

Appendix 1. Spirit checklist

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____2_____
	2b	All items from the World Health Organization Trial Registration Data Set	_____
Protocol version	3	Date and version identifier	_____11_____
Funding	4	Sources and types of financial, material, and other support	_____13_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___1 & 13___
	5b	Name and contact information for the trial sponsor	_____13_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____13_____

5d Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) _____12_____

Introduction

Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____2 & 3_____

6b Explanation for choice of comparators _____6_____

Objectives 7 Specific objectives or hypotheses _____7_____

Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____3 & 4_____

Methods: Participants, interventions, and outcomes

Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____3_____

Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____6_____

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____6 & 7_____

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____8 & 9_____

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_____8_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	_____n/a_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_____5 & 7 & 8_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_____4 & 5_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_____10_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____6_____

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_____4_____
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Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____4_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_____4_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_____4_ & 6__
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____9_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_____10_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____9_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_____10_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_____10 & 11__

20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____11_____
20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____11_____

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____12_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____10_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____10_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____12_____
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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____12_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____12_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____NA_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____10_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____13_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____10_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____NA_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____11_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____NA_____

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical _____10_____ code

Appendices

Informed consent 32 Model consent form and other related documentation given to participants and authorised ____21-38____
materials surrogates

Biological 33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or ____10____
specimens molecular analysis in the current trial and for future use in ancillary studies, if applicable

Appendix 2a. Participant Information Sheet for adult women (English).

Study name: Addressing Hidden Hunger with Agronomy (AHHA) Malawi.

Protocol version: 4.2

Date	Participant ID [on copy kept by RA]

The following information should be provided to participant women (aged 20-45 years) prior to seeking consent. The information should be provided verbally with printed copies available on request.

I am..... from

Introduction

We are conducting research in your village and neighbouring villages. Your participation is voluntary and you do not have to take part. Now we are going to provide you with information about the proposed research, so you can decide on your participation. Please ask questions if anything is not clear.

What is the purpose of the study?

The study aims to determine whether consumption of maize flour enriched with the micronutrient selenium delivers a health benefit. Selenium is a vital nutrient for the health of you and your children. Previous research has shown that selenium is typically deficient among populations in rural Malawi, including in Wimbe TA. We are looking at ways to sustainably increase consumption of selenium so that everyone can be healthier.

Why are we asking you to take part?

We have randomly selected villages in Wimbe TA to take part in this study. Every household within participating villages can be involved, if they wish. In your household there is at least one woman aged 20-45 years and at least one child aged 5-10 years. This means that your household is eligible for the trial. We have subsequently selected one eligible woman and one eligible child in your household to participate in the trial.

Do you have to take part?

You do not have to take part in the study.

What will happen if you take part?

Every household in the village will be provided free maize flour for 12 weeks, from early July through to early October this year. If your household takes part in the study then we will randomly assign you to one of two groups: flour enriched with selenium, or standard maize flour. We enriched the flour using fertilizers applied during the maize production. Maize was grown at Lilongwe University of

Agriculture and Natural Resources, near Lilongwe. We will invite you and community members to visit the maize production site to see the process.

The flour will be distributed free of charge and we will request households to use this flour for their own consumption for the 12-week duration of the trial. Each household will be provided with enough flour to meet their daily requirements. Every 2 weeks we will arrange distribution of the maize flour to your household and we will monitor the consumption of the trial flour through observations and short questionnaires with the member of your household who is responsible for meal preparation.

To measure whether the flour has an effect on your nutritional status we will need to collect blood samples (6 mL) at the start and end of the trial. We will also collect blood samples from the selected school-aged child in your household, provided the child's caregiver provides assent. These samples will be analysed in laboratories in Malawi and in the UK to measure the nutritional status of the participants so that we can determine whether the enriched flour has made a difference. The samples will be analysed to provide information on the selenium status of the participant. Other parameters including HIV infection will not be tested.

What will you have to do?

We require the support of you and your community for this trial to work. We request that your households consumes the flour that they are provided with for the 12-week period, and we request that the trial flour is not sold or exchanged. For you, as a participating individual, we will conduct a short questionnaire including capturing information on your recent dietary consumption. We will then collect a blood sample (6 mL) at a mobile clinic in your village, at the start and end of the trial. Blood samples will be collected by trained nurses.

What are the possible benefits?

You and your household will receive free maize flour for a 12-week period. This will allow you to conserve your own stocks of maize for later in the year. Consumption of more selenium is likely to deliver health benefits and we might see some benefits occur during the short duration of the trial, such as lower incidence and duration of diarrhoea. However, we won't know until the trial is complete whether you and your household are provided with the enriched flour or with control flour. Overall, the trial will deliver important information to researchers and the Malawi government. This information will inform decisions to improve nutrition through agriculture, including fertilizer recommendations.

What if something goes wrong?

We have conducted a thorough risk assessment and have plans in place to monitor and respond to any problems. There will be regular opportunities to meet the study team and you can let them know if you have any immediate concerns. If they are unable to address these concerns, then please contact Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

Can you change your mind about your household taking part?

You can change your mind and withdraw your consent to participate. Withdrawal can mean no further participation in the trial but continued receipt of control flour, or no further participation in the trial and no further receipt of flour, depending on your preference.

What will happen to the information generated during the trial?

The information we generate during the trial will be kept private. Only staff working on the trial will be able to access and use this information. Data will be anonymised, so any names and other identifying information will be removed before these datasets are shared.

Data will be hosted on a secure server accessible only to the study team. When data files are transferred they will be encrypted to ensure security. Data will be archived for a minimum of 10 years after the study end and will be destroyed once no longer needed.

What will happen to the results of this study?

This trial aims to determine the potential health benefits of consuming maize flour enriched with the selenium. We are planning to conduct this trial here and in neighbouring villages. The results of the trial will be used to inform policies and programmes in Malawi, including fertilizer recommendations. We will communicate the study findings to you and your community once the trial is complete.

Who has checked this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by a committee at the College of Medicine, Blantyre, and by a committee at the London School of Hygiene & Tropical Medicine in the United Kingdom.

Further information and contact details

For further information about the trial or for any questions, please contact:

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe.
0997 69 29 87

For further information about the ethical procedures related to this trial, or if you have any concerns about the conduct of the trial, please contact:

College of Medicine Research Ethics Committee, 3rd Floor, John Chiphangwi Learning Resource Centre, Private Bag 360, Chichiri, Blantyre. +265 (0)11 871 911

Appendix 2b. Participant Information Sheet for adult women (Chichewa).

Study name: Addressing Hidden Hunger with Agronomy (AHHA) Malawi.

Protocol version: 4.2

Date	Participant ID [on copy kept by RA]

Uthenga otsatirawu uyenera kupelekedwa kwa amayi amene akutenga nawo gawo (azaka 20-45) kumayambiri kopempha chilolezo. Unthengawu upelekedwe pofototozoza ndipo mapepala a unthengawu atha kupatsidwa ngati apempha.

Ine..... kuchokera ku.....

Mawu woyambirira

Tikupanga kafukufuku m'mudzi wanu ndi midzi ina yoyandikana ndi mudzi wanu. Kutenga nawo gawo monga mudzi komanso ngati munthu ndi kufunakwanu ndipo simukuyenera kutelo ngati simukufuna. Tsopano tikupatsani uthenga okhudza kafukufuku amene tikupempha kuti apangidweyu ndicholinga chakuti mupange chisankho chanu chotenga nawo mbali. Chonde funsani mafunso ngati penapake pasakumveka.

Kodi cholinga chakafukufukuyu ndi chiyani?

Kafukufukuyu akufuna kuwunika ngati kudya ufa ophatikiza ndi michere ina ngati selenium kumabweretsa phindu lokhudza umoyo. Selenium ndi michere yofunika ku umoyo wanu ndi wa ana anu. Kafukufuku wam'mbuyo waonetsa kuti michereyi ndiyopelewerwa mwa anthu ambiri akumudzi mu Malawi, ndi mwa TA Wimbe momwe. Tikuyang'ana njira zomwe tingapitsire patsogolo kadyedwe ka michereyi mopitilira ndicholinga chakuti aliyense akhale wa umoyo wabwino.

Ndi chifukwa chiyani tikukupemphani kuti mutenge nawo mbali?

Tasankha mwachisawawa Midzi yomwe ili mwa TA Wimbe kuti itenge nawo gawo mukafukufukuyu. Khomo lina lililonse lomwe lili mu midzi yomwe kafukufukuyu akuchitika litha kutenga nawo mbali, ngati angafune. Pakhomo panu pali mwina mayi wazaka makumi awiri kulekeza zaka makumi anayi ndi zisanu ndi mwana m'modzi wa zaka zisanu kulekeza zaka khumi. Izi zikutanthauzi khomo lanu ndilololedwa kutenga nawo mbali mukafukufukuyu. Tikuyankhula ndi inu monga mmayi wazaka makumi awiri kulekeza makumi anayi, ndipo tikupempha chilolezo chotenga nawo gawo mukafukufukuyu.

Kodi mukuyenera kutenga nawo mbali?

Simukuyenera kutenga nawo mbali mukafukufukuyu.

Chidzachitike ndi chiyani ngati mwatenga nawo gawo?

Banja lina lililonse mu m'mudzidzi mwanu lidzalandira Ufa mwaulere kwa masabata khumi ndi awiri (12), kuyambira kumayambililo kwa mwezi wa July mpakana kumayambililo kwa mwezi wa October chaka chino. Ngati banja lanu latenga gawo mukafukufukuyu ndekuti lidzasankhidwa mwachisawawa ndikuikidwa ku gulu limodzi mwa magulu awiriwa: la ufa ophatikiza ndi Selenium kapena la Ufa osaphatikiza ndi chilichonse omwe umadyedwa nthawi zonse. Tidzaphatikiza michereyi pogwiritsa ntchito feteleza amene amathiridwa munthawi yaulimi wa chimanga. Chimanga chidalimidwa ku Sukulu ya ukachenjede ya Ulimi ya LUANAR, yomwe ili kufupi ndi Lilongwe. Tidzakuitanani inuyo ndi anthu ena a m'mudzi mwanu kuti mukayendere komwe kukagayidwe ufa ndikukaona ndondomeko yake.

Ufawu udzagawidwa mwaulere ndipo tidzapempha makomo kuti adzagwiritse ntchito ufawu pakudya kwa masabata khumi ndi awiri akafukufukuyu. Khomo lililonse lidzapatsidwa ufa okwanira kadyedwe kawo ka tsiku ndi tsiku. Pa masabata awiri aliwonse tidzapanga kuti ufa upelekedwe ku Banja lanu ndipo tidzaunikira ngati ufa wamu kafukufukuyu ukudiyedwa kudzera mu kuwona ndi kugwiritsa ntchito mapepala amafunso ochepa kwa munthu m'modzi wapa banja lanu amene amakhudzidwa ndikuphika.

Kuti tiyeze ngati ufawu ukubweretsa kusintha ku nthanzi tidzafunika kutenga ma sampulo a magazi (6 mL) kumayambiliro ndi kumathero kwa kafukufukuyu. Tikuika chidwi chatu pa azimayi oyambira zaka makumi awiri ndi zisanu kulekeza azaka makumi anayi ndi zisanu (20-45) chifukwa chakuti thanzi lawo ndilofunika mwapaderadera, kotero tisankha inuyo ngati m'mayi m'modzi ndi mwana m'modzi mu banja lanu kuti apeline sampulo ya magazi. Ma sampulo amenewa adzawunikidwa kuti angopeleka unthenga okhudza mlingo wa Seleniyamu. Zinthu zina monga tizilombo toyambitsa matenda a EDZI sizidzayezedwa.

Kodi ndikuyenera kutani?

Tikupempha kudzipoleka kwanu ngati mayi wazaka zapakati pa makumi awiri ndi makumi anayi ndi zisanu (20-45) kutenga nawo gawo mukafukufukuyu. Ngati mwavomera kutenga nawo gawo ndiye kuti tipempha kuti mudzadye ufa omwe mu patsidwe kwa nthawi yokwana masabata khumi ndi awiri (12), ndipo tikupempha kuti ufa opatsidwa mukafukufukuyu usadzagulisidwe kapena kusinthitsidwa kuti mukapeleke chithunzithuzi chabwino. Kwa inuyo panokha ngati otenga mbali, tikufunsani mafunso ochepa chabe ndikutenga unthenga okhudza m'mene mumadyera panopa. Tikatero tidzatengako sampulo ya magazi (6 mL) pachipatala chatu choyenda cha m'mudzi, kumayambiliro ndi kumathero kwa kafukufukuyu. Ma sampulo amagazi adzatengedwa ndi anamwino ophunzitsidwa bwino.

Kodi phindu lomwe lingapezeke ndi lanji?

Inuyo ndi mudzi wanu mulandira ufa waulere kwanthawi yokwana masabata khumi ndi awiri (12). Izi zikulolani kusunga chimanga chanu ndikudzagwiritsa ntchito nthawi ina muchakachi. Kuwonjezera kupezeka kwa Seleniyamu kuli ndikuthekera kobweretsa phindu lokhudza umoyo wanu ndipo titha kuwona lina mwa phinduli likuchitika mu nthawi yochepa yakafukufukuyi, monga kutsika kwa matenda komanso nthawi yomwe matenda otsegula m'mimba amatenga kuti athe. Ngakhale zili choncho, sitingathe kudziwa pokhapokha kafukufukuyu atatha inu kapena banja lanu litamapatsidwa ufa owonjezedwa ndi michere kapena ufa wa nthawi zones osonjezera michere. Kuomba mkota, kafukufukuyu adzabweretsa unthenga ofunika kwa opanga kafukufuku ndi Boma la Malawi. Unthenga umenewu udzathandiza kupanga ziganizo zopititsira patsogolo thanzi kudzera mu ulimi, komanso kutsimikizira zafeteleza wabwino.

Nanga chinachake chitalakwika?

Tapanga kawuniwuni okwanira waziopsezo ndipo taika kale ndondomeko m'malo kuti zikathandizire kuyang'anira ndi kuthandizira mavuto ena aliwonse. Kudzikhala mwayi wapafupipafupi okumana ndi gulu la opanga kafukufukuyu ndipo mutha kuwadziwitsa ngati muli ndi zokhudza zina zili zones. Ngati sanathe kukuthandizani kumavuto anuwo, chonde lumikizanani ndi awa Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

Mungasinthe maganizo okhudza kutenga nawo gawo kwa banja lanu?

Mutha kusintha maganizo anu ndi kulanda chilolezo chomwe munapeleka m'malo. Kulanda chilolezo kutha kutanthauza kusiya kutenga nawo gawo mukafukufuku koma kupitiliza kulandira ufa osaphatikiza ndi michere, kapena kusiya kutenga nawo gawo mukafukufuku ndi kusiya kulandira ufa, kutengera ndi m'mene inu mwasankhira.

Kodi chidzachitike ndi chiyani ku unthenga omwe upezedwe mukafukufuku ameneyu?

Unthenga omwe upezedwe mukafukufuku ameneyu udzasungidwa mwachinsinsi. Amene adzakhale ndi mwayi owona kapena kugwiritsa ntchito unthengawu ndi okhawo ogwira ntchito nafe. Unthengawu udzakhala wachinsinsi, kotero dzina lanu ndi unthenga wanu wina omwe munthu angakudziwireni udzachotsedwapo unthengawu usanagawidwe

Unthenga udzasungidwa pamakina otetezedwa amene angagwiridwe ndi okhawo okhudzidwa ndi kafukufukuyu. Pamene ma fayilo a unthenga azatumizidwe kumakinawa adzabisidwa mumakinamo kuti tidzaonetsetse kuti unthengawu ukutetezedwa. Unthengawu udzasungidwa kwa dzaka dzosachepera khumikuchokera pamene adzathere kafukufukuyu ndipo udzatayidwa mosamala ngati sudzafunikanso.

Chidzachitike ndi chiyani kuzotsatira zakafukufukuyu?

Kafukufukuyu akufuna kufufuza phindu lokhudza umoyo lomwe lingapezeke pakudya ufa ophatikiza ndi michere ya seleniyamu. Tikulingalira kupanga kafukufukuyu kuno ndi midzi ina yoyandikana nanu. Zotsatira zakafukufukuyu zitsagwiritsidwa ntchito popeleka umboni ku malamulo ndi mapologalamu aku Malawi, komanso ndemanga zokhudza fetelezawofunika. Tidzakudziwitsani inuyo ndi mudzi wanu za zotsatira zakafukufukuyu pamene kafukufuku wamalizidwa.

Awunika kafukufuyu ndi ndani?

Kafukufuku wina aliyense okhudza anthu amawunikidwa ndi gulu loyima palokha lotchedwa Research Ethics Committee lomwe limateteza udulu wanu. Kafukufukuyu wawunikidwa ndi kulolezedwa ndi komiti yomwe ili ku sukulu yaukachenjede ya College of Medicine ku Blantyre, komanso sukulu ya Ukachenjede ya London School of Hygiene & Tropical Medicine yomwe ili kunja kwa dziko lino ku United Kingdom.

Unthenga owonjezera ndi wothandizira kulumizana

Mukafuna kudziwa zambiri zakafukufukuyu kapena mukakhala ndi mafunso, chonde lumikizanani ndi:

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87

Mukafuna kudziwa zambiri zokhudzana ndondomeko yokhudzana ndi kayendetsedwe ka kafukufukuyu, kapena mukakhala ndi madandaulo aliwonse okhudza kafukufukuyu chonde lumikizananani ndi:

College of Medicine Research Ethics Committee, 3rd Floor, John Chipangwi Learning Resource Centre, Private Bag 360, Chichiri, Blantyre. +265 (0)11 871 911

Appendix 2c. Informed consent form for adult women (English).

Statement	Initial or thumbprint
I confirm that the information about the AHHA study (version 4.2) has been read to me and I understand it. I have had a chance to consider the information and any questions have been answered to my satisfaction.	
I understand that my participation is voluntary and that individuals are free to withdraw at any time without giving any reason, without medical care or legal rights being affected.	
I understand that data about me may be shared via a public data repository or by sharing directly with other researchers, and that all data will be anonymised so that people are not be identifiable from this information.	
I agree to taking part in the AHHA study	

Printed name of participant	Signature of participant	Date
Printed name of witness*	Signature of witness	Date

*If the participant is unable to read or write

I attest that I have explained the AHHA study information accurately, and to the best of my knowledge this was understood by the participant and that he/she has freely given their consent to participate* in the presence of the above named impartial witness (where applicable).

Printed name of researcher*	Signature of researcher	Date

A copy of this consent form has been provided to the participant.

Appendix 2d. Informed consent form for adult women (Chichewa).

Mfundo	Sayini kapena chidindo
Ndikuvomeleza kuti ndawerengeledwa unthenga okhudza kafukufuku ameneyu othetsa njala yobisika kudzera mu ulimi wachakudya (version 4.2) ndipo ndaumvetsetsa. Ndinali ndi mwayi wolingalira unthengawu ndipo mafunso ena aliwonse ayankhidwa ndipo ndakutitsidwa.	
Ndamvetsetsa kuti kutenga nawo mbali kwanga ndipo ndili omasuka kusiya nthawi ina iliyonse osapelekanso chifukwa china chilichonse, komanso popanda kupheledwa ufulu olandira nthandizo lakuchipatala kapena ufulu wawo wovomelezeka wina ulionse.	
Ndamvetsetsa kuti unthenga okhudza ine utha kugawidwa kudziko lonse kudzera njira zogawira unthenga kapena kuwapatsa opanga kafukufuku ena komanso unthenga onso udzapangidwa kukhala opanda dzina kapena chizindikiro change china chilichonse kuti anthu asadzathe kundizindikira kudzera muunthengawu	
Ndavomera kuti nditenga nawo gawo mukafukufuku wothetsa njala yobisika kudzera mu ulimi wachakudya	

Dzina la wotenga nawo mbali	Sayini ya wotenga nawo mbali	Tsiku
Dzina la mboni*	Sayini ya mboni	Tsiku

*Ngati wotenga nawo mbali samatha kuwerenga kapena kulemba

Ndikutsimikiza kuti ndafotokoza moyenera unthenga okhudza kafukufuku wothetsa njala yobisika kudzera mu ulimi wachakudya, ndipo mumkudziwa kwanga otenga nawo mbali amvetsetsa ndiponso apeleka chilolezo chawo kuti atenge nawo mbali.

Dzina lawopanga kafukufuku*	Sayini ya wopanga kafukufuku	Tsiku

Pepala langati lomweli lapelekedwanso kwa wotenga nawo mbali.

Appendix 2e. Participant Information Sheet for the parent or guardian of school-aged children (English)

Study name: Addressing Hidden Hunger with Agronomy (AHHA) Malawi.

Protocol version: 4.2

Date	Participant ID [on copy kept by RA]

The following information should be provided to the guardians of children prior to seeking assent. The information should be provided verbally with printed copies available on request.

I am..... from

Introduction

We are conducting research in your village and neighbouring villages. We are speaking to you as the primary caregiver of the eligible child in your household. Participation is voluntary and the child in your care does not have to take part. Now we are going to provide you with information about the proposed research, so you can decide on the participation of the child in your care. Please ask questions if anything is not clear.

What is the purpose of the study?

The study aims to determine whether consumption of maize flour enriched with the micronutrient selenium delivers a health benefit. Selenium is a vital nutrients for the health of you and your children. Previous research has shown that selenium is typically deficient among populations in rural Malawi, including in Wimbe TA. We are looking at ways to sustainably increase consumption of selenium so that everyone can be healthier.

Why are we asking the child in your care to take part?

We have randomly selected villages in Wimbe TA to take part in this study. Every household within participating villages can be involved, if they wish. In your household there is at least one woman aged 20-45 years and at least one child aged 5-10 years. This means that your household is eligible for the trial. We have subsequently selected one eligible woman and one eligible child in your household to participate in the trial.

Does the child in your care have to take part?

The child in your care does not have to take part in the study.

What will happen if the child in your care takes part?

Every household in the village will be provided free maize flour for 12 weeks, from early July through to early October this year. If your household takes part in the study then we will randomly assign you

to one of two groups: flour enriched with selenium, or standard maize flour. We will enrich the flour using fertilizers applied during the maize production. Maize will be grown at Lilongwe University of Agriculture and Natural Resources, near Lilongwe. We will invite you and community members to visit the maize production site to see the process.

The flour will be distributed free of charge and we will request households to use this flour for their own consumption for the 12-week duration of the trial. Each household will be provided with enough flour to meet their daily requirements. Every 2 weeks we will arrange distribution of the maize flour to your household and we will monitor the consumption of the trial flour through observations and short questionnaires with the member of your household who is responsible for meal preparation.

To measure whether the flour has an effect on the nutritional status of the child in your care we will need to collect blood samples (6 mL) at the start and end of the trial. We will also collect blood samples from the selected woman of reproductive age in your household. These samples will be analysed in laboratories in Malawi and the UK to measure the nutritional status of the participants so that we can determine whether the enriched flour has made a difference. The samples will only be analysed to provide information on the selenium status of the participant. Other parameters including HIV infection will not be tested.

What will your child have to do?

We require the support of you and your community for this trial to work. We request that your households consumes the flour that they are provided with for the 12-week period, and we request that the trial flour is not sold or exchanged. For your child, as a participating individual, we will collect a blood sample (6 mL) at a mobile clinic in your village, at the start and end of the trial. Blood samples will be collected by trained nurses. We request that you, as the primary caregiver of the child, assist in this process by accompanying the child to the mobile clinic and ensuring that they are provided with sufficient relevant information.

What are the possible benefits?

You and your household will receive free maize flour for a 12-week period. This will allow you to conserve your own stocks of maize for later in the year. Consumption of more selenium is likely to deliver health benefits and we might see some benefits occur during the short duration of the trial, such as lower incidence and duration of diarrhoea. However, we won't know until the trial is complete whether your household are provided with the enriched flour or with control flour. Overall, the trial will deliver important information to researchers and the Malawi government. This information will inform decisions to improve nutrition through agriculture, including fertilizer recommendations.

What if something goes wrong?

We have conducted a thorough risk assessment and have plans in place to monitor and respond to any problems. There will be regular opportunities to meet the study team and you can let them know if you have any immediate concerns. If they are unable to address these concerns, then please contact

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

Can you change your mind about the child in your care taking part?

You can change your mind and withdraw your assent for participation of the child in your care. Withdrawal can mean no further participation in the trial but continued receipt of control flour, or no further participation in the trial and no further receipt of flour, depending on your preference.

What will happen to the information generated during the trial?

The information we generate during the trial will be kept private. Only staff working on the trial will be able to access and use this information. Data will be anonymised, so any names and other identifying information will be removed before these datasets are shared.

Data will be hosted on a secure server accessible only to the study team. When data files are transferred they will be encrypted to ensure security. Data will be archived for a minimum of 10 years after the study end and will be destroyed once no longer needed.

What will happen to the results of this study?

This trial aims to determine the potential health benefits of consuming maize flour enriched with the micronutrient selenium. We are planning to conduct this trial here and in neighbouring villages. The results of the trial will be used to inform policies and programmes in Malawi, including fertilizer recommendations. We will communicate the study findings to you and your community once the trial is complete.

Who has checked this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by a committee at the College of Medicine, Blantyre, and by a committee at the London School of Hygiene & Tropical Medicine in the United Kingdom.

Further information and contact details

For further information about the trial or for any questions, please contact:

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

For further information about the ethical procedures related to this trial, or if you have any concerns about the conduct of the trial, please contact:

College of Medicine Research Ethics Committee, 3rd Floor, John Chipangwi Learning Resource Centre, Private Bag 360, Chichiri, Blantyre. +265 (0)11 871 911

Appendix 2f. Participant Information Sheet for the parent or guardian of school-aged children (Chichewa)

Study name: Addressing Hidden Hunger with Agronomy (AHHA) Malawi.

Protocol version: 4.2

Date	Participant ID [on copy kept by RA]

Uthenga otsatirawu uyenera kupelekedwa kwa kholo kapena aliyense amene amayang'anira mwana amene akutenga nawo gawo (azaka 5-10) kumayambiro kopempha chilolezo. Unthengawu upelekedwe pofototozoza ndipo mapepala a unthengawu atha kupatsidwa ngati apempha.

Ine..... kuchokera ku.....

Mawu woyambirira

Tikufuna kupanga kafukufuku mu m'mudzi wanu ndi midzi ina yoyandikana ndi mudzi wanu. Tikuyankhula ndi inu monga amene mumasamalira mwana amene atha kulowa mukafukufukuyu nthawi zambiri ndipo mwana amene mumamusamalirayu sakuyenera kutenga nawo gawo. Kutenga nawo gawo ndi kosakakamiza ndipo mwana amene mumamusamalirayu sakuyenera kutenga nawo gawo. Tsopano tikupatsani uthenga okhudza kafukufuku amene tikupempha kuti apangidweyu ndicholinga chakuti mupange chisankho chakuti mwana wanu atenga nawo mbali. Chonde funsani mafunso ngati penapake pasakumveka.

Kodi cholinga chakafukufukuyu ndi chiyani?

Kafukufukuyu akufuna kuwunika ngati kudya ufa ophatikiza ndi michere ina ngati selenium kumabweretsa phindu lokhudza umoyo. Selenium ndi michere yofunika ku umoyo wanu ndi wa ana anu. Kafukufuku wam'mbuyo waonetsa kuti michereyi ndiyopelewerwa mwa anthu ambiri akumudzi mu Malawi, ndi mwa TA Wimbe momwe. Tikuyang'ana njira zomwe tingapitsire patsogolo kadyedwe ka michereyi mopitilira ndicholinga chakuti aliyense akhale wa umoyo wabwino.

Nchifukwa chiyani tikupempha mwanayo kuti asamalire?

Tasankha mwachisawawa Midzi yomwe ili mwa TA Wimbe kuti itenge nawo gawo mukafukufukuyu. Khomo lina lililonse lomwe lili mu midzi yomwe kafukufukuyu akuchitika litha kutenga nawo mbali, ngati angafune. Pakhomo panu pali mwina mayi wazaka makumi awiri kulekeza zaka makumi anayi ndi zisanu ndi mwana m'modzi wa zaka zisanu kulekeza zaka khumi. Izi zikutanthauzi khomo lanu ndilololedwa kutenga nawo mbali mukafukufukuyu. Tikuyankhula ndi inu monga woyang'anira pakhomo, ndipo tikupempha chilolezo chotenga nawo gawo mukafukufukuyu.

Kodi mwana amene mumamusamalirayu akuyenera kutenga nawo gawo?

Mwana wanu sakuyenera kutenga nawo mbali mukafukufukuyu.

Chidzachitike ndi chiyani ngati mwana wanu watenga nawo gawo?

Banja lina lililonse mu m'mudzi mwanu lidzalandira Ufa mwaulere kwa masabata khumi ndi awiri (12), kuyambira kumayambililo kwa mwezi wa July mpakana kumayambililo kwa mwezi wa October chaka chino. Ngat banja lanu latenga gawo mukafukufukuyu ndekuti lidzasankhidwa mwachisawawa ndikuikidwa ku gulu limodzi mwa magulu awiriwa: la ufa ophatikiza ndi Selenium kapena la Ufa osaphatikiza ndi chilichonse omwe umadyedwa nthawi zonse. Tidzaphatikiza michereyi pogwiritsa ntchito feteleza amene amathiridwa munthawi yaulimi wa chimanga. Chimanga chidzalimidwa ku Sukulu ya ukachenjede ya Ulimi ya LUANAR, yomwe ili kufupi ndi Lilongwe. Tidzakuitanani inuyo ndi anthu ena a m'mudzi mwanu kuti mudakayendere komwe kukulimidwa chimangacho ndikukaona ndondomeko yake.

Ufawu udzagawidwa mwaulere ndipo tidzapempha makomo kuti adzagwiritse ntchito ufawu pakudya kwa masabata khumi ndi awiri (12) akafukufukuyu. Khomo lililonse lidzapatsidwa ufa okwanira kadyedwe kawo ka tsiku ndi tsiku. Pa masabata awiri aliwonse tidzapanga kuti ufa upelekedwe ku banja lanu ndipo tidzaunikira ngati ufa wamu kafukufukuwu ukudiyedwa kudzera mu kuwona ndi kugwiritsa ntchito mapepala amafunso ochepa kwa munthu m'modzi wapa banja lanu amene amakhudzidwa ndikuphika.

Kuti tiyeze ngati ufawu ukubweretsa kusintha ku nthanzi la mwana amene mumamusamalira tidzafunika kutenga ma sampulo a magazi (6 mL) kumayambiliro ndi kumathero kwa kafukufukuyu. Tidzatenganso sampulo ya magazi a mzimayi amene anakwanitsa dzaka dzakuti angabeleke pakhomu panupo. Masampulowa adzayezedwa ku malo oyezera kuti awunike mlingo wa nthanzi la wotenga nawo mbali ndicholinga chakuti tidziwe ngati ufa owonjexera micherewu wabweretsa kusintha. Ma sampulo amenewa adzawunikidwa kuti angopeleka unthenga okhudza mlingo Seleniyamu mwa otenga nawo mbali. Zinthu zina monga tizilombo toyambitsa matenda a EDZI sizidzayezedwa.

Kodi mwana wanu akuyenera kutani?

Tikupempha kudzipeleka kwanu ndi mwana wanu kutenga nawo gawo mukafukufukuyu. Tikupempha kuti banja lanu lidzidya ufa omwe apatsidwe kwa masabata khumi ndi awiri (12), ndipo tikupempha kuti ufa umenewu usadzagulitsidwe kapena kusinthitsidwa. Kwa mwana wanu ngati munthu wotenga nawo gawo, tidzatenga sampulo ya magazi okwana (6 mL) ku chipatala choyendayenda m'mudzi mwanu. Tikukupemphani inuyo ngati osamalira mwanayu nthawi yambiri kuti muthandizire ndondomeko imeneyi pakumupelekeza mwanayu kuchipatala choyendayenda ndikuonetsetsa kuti akupatsidwa uthenga woyenera.

Kodi phindu lomwe lingapezeke ndi lanji?

Inuyo ndi Mudzi wanu mulandira ufa waulere kwanthawi yokwana masabata khumi ndi awiri (12). Izi zikulolani kusunga chimanga chanu ndikudzagwiritsa ntchito nthawi ina muchakachi. Kuwonjezera kupezeke kwa Seleniyamu kuli ndikuthekera kobweretsa phindu lokhudza umoyo wanu ndipo titha kuwona lina mwa phinduli likuchitika mu nthawi yochepe yakafukufukuyi, monga kutsika kwa matenda komanso nthawi yomwe matenda otsegula m'mimba amatenga kuti athe. Ngakhale zili choncho, sitingathe kudziwa pokhapokha kafukufukuyu atatha inu kapena banja lanu litamapatsidwa ufa owonjezedwa ndi michere kapena ufa wa nthawi zones osonjezera michere. Kuomba mkota, kafukufukuyu adzabweretsa unthenga ofunika kwa opanga kafukufuku ndi Boma la Malawi. Unthenga umenewu udzathandiza kupanga ziganizo zopititsira patsogolo thanzi kudzera mu ulimi, komanso kutsimikizira zafeteleza wabwino.

Nanga chinachake chitalakwika?

Tapanga kawuniwuni okwanira waziopsezo ndipo taika kale ndondomeko m'malo kuti zikathandizire kuyang'anira ndi kuthandizira mavuto ena aliwonse. Kudzikhala mwayi wapafupipafupi okumana ndi gulu la opanga kafukufukuyu ndipo mutha kuwadziwitsa ngati muli ndi zokhudza zina zili zones. Ngati sanathe kukuthandizani kumavuto anuwo, chonde lumikizanani ndi awa

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

Mungasinthe maganizo okhudza kutenga nawo gawo kwanu?

Mutha kusintha maganizo anu ndi kulanda chilolezo chomwe munapeleka m'malo mwa banja lanu. Kulanda chilolezo kutha kutanthauza kusiya kutenga nawo gawo mukafukufuku koma kupitiliza kulandira ufa osaphatikiza ndi michere, kapena kusiya kutenga nawo gawo mukafukufuku ndi kusiya kulandira ufa, kutengera ndi m'mene inu mwasankhira.

Kodi chidzachitike ndi chiyani ku unthenga omwe upezedwe mukafukufuku ameneyu?

Unthenga omwe upezedwe mukafukufuku ameneyu udzasungidwa mwachinsinsi. Amene adzakhale ndi mwayi owona kapena kugwiritsa ntchito unthengawu ndi okhawa ogwira ntchito nafe. Unthengawu udzakhala wachinsinsi, kotero dzina lanu ndi unthenga wanu wina omwe munthu angakudziwireni udzachotsedwapo unthengawu usanagawidwe

Unthenga udzasungidwa pamakina otetezedwa amene angagwiridwe ndi okhawa okhudzidwa ndi kafukufukuyu. Pamene ma fayilo a unthenga azatumizidwe kumakinawa adzabisidwa mumakinamo kuti tidzaonetsetse kuti unthengawu ukutetezedwa. Unthengawu udzasungidwa kwa dzaka dzosachepera khumikuchokera pamene adzathere kafukufukuyu ndipo udzatayidwa mosamala ngati sudzafunikanso.

Chidzachitike ndi chiyani kuzotsatira zakafukufukuyu?

Kafukufukuyu akufuna kufufuza phindu lokhudza umoyo lomwe lingapezeke pakudya ufa ophatikiza ndi michere ya seleniyamu. Tikulingalira kupanga kafukufukuyu kuno ndi midzi ina yoyandikana nanu. Zotsatira zakafukufukuyu zitsagwiritsidwa ntchito popeleka umboni ku malamulo ndi mapologalamu aku Malawi, komanso ndemanga zokhudza fetelezawofunika. Tidzakudziwitsani inuyo ndi mudzi wanu za zotsatira zakafukufukuyu pamene kafukufuku wamalizidwa.

Awunika kafukufuyu ndi ndani?

Kafukufuku wina aliyense okhudza anthu amawunikidwa ndi gulu loyima palokha lotchedwa Research Ethics Committee lomwe limateteza udulu wanu. Kafukufukuyu wawunikidwa ndi kulolezedwa ndi komiti yomwe ili ku sukulu yaukachenjede ya College of Medicine ku Blantyre, komanso sukulu ya Ukachenjede ya London School of Hygiene & Tropical Medicine yomwe ili kunja kwa dziko lino ku United Kingdom.

Unthenga owonjezera ndi wotheandizira kulumizana

Mukafuna kudziwa zambiri zakafukufukuyu kapena mukakhala ndi mafunso, chonde lumikizanani ndi:

Mr Leonard Banda, Lilongwe University of Agriculture and Natural Resources, P.O. Box 143, Lilongwe. 0997 69 29 87.

Mukafuna kudziwa zambiri zokhudzana ndondomeko yokhudzana ndi kayendetsedwe ka kafukufukuyu, kapena mukakhala ndi madandaulo aliwonse okhudza kafukufukuyu chonde lumikizananani ndi:

College of Medicine Research Ethics Committee, 3rd Floor, John Chipangwi Learning Resource Centre, Private Bag 360, Chichiri, Blantyre. +265 (0)11 871 911

Appendix 2g. Assent form for children (English)

Child/young person (or if unable to, parent on their behalf) to complete	Please <u>circle</u> all you agree with:	
Has information about this project been read to you?	Yes	No
Do you understand what this project is about?	Yes	No
Have you had any questions answered in a way you understand?	Yes	No
Do you understand that it is ok to stop taking part at any time?	Yes	No
Are you happy to take part?	Yes	No

If you would like to take part in this project please write your name and today's date:

Your name	Date

Your parent or guardian must write their name here too if they are happy for you to take part:

Name of parent/guardian	Signature of parent/guardian	Date

The researcher who explained this project to you needs to sign too:

Printed name of researcher*	Signature of researcher	Date

A copy of this consent form has been provided to the participant.

Appendix 2h. Assent form for children (Chichewa)

Mwana/ wachinyamata (ngati sangathe, uzani kholo m'malo mwake) kuti lipitilize	Chonde zungulizani zomwe mukugwirizana nazo:	
Kodi akuwelengerani unthenga okhudza kafukufukuyu?	Eya	Ayi
Kodi mwamvetsetsa kuti kafukufukuyi ndi yokhudza chiyani?	Eya	Ayi
Kodi mwayankhidwa funso lina lililonse munjira yakuti mwamvetsetsa?	Eya	Ayi
Mukumvetsetsa kuti ndizabwinobwino kusiya kutenga nawo mbali nthawi ina iliyonse?	Eya	Ayi
Muli osangalala kutenga nawo mbali?	Eya	Ayi

Ngati mukufuna kutenga gawo mu kafukufukuyi chonde lembani dzina lanu ndi tsiku la lero:

Dzina lanu	Tsiku

Makolo anu kapena okuyang'anirani ayenera kulemba dzina lawo ngati ali osangalatsidwa kutenga gawo:

Dzina la kholo/ woyan'ganira mwana	Sayini ya kholo/woyan'ganira mwana	Tsiku

Wopanga kafukufuku amene wakufotokerani za pulojekitiyi aynene kusayinanso:

Dzina laopanga kafukufuku	Sayini ya opaanga kafukufuku	Tsiku

Pepala langati lomweli lapelekedwanso kwa wotenga nawo mbali.

Appendix 2i. Sample participant and maize flour recipient ID cards. A = Adult, C = Child, R = Recipient. Recipients are households in the study area but not participating in the trial. Recipient and Adult ID cards will be used at flour distribution points to ensure the correct allocation of flour for non-participant and participant households, respectively.



Reverse of all cards:

