




# BMJ Open Meals, Education, and Gardens for In-School Adolescents (MEGA): study protocol for a cluster randomised trial of an integrated adolescent nutrition intervention in Dodoma, Tanzania

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## ABSTRACT

**Introduction** Secondary schools have the transformative potential to advance adolescent nutrition and provide a unique entry point for nutrition interventions to reach adolescents and their families and communities. Integrated school nutrition interventions offer promising pathways towards improving adolescent nutrition status, food security and building sustainable skill sets.

**Methods and analysis** The Meals, Education, and Gardens for In-School Adolescents (MEGA) project aims to implement and evaluate an integrated, school-based nutrition intervention package among secondary schools in the Chamwino District of Dodoma, Tanzania. MEGA is a cluster-randomised controlled trial, including six public secondary schools assigned to three different arms. Two schools will receive the full intervention package, including school meals, school gardens, nutrition education and community workshops. Two schools will receive the partial intervention package, including the school garden, nutrition education and community workshops. Two schools will serve as the controls and will not receive any intervention. The intervention will be implemented for one academic year. Baseline and end-line quantitative data collection will include 750 adolescents and 750 parents. The domains of outcomes for adolescents will include haemoglobin concentrations, anthropometry, educational outcomes and knowledge, attitudes and practices regarding nutrition, agriculture and health. The domains of outcomes for parents will include knowledge, attitudes and practices of nutrition, agriculture and health. End-line focus group discussions will be conducted among selected adolescents, parents and teachers to assess the facilitators and barriers associated with the intervention.

**Ethics and dissemination** This study was approved by the Institutional Review Board at Harvard T.H. Chan School of Public Health (approval number: IRB20-1623), the Institutional Research Review Committee at the University of Dodoma (approval number: MA.84/261/02) and the Tanzania National Institute for Medical Research (approval number: NIMR/HO/R.8a/Vol. IX/3801). A manuscript with the research findings will be developed for publication.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will implement an integrated intervention package that includes school meals, nutrition education, school gardens and community workshops, which were typically evaluated in silos in previous studies.
- ⇒ The intervention implementation will involve not only adolescents themselves but also parents, teachers and members of the broader community to increase the sense of ownership and the potential for sustainability.
- ⇒ The study has a robust sample size, a relatively long follow-up period of one academic year and comprehensive evaluations of nutrition knowledge, attitudes and practices for adolescent and their parents.
- ⇒ The study focuses on in-school adolescents, so it is expected to have limited impact on out-of-school adolescents.

Local dissemination meetings will be held with key stakeholders.

**Trial registration number** NCT04788303.; ClinicalTrials.gov Identifier.

## INTRODUCTION

There are 1.8 billion adolescents globally, with 90% residing in low and middle-income countries (LMICs).<sup>1</sup> The period of adolescence, defined as 10–19 years of age, is marked by crucial physical, cognitive and psychosocial changes with critical implications on health and development throughout the life course.<sup>2–4</sup> Despite significant improvements in adolescent nutrition over the last decade, malnutrition remains a critical issue in Tanzania. Among adolescent girls aged 15–19 years in Tanzania, 18.0% are underweight and 47.3% are anaemic in 2015–2016.<sup>5</sup> At the same time, Tanzania is faced with a



rapidly increasing burden of overweight and obesity in adolescent girls aged 15–19 years, rising from 5.7% in 1996 to 10.6% in 2015.<sup>5 6</sup> Existing data for Tanzanian adolescent boys also indicate a significant double burden of malnutrition; 13%–17% of urban adolescent boys are overweight or obese,<sup>7 8</sup> and 10% are underweight or iron deficient.<sup>8 9</sup> Several factors may have contributed to malnutrition among adolescents in Tanzania, including lack of access to diverse foods and limited knowledge about nutrition among adolescents and their household members.

Adolescence is a time of nutrition-sensitive, transformative phase of growth when both undernutrition and overweight or obesity affect the maturation of multiple physiological systems, thereby hampering the prospects of reaching their full health and development potential.<sup>10</sup> On the one hand, undernutrition during adolescence reduces physical growth and impairs the learning and development of essential life skills. On the other hand, overweight and obesity during adolescence increase the risk of non-communicable diseases later in life. Lifestyle behaviours established in adolescence, such as dietary intake and physical activity, also shape the behaviours during adulthood and affect long-term health outcomes for themselves and their future families.<sup>4 11–13</sup> Given the unique role of adolescence as a transition period between childhood and adulthood, this population group requires policies and programmes tailored to their distinct needs. However, adolescents in sub-Saharan Africa have especially been neglected in health and nutrition programming, which has traditionally focused more on pregnant women and young children, with few efforts specifically targeting the critical life stage of adolescence.<sup>14</sup> Adolescents have also been largely ignored in global nutrition policy frameworks.<sup>4</sup>

With secondary school enrolment rates rising in most LMICs, secondary schools offer the transformative potential to advance adolescent nutrition by providing healthy food environments, nutrition-sensitive social protection and imparting the knowledge and skills for adolescents to adopt and sustain healthy lifestyle behaviours.<sup>4 15</sup> Schools also provide easy access to key stakeholders, including adolescents, parents, teachers and the wider community. Therefore, schools are an exceptional platform for health education and community engagement that simultaneously targets the multiple influencers of adolescent lives. School-based interventions have proved to be beneficial for the health and well-being of children and adolescents. School feeding improves school attendance, academic performance, nutritional status and local agriculture economies in settings across the world.<sup>16–18</sup> School gardens, where nutritious foods are grown, are effective in improving children's and adolescents' knowledge about sustainable agriculture and their preferences for healthy foods.<sup>19 20</sup> However, previous school-based interventions were often provided as standalone programmes without a concerted delivery mechanism. To maximise the impacts of school-based nutrition actions and fully

realise the potential of secondary schools for adolescent nutrition, diverse and evidence-based interventions need to be combined and fully integrated into the school environment.<sup>15</sup>

The Meals, Education, and Gardens for In-School Adolescents (MEGA) project aims to implement and evaluate an integrated, school-based nutrition intervention package among secondary schools in Dodoma, Tanzania. The aim of the MEGA project is to improve adolescent nutrition directly through the consumption of healthy food and indirectly by improving nutritional and agricultural capacity and resources at the household and community levels. The findings from this study will inform the scale-up of future school-based or community-based interventions to improve the nutrition of adolescents, their households and their communities.

## METHODS AND ANALYSIS

### Study setting

The study will be conducted in public secondary schools in the Chamwino District in Dodoma, Tanzania. Dodoma, the capital of Tanzania, is in a highly food-insecure region.<sup>21</sup> The Chamwino District in the Dodoma Region is a predominantly rural and semiarid area with an exceptionally high level of food insecurity due to prolonged droughts, inadequate means of food storage and limited alternatives for the food insecurity coping strategies.<sup>21 22</sup>

### Study design

This study will be a cluster-randomised controlled trial with three intervention arms. We will include six public secondary schools, with two schools in each arm. Two schools will receive the full intervention package, which includes school meals, school gardens, nutrition education and community workshops. Two schools will receive the partial intervention package, including school gardens, nutrition education and community workshops (ie, the full intervention minus the school meals component). Two schools will serve as the controls to receive the 'standard of care' in Dodoma, which does not include any intervention component. The inclusion of full intervention, partial intervention and controls enables examinations of the combined effect of the full intervention package, the effect of school gardens and the educational components and the independent effect of the school meals component. We will implement the intervention over one academic year. We started the participant enrollment on 24 January 2022 and plan to complete the end-line data collection by 31 December 2022.

### Selection of schools

The eligibility criteria for the schools include: (1) no existing school lunch programme, (2) no existing school garden, (3) availability of land for school gardens and (4) availability of water for drinking and gardening all year round. We screened all 27 public secondary schools in the Chamwino District to evaluate their eligibility,

and 13 schools were determined to meet all criteria. We then matched the 13 schools based on three characteristics, including: (1) school size (quantified by the total number of students in the school), (2) geographical location (quantified by distance from the school to the council headquarter) and (3) overall school performance (quantified by the regional academic ranking of the school). We conducted coarsened exact matching using the *cem* command<sup>23</sup> of STATA V.16 (StataCorp, College Station, Texas) and then manually finetuned the matches to arrive at two matches with three schools per match. The three schools in each match were roughly comparable in the three matching factors. Within each match, we generated a random allocation sequence using a list randomiser available at <https://www.random.org/lists/>.<sup>24</sup> Based on the allocation sequence, one school in the match was randomly allocated to receive the full intervention package, one to receive the partial intervention package, and one to serve as a control and will receive no intervention.

### Selection of participants

The eligibility criteria for adolescents to participate are: (1) enrolment in forms 1 or 2 (roughly equivalent to grades 8 or 9 in the USA) in a participating school, (2) between the ages of 14 and 17 years, (3) informed consent by parent or guardian, (4) informed assent by the adolescent, (5) fluent in Swahili or English. For each eligible adolescent, one parent (or guardian) will be invited to participate in the community workshop component.

### Interventions

The full intervention package includes four components, namely, school meals, school gardens, nutrition education and community workshops. We identified these intervention components through a literature review on school-based nutrition interventions and a desk review of policy documents pertinent to adolescent nutrition in Tanzania. We conducted key informant interviews with governmental officials in Dodoma. We also visited selected public secondary schools in the Chamwino District, where we conducted focus group discussions with adolescents, teachers and parents to codesign the specific elements of the interventions. This formative research, which we described in detail elsewhere,<sup>22</sup> ensures the feasibility and acceptability of the intervention package.

### School meals

In the two schools receiving the full intervention package, we will provide school lunch to all students enrolled in that school, regardless of form or study participation. The school lunch will consist of traditional Tanzanian staples (eg, maize stiff porridge/ugali and beans) and green leafy vegetables. We designed the school lunch menu based on the nutritional requirements of adolescents and the school feeding policies and guidelines in Tanzania. Specifically, each lunch plate will include a minimum of 150g of maize flour, 150g of kidney beans and 15g of

cooking oil, providing at least 212g of carbohydrates, 42g of protein and 19.5g of fat. The meals are designed to meet at least 60% of the daily requirement of total energy intake for adolescents. The meals will be provided around 1 PM on every school day. Each school will hire a designated cook to prepare and serve the standardised lunch. Vegetables grown from the school garden will contribute to the menu of the school lunch programme. The project will provide the resources to support the school lunch on two school days per week. We will encourage the parents to contribute financial or in-kind support to sustain the remaining school days, as often done in Tanzanian secondary schools, to improve sustainability and obtain community buy-in. The two partial intervention schools and the two control schools will not receive the school meal intervention.

### School gardens

A school vegetable garden will be established in the two schools receiving the full intervention package and the two schools receiving the partial intervention package. Adolescents enrolled in the study will participate in gardening activities through the format of school garden clubs. Each intervention school will establish two parallel school garden clubs, with approximately 60 adolescents in each club. The school garden will be approximately 0.5 acres (ie, approximately 2000 square metres) and grow nutritious green leafy vegetables on school land. In the two intervention schools receiving the full intervention package (ie, with school meals), the vegetables grown in the school garden will be used to supplement the school lunch. In the two intervention schools receiving the partial intervention package (ie, without school meals), the schools will sell the vegetables at local markets; the income will strictly be used for the betterment of the adolescents' education, such as purchasing textbooks and other school supplies. The two control schools will not receive the school garden intervention. However, the study team will provide the school with a copy of an education manual with educational content on school gardens for schools to use at their discretion.

Each school will appoint one focal teacher who will oversee the gardening activities. The focal teacher will also provide necessary maintenance of the gardens during holidays or school vacations. The focal teacher will be chosen from among the biology teachers, science teachers or teachers of subjects relevant to agriculture or health. Under the supervision of the focal teacher, participating adolescents will spend approximately 30 min/day on the gardening activities before or after school hours, as is customary for school club activities. Study staff will train the focal teachers on maintaining the garden and overseeing the gardening activities in Tanzania. An agricultural extension worker (AEW), also trained by study staff, will be assigned to each intervention school and will visit the garden every 2 weeks to monitor its upkeep and address any technical questions by the school.



### Nutrition education

The goal of the adolescent education component is to provide adolescents with a solid foundation for choosing, growing and eating clean and nutritious foods, and staying active and healthy over the life course. The education materials include five modules to be covered over 41 weeks, including (1) health and nutrition, (2) agriculture and school gardening, (3) health benefits of vegetables, (4) physical activity and body size and (5) wash, sanitation and hygiene (WASH). Each module covers several specific topics, with one topic per week (online supplemental table 1). The education materials combine didactic content and hands-on, interactive activities such as multiple-choice questions and matching exercises. Focal teachers will be trained and will receive a training manual to prepare themselves for leading the education activities. The education materials were developed by adapting existing educational resources<sup>25–28</sup> and materials from another integrated nutrition intervention conducted by our team.<sup>29</sup>

In the two schools receiving the full intervention package and the two schools receiving the partial intervention package, the same students participating in the school garden club will also participate in a nutrition education programme. Similarly, the same focal teachers appointed for the school gardens will be responsible for teaching the education materials to the participating students in the school garden clubs using the education materials. The focal teachers will lead the education activities once per week for approximately 40 min on Friday afternoons after school. The two control schools will be provided with a copy of the education manual to be used at their discretion.

### Community workshops

In full and partial intervention schools, the school garden will serve as a hub for community workshops on agricultural best practices, nutrition, hygiene and the use of sustainable gardening technologies. We will invite the parents of all participating adolescents to attend the workshops, which will be led by the same AEW supporting each school garden. We developed a manual for the community workshops, which covers nutrition messages, agricultural messages and hands-on activities on nutrition, agriculture and WASH (online supplemental table 2). The frequency of the community workshops will be every 2 weeks, and each workshop will last approximately 1 hour.

### Data collection

We will collect quantitative data at baseline and end-line among participating adolescents and parents. We conducted the baseline data collection during January–February 2022, around the beginning of the academic school year and before implementing the interventions. We will conduct the end-line data collection at the conclusion of the academic year. Trained data collectors will use standardised questionnaires and interview guides, which

were translated into the local language of Swahili and programmed into the Open Data Kit software<sup>30</sup> to enable electronic collection.

In each of the six schools, we will enrol 125 adolescents to participate in baseline and end-line data collection. Within each school, we enrolled all adolescents from form 2 (roughly equivalent to grade 9 in the USA). If the number of all form 2 students was much greater than 125, we randomly selected 125 from all eligible form 2 students. If the number of all form 2 students was less than the target sample size of 125, we randomly selected a small number of students from form 1 (roughly equivalent to grade 8 in the USA) until the sample size target was reached.

One parent (or guardian) of each participating adolescent will also participate in the baseline and end-line data collection. From adolescents and their parents, we will collect information on demographic characteristics, socioeconomic status, WASH practices, nutrition knowledge, dietary intake and eating habits and food security through a questionnaire. For adolescents, the questionnaire will additionally include questions on physical activity, female menstruation, food preferences and socioemotional development. For parents, the questionnaire will additionally include questions on home gardening practices. For adolescents, data collectors will also measure height using validated height boards and weight using validated weight scales, and body mass index (BMI) will be calculated. Each adolescent will be weighed with light clothing and no footwear. The anthropometric measurements will be taken two times, and the average value will be used. Any discrepancies will be resolved by a third measurement. Data collectors will also measure the haemoglobin concentrations of the adolescents using a finger prick sample and a portable haemoglobinometer (HemoCue Hb201 +Analyzer, Ängelholm, Sweden).

At the end-line data collection, selected adolescents, parents and teachers in the two schools receiving the full intervention will participate in focus group discussions. From each of the two schools, three focus group discussions with six adolescents, six parents and six teachers, respectively, will be conducted. The six adolescents per school will be nominated by their teachers to ensure adequate engagement and in-depth responses. The parents of the same adolescents will be included in the focus group discussion intended for parents. The focus group discussions for teachers will include the two focal teachers and four teachers not directly affiliated with the project. The focus group discussions with adolescents will cover topics including experience with the school meals, school gardening and nutrition education programmes, and their attitudes towards nutrition, agriculture and WASH. The focus group discussions with parents will cover topics including the impacts of the intervention and community workshops on knowledge, attitudes and practices of agriculture, nutrition and WASH. The focus group discussions with teachers will collect feedback and experience with implementing the intervention

**Table 1** Summary of data collection plans in the MEGA project, 2022

Intervention arm	Participant group	Baseline data collection		End-line data collection	
		Data type	Number of participants per school	Data type	Number of participants per school
Two schools receiving full intervention package	Adolescents	Quantitative data*	125	Quantitative data	125
				Focus group discussion	6
	Parents	Quantitative data	125	Quantitative data	125
				Focus group discussion	6
	Teachers	None	0	Focus group discussion	6
Two schools receiving partial intervention package	Adolescents	Quantitative data	125	Quantitative data	125
	Parents	Quantitative data	125	Quantitative data	125
Two control schools	Adolescents	Quantitative data	125	Quantitative data	125
	Parents	Quantitative data	125	Quantitative data	125

\*The quantitative data collection for both adolescents and parents will include demographic characteristics, socioeconomic information, practices of water, sanitation, and hygiene, nutrition knowledge, dietary intake and eating habits and food security. For adolescents, the quantitative data collection will additionally cover physical activity, female menstruation, food preferences, socioemotional development, height, weight and haemoglobin concentrations. For parents, the quantitative data collection will additionally cover home gardening practices.

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packages. The ultimate goal of the focus group discussions is to qualitatively assess the facilitators and barriers to the intervention components and codesign strategies for further improvement and scale-up of the intervention package. All focus group discussions will be led by trained interviewers in Swahili and audio recorded. The recordings will be transcribed and translated into qualitative data in English. We will use an inductive approach for thematic content analysis to identify major themes and trends in the qualitative data.

Throughout the intervention period, focal teachers will be instructed to use short checklists to monitor the fidelity of the intervention component every time an intervention is given. Every 2 weeks, the study team will visit each intervention school and use more expanded checklists to monitor the adherence to the intervention components in each school.

Details of the data collection, including the type of data and the number of participants, are summarised in [table 1](#). In total, we will include 750 adolescents and 750 parents in the baseline and end-line collection of quantitative data. We will include 12 adolescents, 12 parents and 12 teachers in the end-line collection of qualitative data through focus group discussions.

### Sample size calculation

We used school feeding as the main intervention and weight gain in a year (in kilogram) as the outcome in the sample size calculation. The design effect was calculated to account for clustered design and was computed as  $1+(n-1)\times ICC$ , where  $n$  is the number of students needed to be enrolled in each school. ICC represents the intra-class correlation coefficient due to clustering. Assuming an ICC of 0.025<sup>16</sup> and an  $n$  of 100, the design effect equals 3.475. Therefore, the statistically effective sample size

from each school was calculated as 29 (ie,  $100/3.475$ ), and the total effective sample size was calculated as 58 in each intervention arm. Then, assuming a two-sided  $\alpha$  level of 0.05, a power of 80% and a within-group SD of 1.5 kg,<sup>16</sup> we will be able to detect a mean difference in weight gain of 0.787 kg, similar to the expected effect size of 0.71 kg in the literature.<sup>16</sup> To further allow for a 20% loss to follow-up (eg, due to school dropout) before the end-line data collection, we will need to enrol 125 students from each school (calculated as  $100/0.8$ ). The calculations were conducted using the *Power and Sample Size Calculation Programme* by Dupont and Plummer.<sup>31</sup>

### Outcomes and statistical analysis

The domains of outcomes will include: (1) haemoglobin concentrations and anaemia status of adolescents (primary outcome); we define anaemia status using the diagnostic criteria by the WHO<sup>32</sup>; (2) anthropometry of adolescents, including height, weight and BMI; (3) knowledge, attitudes and practices of adolescents regarding nutrition and dietary intake; (4) knowledge, attitudes and practices of adolescents regarding agriculture and WASH; (5) educational outcomes of adolescents and (6) knowledge, attitudes and practices of nutrition, agriculture and WASH among parents. We will use linear regression models to estimate the effect of the intervention on continuous outcomes. We will use logistic or log-binomial models to estimate the effect of the intervention on binary outcomes. Generalised estimating equations will be used to account for the clustered design by school. We will compare the full intervention group with the control group to examine the combined effect of the full intervention package. We will compare the partial intervention group with the control group to examine the effect of school gardens and the education components.

Finally, we will compare the full intervention group with the partial intervention package to examine the independent effect of the school meals component. We will conduct all analyses using SAS V.9.4 (SAS Institute, Cary, North Carolina) at a two-sided  $\alpha$  level of 0.05.

### Patient and public involvement

The intervention package requires intensive community engagement and participation. The public will be involved in the conduct of the research and the dissemination of the study findings in several ways. First, the school meal component of the intervention package involves cooks hired from the local community, and we will encourage financial or in-kind donations from parents to supplement the school feeding programme. Second, the nutrition education, school gardens and community workshops inherently involve collaboration with adolescents, focal teachers, AEWs, parents and other community members. Third, we will disseminate the study findings to local schools and communities and invite adolescents, parents, teachers and community members to attend the study finding dissemination meetings.

### ETHICS AND DISSEMINATION

This study was approved by the Institutional Review Board at Harvard T.H. Chan School of Public Health (approval number: IRB20-1623), the Institutional Research Review Committee at the University of Dodoma (approval number: MA.84/261/02), and the Tanzania National Institute for Medical Research (approval number: NIMR/HO/R.8a/Vol. IX/3801). Data for adolescents will be collected after written parental consent and informed assent. Data for parents and teachers will be collected after written informed consent. The confidentiality of participants' information will be described in the consent and assent forms for all study participants. The forms will also explain that participation is entirely voluntary and that refusal to participate or discontinue the study at any point is granted without penalty and would not have any influence on any aspect of their lives.

Data will be entered into password-protected tablets and uploaded to a secure server. The data manager will strip the data of identifiers and store the linkage key separately. Analyses will only be conducted on a deidentified data set. The deidentified data will be available only to the principal investigators and selected key study team members while adhering to the Data Transfer Agreement approved by the Tanzania National Institute for Medical Research.

We will develop a manuscript with the primary research findings for publication in a peer-reviewed journal. We will organise meetings with governmental officials at local, regional and national levels to share key findings and policy recommendations and discuss the next steps for the potential scale-up. During these meetings with governmental officials, we will disseminate findings on not only the effectiveness of

the intervention but also the cost implications of the intervention components, including our estimates on the potential cost of implementing each intervention component. Lessons learnt on potential strategies for increasing parental financial or in-kind contributions to the school meal programmes will also be shared. We will also hold dissemination meetings in the participating schools and invite adolescents, parents, teachers and community members to attend.

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**Contributors** TY, AI, MM-S, DM, SV and WWF contributed to the conception of the study. MM-S, LKK and ARM led the development of the school meals program. DW and ARM led the development of the nutrition education program. LKK and ARM led the development of the school gardening program. DM led the development of community workshops. TY, AI, MM-S, AT and LKK led the trial registration and application for ethical approval. DW, AI and AM led the selection of schools. DW and LKK wrote the first draft of this study protocol. ARM is the project coordinator in Dodoma. LKK and WWF are the co-principal investigators of the study. All authors reviewed and critiqued the manuscript and approved the final version.

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