Supplemental Material 2: Example Statistical Analysis Plan (SAP) for the Informed Health Choices Study

Statistical Analysis Plan:
Effects of the Informed Health Choices podcast on the ability of parents of primary school children in Uganda to assess claims about treatment effects: a randomised controlled trial

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Background:
The ability of an individual to obtain, process, and understand basic health information is crucial for making sound health choices. Previous research has demonstrated that people's ability to accurately assess claims about the effects of treatment is limited; they will typically overestimate the potential benefits and underestimate the potential harms of a particular treatment. This can lead to poor health outcomes and inappropriate use of health services at both the individual and community level. This is especially problematic in low-income communities, where people cannot afford waste.

The Informed Health Choices podcast was developed to help people understand how to make beneficial health choices. The aim was to assess the effects of the podcast on the ability of parents of primary school children in Uganda to assess claims about the effects of treatments. While a number of learning resources are available to teach critical treatment appraisal skills to non-health professionals, few have been formally and scientifically evaluated. To the best of our knowledge, this is the first randomized controlled trial aimed at such an evaluation.

Primary Objectives and Hypotheses:
Objective 1: Determine if mean test score is different between study arms.

- Hypothesis 1: Mean test score is not different between study arms.

Objective 2: Determine if the proportion of passing score is different between study arms.

- Hypothesis 1: The proportion of passing score is not different between study arms.

Objective 3: Determine if the proportion of mastery score is different between study arms.

- Hypothesis 1: The proportion of mastery score is not different between study arms.

Study Design:
The study was a randomized controlled trial in central Uganda. The intervention group was to listen to the Informed Health Choices podcast and the control group was to listen to a series of typical public service announcements about health issues. Nine key concepts were identified to help people asses claims about treatments. The intervention podcast included 13 episodes (an introduction, eight main episodes, three recap episodes, and a conclusion). Episodes of the podcast of the public service announcement were delivered over a period of 7-10 weeks. After listening to all episodes or public service announcements, a test was given to each participant to assess claims about the effects of

treatments. The test included 18 multiple choice questions – two for each of the nine key concepts. A Luganda version of the test was also created because many of the parents did not have English as their first language. To receive a passing score, participants had to answer 11 or more of the 18 questions correctly. Similarly, a mastery score was 15 or more questions answers correctly.

Study Population:
The study population consisted of parents of children aged 10-12 years in the fifth year of primary school who were participating in a linked cluster-randomized trial of the Informed Health Choices primary school resources, which are designed to teach children to assess claims about treatment effects (Nsangi et al., 2017). Parent were recruited from both intervention and control schools.

Inclusion Criteria:
Parents had to:

- Understand either English or Luganda and
- Provide written consent to participate in the study

Exclusion Criteria:
Parents who were:

- Not able to hear
- Not contactable by phone
- Health researchers
- Participants in the development of the podcast
- Parents of children who participated in the development of the primary school resources

Primary Outcomes:

Outcome	Specifications	Variables
1. Mean score	Percentage: Each participant's score is the % of test questions they answered correctly out of a total of 18 questions. Note that this variable is treated as a continuous variable in analysis.	score100
2. Passing score	Binary: A participant has a passing score (1) if they answered 11 or more test questions correctly (0 otherwise).	pass

Secondary Outcomes:

Outcome	Specifications	Variables
3. Mastery score	Binary: A participant demonstrates master of key concepts (1) if they answered 15 or more test questions correctly (0 otherwise).	master

Covariates:

Covariate	Specifications	Model	Variables
Study group	1 = Intervention 2 = Control	Linear regression – mean score Logistic regression – pass/master	Groups
Education	1 = Primary Education/ None 2 = Secondary Education 3- Tertiary Education/ University	Linear regression – mean score Logistic regression – pass/master	Educ
School Group	1 = Intervention 2 = Control	Linear regression – mean score Logistic regression – pass/master	SchoolGroup

Statistical Plan:

Statistical analysis will be completed in SAS 9.4.

Unadjusted Comparisons

Mean score will be treated as a continuous outcome. Unadjusted differences between groups will be evaluated for statistical significance using a two-sample t-test. The t-test assumes the mean scores are normally distributed; this assumption will be evaluated graphically, and a non-parametric alternative (e.g. Wilcoxon rank-sum test) employed should it be found to be untenable.

Passing score and mastery score will be treated as binary outcomes. Unadjusted differences between groups will be evaluated using a chi-square test for independence and a two-sample Z-test of proportions. The chi-square test is only valid if the expected cell counts of each cell of the 2x2 table are greater than 5; if this is found to not be the case, a Fisher's exact test will be used instead. The Z-test assumes the proportions are normally distributed; this assumption will be evaluated graphically and if found to be untenable an unadjusted logistic regression model will be substituted.

Models

A linear regression model will be used for mean score. The adjusted model will be specified as:

$$Mean\ Score = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$

Where "Group" denotes the indicator variable for randomized group assignment (1 = podcast, 0 = control), the dummy variables for parental education are given by "SecondEdu" (1 = Secondary

Education, 0 = Primary Education/None) and "TertEdu" education (1 = Tertiary Education, 0 = Primary Education/None), and "School Group" denotes the indicator variable for the parent's child's randomized group assignment in the associated trial (1=intervention, 2 = control). Note that ε denotes the normally distributed error term. An unadjusted model will also be fit, including only the indicator variable for randomized group assignment.

Linear regression assumes normality and homoskedasticity of the errors. These assumptions will be checked by graphically evaluating the residuals from the fitted model. Violation of these assumptions undermines the validity of the parameter and standard error estimates. If this is found to be the case, alternative modeling strategies (e.g. robust standard errors) will be employed.

Logistic regression models will be used for passing and mastery scores. The adjusted models will be specified as:

$$\ln\left(\frac{\pi_{passing}}{1-\pi_{passing}}\right) = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$

$$\ln\left(\frac{\pi_{mastery}}{1-\pi_{masteru}}\right) = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$

Where "ln" represents the natural log, π represents the probability of a passing or mastery score respectively, and all other quantities defined as above. Note that the use of β for each equation is not to imply equivalence of parameter estimates between models. As with the linear regression, an unadjusted model will also be fit, including only the indicator variable for randomized group assignment.

As with the linear regression, graphical evaluation of the residuals for each model will be used to assess for possible violations of homoskedasticity. If such a violation is found, alternative modeling strategies (e.g. robust standard errors) will be employed.

Adjusted risk differences will be found by fitting the following models:

$$\pi_{passing} = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$
$$\pi_{mastery} = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$

Adjusted risk ratios will be found by fitting the following models:

$$\ln(\pi_{passing}) = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$
$$\ln(\pi_{mastery}) = \beta_0 + \beta_1 Group + \beta_2 SecondEdu + \beta_3 TertEdu + \beta_4 SchoolGroup + \varepsilon$$

Note that all 3 models for these outcomes correspond to a generalized linear model with a binomial error structure, with 3 different link functions (logit, identity, and log, respectively). These additional models are being fitted only for purposes of comparison, and we will not explore in-depth diagnostics or alternatives.

Table shells:

Table 1.1: Baseline and demographic characteristics

The table below shows the descriptive attributes of the data.

	Intervention	Control
n		
Education (%)		
Primary Education/None		
Secondary Education		
Tertiary Education		
Training in research (%)		
Prior Participation in research (%)		
Sex (%)		
Female		
Male		
Sources of health care (%)		
Government health facility		
Private not-for-profit health facility		
Private for-profit health facility		
Alternative Medical practitioners		
Advice about treatment (%)		
Friends or relatives		
Health workers		
Community leaders		
Radio or television programs		
Alternative medicine practitioners		
Internet		

Table 1.2: Baseline and demographic characteristics by included and dropped out

The table below shows the descriptive attributes of the data.

	Included	Dropped out
n		
Took the test in Luganda		
Education		
Primary		
Secondary		
Tertiary		
Training in research*		
Prior participation in research†		
Sex		
Female		
Male		

Sources of health care
Government health facility
Private not-for-profit health facility
Private for-profit health facility
Alternative medicine practitioners
Advice about treatment
Friends or relatives
Health workers
Community leaders
Radio or television programmes
Alternative medicine practitioners
Internet

Table 1.3: Baseline and demographic characteristics from the published paper

The table below shows the descriptive attributes of the data.

	Control		Podcast	
	Included	**Dropped out**	**Included**	**Dropped out**
Completed tests				
Took the test in Luganda				
Education				
Primary				
Secondary				
Tertiary				
Training in research*				
Prior participation in research†				
Sex				
Female				
Male				
Source of health care				
Government health facility				
Private not-for-profit health facility				
Private for-profit health facility				
Alternative medicine practitioners				
Advice about treatment				
Friends or relatives				
Health workers				
Community leaders				
Radio or television programmes				
Alternative medicine practitioners				
Internet				

Table 2: Two sample t-test and chi-square tests

	Intervention	Control	Test Statistic	Df	P-value
n					
Mean Score (sd)[1]					
Passing Score[2]					
Mastery Score[2]					

1. Test performed was two sample t-test
2. Test performed was a chi-square test

Table 3: Two sample Z-test of proportions

	Intervention	Control	Z Statistic	Difference in Proportion	P-value
n					
Passing Score					
Mastery Score					

Table 4: Unadjusted odds ratios – logistic regression without education and school group in the model

	Intervention	Control	Unadjusted Odds Ratio	Unadjusted Mean Difference	Adjusted Mean Difference
n					
Mean Score (sd)					
Passing Score					
Mastery Score					

Table 5: Regression Analysis – linear regression for mean score and logistic regression for passing and mastery score

	Intervention	Control	Adjusted Odds Ratio	P-value
n				
Mean Score (sd)				
Passing Score				
Mastery Score				

Table 6: Analysis using Risk – Unadjusted risk difference, adjusted risk difference, and relative risk

	Intervention	Control	Unadjusted Risk Difference (%)	Adjusted Risk Difference (%)	Adjusted Relative Risk
n					
Passing Score					
Mastery Score					

Supplemental Material 3: Example contingency table analysis

The following example demonstrates how to calculate the unadjusted odds ratio, relative risk, and risk difference using a contingency table for the second co-primary outcome, proportion of participants with a passing score (at least 11 test questions answered correctly).

A 2x2 contingency table divides the total number of participants in the study (561) into four cells, defined by the group (podcast vs. control) and the binary outcome (passing score vs. no passing score).

		Group		
		Podcast	**Control**	**Total**
Outcome	**Passing score**	203	103	306
	No passing score	85	170	255
	Total	288	273	561

1) Odds ratio:

To calculate the odds ratio, we must first calculate the odds of a participant having a passing score for each group. The odds for a group are calculated by dividing the proportion of participants who have a passing score (203/288 = 0.705 for podcast, and 103/273 = 0.377 for control) by the proportion of participants who did not have a passing score (85/288 = 0.295 for podcast, and 170/273 = 0.623 for control).

This gives us odds of 0.705/0.295 = 2.39 for the podcast group and 0.377/0.623 = 0.605 for the control group. The interpretation of these is that a participant in the podcast group is 2.39 times more likely to have a passing score than they are to not have a passing score, and that a participant in the control group is 0.605 times less likely to have a passing score than they are to not have a passing score.

The odds ratio to compare the groups is then 2.399/0.605 = 3.95. This tells us that the odds of having a passing score are 3.95 times higher in the podcast group than in the control group. Not that this is *NOT* interpreted as a participant in the podcast group being 3.95 times more likely to have a passing score than a participant in the control group. For that interpretation, we use the relative risk.

2) Relative risk:

The relative risk comparing the groups is simply the proportion of participants having a passing score in the podcast group (203/288 = 0.705) divided by the proportion of participants having a passing score in the control group (103/273 = 0.377). The relative risk is 0.705/0.377 = 1.87, indicating a participant in the podcast group is 1.87 times more likely to have a passing score than a participant in the control group.

3) Risk difference:

The risk difference is simply the absolute difference between the proportion of participants having a passing score in each group. The risk difference is 0.705-0.377 = 0.328, indicating that the probability of having a passing score in the podcast group is 0.328 higher than the probability of having a passing score in the control group.