligible to give consent. However, the guardian will be encouraged to contact the biological parent (if possible) for consent. Emancipated minors i.e. participants who are married, have children or are the main care-givers for their younger siblings will be able to give consent independently for participation in the study. No participants will be interviewed without their informed consent. All interviews will be conducted in private and not in the presence of the parent/guardian.

Information will be provided about the study, its objectives and procedures, possible risks and procedures to maintain confidentiality. Participants and their parents/guardians will be able to ask any questions they may have. Contact details of the study team will be shared with participants in case they may have questions at a later stage. All participants will be reminded that participation is entirely voluntary and will be told that they can leave the discussion or stop the interview at any time.

The check-up consent forms and research cohort consent forms to be used are attached to this protocol. The research cohort consent forms follow the template required by the Medical Research Council of Zimbabwe, and have been translated into Shona. Written consent for participation in the research cohort will be obtained from all participants, except where a telephone interview has been requested. In these cases, the interviewer will conduct the informed consent procedure verbally, and sign the form on the respondent's behalf.

7.6 Information sharing and disclosure

The protocol for sharing the results of the screening tests will vary according to the perceived seriousness of the condition and the age of the participant. The conditions that will be considered more or less serious or seriously stigmatized will be decided in collaboration with adolescents and stakeholders during Phase 1. More serious or seriously stigmatised conditions may include HIV, drug use, alcohol abuse, experiencing violence, suspected epilepsy, and serious musculoskeletal disorders Less serious or seriously stigmatised conditions may include anaemia, overweight, underweight, pre-hypertension, hypertension, myopia or a hearing disorder.

If the adolescent is diagnosed with a condition that is considered to be more serious and/or more seriously stigmatized, the adolescent's trusted adult (Y-Check 2 community hub) or the parent/guardian (Y-Check 1 and Y-Check 2 school-recruited) will be sent a message as soon as possible indicating that they should make an appointment with the Y-Check nurse/counsellor to discuss the adolescent's health. The nurse or counsellor would then meet with the adolescent and the adult/parent(s) together and would explain the condition or suspected condition and what is being recommended. They will ask for the adult/parent´s support to manage the condition and answer any questions and give advice/support as needed. If the adult/parent does not take up the offer of an appointment, the study team will consult with the adolescent, and school, health or social care staff before deciding on next steps. Potential action would include contacting the parent/guardian by phone or through a home visit, and in emergency situations referring the young person to health/social services without the support of the parent/guardian.

If the adolescent is diagnosed with a condition that is considered to be less serious and/or less seriously stigmatized, the trusted adult (Y-Check 2 community hub) or the parent/guardian (Y-Check 1 and Y-Check 2 school-recruited) will be sent a letter indicating the diagnosis and the recommended treatment/action. Trusted adults or parents/guardians will be encouraged to support their adolescent through their treatment/care. The letter will also offer a way for the adult/parent to get an appointment with their adolescent so that they can ask any questions and receive advice/support as needed. If the adolescent needs their adult to accompany them to a referral appointment, then the Y-Check team would attempt to contact the adult by telephone or through a home visit. Otherwise, there will be no follow-up if the adult/parent does not take up the offer of an appointment.

If the adolescent is generally well then the adolescent will receive a one-page summary telling them what has been checked for and that nothing serious has been found. They will be encouraged to continue good health-related behaviours. They will be told about health and well-being services available at the school, the health facility and in the community. For Y-Check 1 and Y-Check 2 (school-recruited), the letter will be sent from the school to the parents. For Y-Check 2 (community-hub), the adolescent will receive the letter and will be encouraged to share with their trusted adult(s).

Victims of rape/sexual abuse

In the event that the Y-Check team discovers a case of rape or sexual abuse amongst the participants, the matter shall be referred to the District Social Development Offices, as per standard reporting guidelines set out by the Ministry of Public Service, Labour and Social Welfare.

7.7 Confidentiality

Strict measures will be in place to safeguard confidentiality of data. All reports, study data collection, process, and administrative forms will be identified by coded numbers only to maintain participant confidentiality.

For adolescent clients accessing the Y-Check services, at registration the clients name, sex, date of birth, address and contact phone number will be recorded in a separate log file along with their national ID number. These identifiers are required for operational purposes e.g. to provide a referral to external service. Personal identifiers on paper will be stored in a locked cabinet. Electronically kept personal identifiers will be stored in separate datasets with password protection only accessible for designated staff (for computers and servers). These measures will ensure that adolescent client information remains confidential.

Research cohort members will be allocated a unique study ID number. Identifying information will additionally be used to allow tracing of the study cohort to invite them to attend follow-up visits, qualitative interviews, or other research activities. Personal identifiers may appear on paper or electronically on appointment books, consent forms, log books, follow up lists and other listings. These listings will NOT include any (sensitive) study information (including diagnoses). Further information on data management is provided in section 5.3.

7.8 Data and Safety monitoring

An independent Scientific Advisory Committee will review operational performance including uptake, retention and adverse events on an ongoing basis, and will advise the study team on study conduct. Data on the uptake of each component of the study intervention will be captured electronically in all communities and used to inform adaptations to improve uptake of and access to the intervention.

Adverse events, defined as an untoward medical occurrence in an individual to whom a medicinal product has been administered including occurrences that are not necessarily caused by or related to that product, among individuals accessing the intervention, will be recorded. The products referred to include iron and folic acid supplements, fluoride varnish and SDF application, vaccinations, STI treatment, modern contraceptives, PrEP and MHH products.

Social harms are defined as any untoward social occurrences that happen to a participant as a result of their participation in the study, with examples including loss of employment, harassment by neighbours, shunned by family, rejection by partner etc. Because this study is a community-based study of a multi-faceted intervention, the majority of people in the community affected by the implementation of the study will not be participants in the screening or follow-up visits, and so the definition of social harm for this study will be expanded to also include any untoward social occurrences that happen to a community, or groups or individuals within a community, as a result of implementation of the study intervention. Social harms will be monitored throughout the study (through report from those accessing the Y-Check intervention) and study staff will be trained to report these on a regular basis and to provide appropriate counselling and/or referral to appropriate resources, as needed. Staff may also become aware of social harms passively for e.g. if they live in the intervention communities, and will be encouraged to report these.

Discussion of social harms will be addressed with the SAC and with the YAG. The qualitative research to be conducted as part of the process evaluation will also explore social harms in the community. The study team will review the social harms reports monthly, or sooner, if a concerning trend or event is

identified. If the team judges an individual social harm, or a trend in social harms, to be serious or unexpected, they will work together with appropriate bodies (IRBs, YAG, SAC, Study sponsor) to determine if a response is indicated, and if so, what it should be.

Adverse events and social harms will be reported to the ethics committees according to their individual requirements.

7.9 Clinical management during and post-study

Clinical management for conditions identified during the check-up visits e.g. anaemia, STI, HIV etc. will follow national guidelines. Where no national guidelines exist we will follow international guidelines issued by WHO. For those who test positive for HIV, treatment will be provided through the national health systems according to national guidelines which stipulate that all individuals who test HIV-positive are eligible for ART regardless of age or disease stage.[56]

7.10 Ethical Review

Approval to conduct this study will be obtained from the MRCZ, the BRTI IRB and the LSHTM Ethics Committee. Where there is disagreement or discordant IRB requirements the condition providing the highest level of human subject protection will be implemented. Adverse events will be reported on a regular basis according to the individual requirements of these IRBs.

8. Administrative Procedures

8.1 Regulatory approvals

The study will be conducted in accordance with the principles of the Declaration of Helsinki and in full conformity with relevant regulations and with the ICH Guidelines for Good Clinical Practice (CPMP/ICH/135/95) June 1996. Prior to implementation of this protocol, and any subsequent full version amendments, the protocol and the consent form(s) will be approved by the MRCZ, the LSHTM Ethics Committee and the BRTI IRB. The PI will register as a foreign researcher with the RCZ.

8.2 Indemnity

LSHTM carries Clinical Trial/Non-Negligent Harm Insurance and Medical Malpractice Insurance applicable to this study.

8.3 Study monitoring

An independent Scientific Advisory Committee will oversee study progress and advise the study team. The study may be subject to audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

8.4 Protocol compliance

The study will be conducted in full compliance with the protocol. The protocol will not be amended without prior written approval by the PI. All protocol amendments will be submitted to and approved by the MRCZ, the LSHTM Ethics Committee and to the BRTI IRB prior to implementing the amendment. At the end of the study the MRCZ will be notified of the completion of the study (using the FORM 105- study termination form) and a final study report will be sent to the MRCZ.

8.5 Maintenance of records

The study team will maintain and securely store complete, accurate and current records throughout the study. All study records will be maintained for five years after the end of the study, as per MRCZ regulations. Study records include including protocol registration documents, all reports and correspondence relating to the study and documentation related to study participants (including informed consent forms, locator forms, case report forms, notations of all contacts with the participant, and all other source documents).

8.6 Use of data and publications

All processes related to data use will follow the principles of Good Clinical Practice.

Publication of the results of this study will be governed by the requirements of the UKRI open access policy. All publications will be made available through PubMed Central (PMC) and Europe PMC as soon as possible and within six months of the journal publisher's official date of final publication. Where possible (and when an open access fee is paid), research papers will be licenced a Creative Commons Attribution licence (CC-BY).

9. Collaborators and Scientific Advisors (in alphabetical order)

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Appendix 1: Conditions with correct management and subsequent outcomes

Condition/risk behaviour	Screening tool	Primary Outcome: Appropriate on the spot care or complete appropriate referral		Secondary clinical or behavioural outcomes
		Appropriate on the spot care	**Complete appropriate referral**	
Psychosocial issues (home environment, education/employment, violence etc.)	Questions from HEEADSSS[23]	Counselling +/- referral	Attend first meeting with social services	Severity of psychosocial issue
Alcohol, tobacco and substance use	ASSIST-Y[57]	Brief intervention +/- referral	Attend first meeting with counsellor	Alcohol use Tobacco use Substance use
Common mental health disorders	Shona symptom questionnaire (SSQ)[24]	Counselling +/- referral to Youth Friendship Bench if SSQ score >=8. If 'red flag' refer to nearest health facility.	Attend first meeting of Youth Friendship Bench	Severity of symptoms
Low levels of physical activity	Questions from HEEADSSS[23]	Counselling and advice		Level of physical activity
Poor diet	Questions from HEEADSSS[23]	Counselling and advice +/- referral	Attended first appointment at food supplementation services	Frequency of fruit and vegetable intake Frequency of sugary beverage intake
Underweight	MUAC, BMI, BVI	Counselling and advice +/- referral	Attended first appointment at food supplementation services	MUAC/BMI/BVI
Overweight	MUAC, BMI, BVI	Counselling and advice		MUAC/BMI/BVI
Anaemia	Hemocue	Iron and folic-acid supplementation (3 months supply) if anaemic. If severely anaemic (<8g/dl) refer to health facility.	Attended first appointment at health facility.	Anaemia

Poor oral health	Questions on oral health. Visual inspection.	Advice, gift of toothpaste and toothbrush, fluoride varnish application +/- SDF application +/- referral	Attended first appointment at dentist	Reported pain or swelling. Frequency of tooth brushing
Uncircumcised	Question on circumcision status. Visual inspection.	Referral for VMMC (males only)	Attended first VMMC referral appointment.	Circumcised
Unprotected sex	Question (s) on sexual activity	Risk reduction counselling, Provision of condoms, Provision of modern contraceptives (emergency contraception, depot injections, oral contraceptive pill) (females only) PrEP (females only)		Frequency of unprotected sex Modern contraceptive use (females) PrEP use (females)
HIV positive	HIV oral mucosal self-test +/- confirmatory blood-based RDT	Counselling + referral	Enrolment in ART programme	ART adherence
STI (CT, NG, TV)	CT/NG test on urine sample, TV test on self-taken vaginal swab	Treatment		STI (CT, NG, T)
Incomplete immunisation	Question on HPV immunisation history. Review of vaccination card.	Immunise +/- referral	Attend referral appointment for second vaccine dose	HPV immunisation
Visual impairment	Peek Acuity or Snellen Tumbling-E	Refer to specialist if <6/12 level in either eye.	Attends first eye appointment	Visual impairment Reported frequency of wearing glasses
Hearing impairment	HearScreen smartphone app +/- HearTest	Inspection for presence of wax and wax removal. Refer to specialist	Attends first hearing specialist appointment	Hearing impairment Reported frequency of wearing hearing aid
Physical impairment	Questions on physical impairment.	Refer to specialist	Attends first appointment with specialist	Upper and lower limb impairment

	Jump or squat test Functional reach test			
Uncontrolled Epilepsy	Questions on experience of convulsions	Refer to specialist	Attends first appointment with specialist	Controlled epilepsy Reported frequency of taking epilepsy medication
Pre-hypertension	Blood pressure measured using digital sphygmomanometer	Counselling and advice if lowest systolic reading 120-129mmHg +/- referral if suspected hypertension (Lowest systolic reading >130mmHg)	Attended first referral appointment	Blood pressure