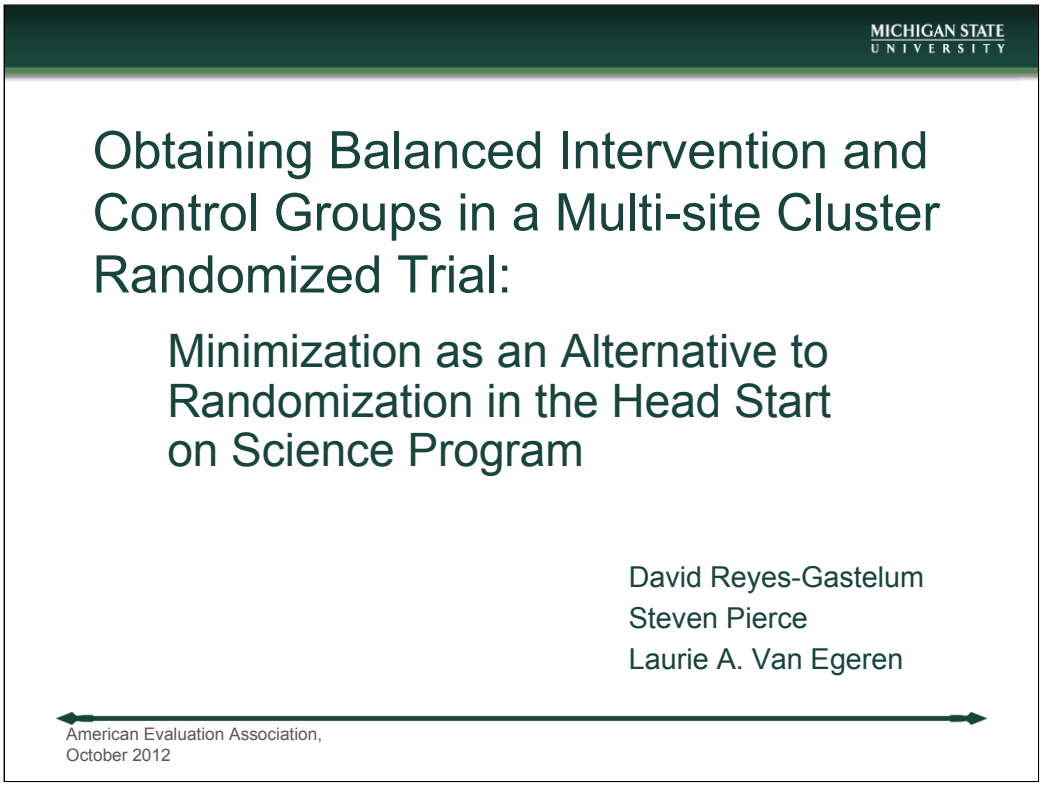
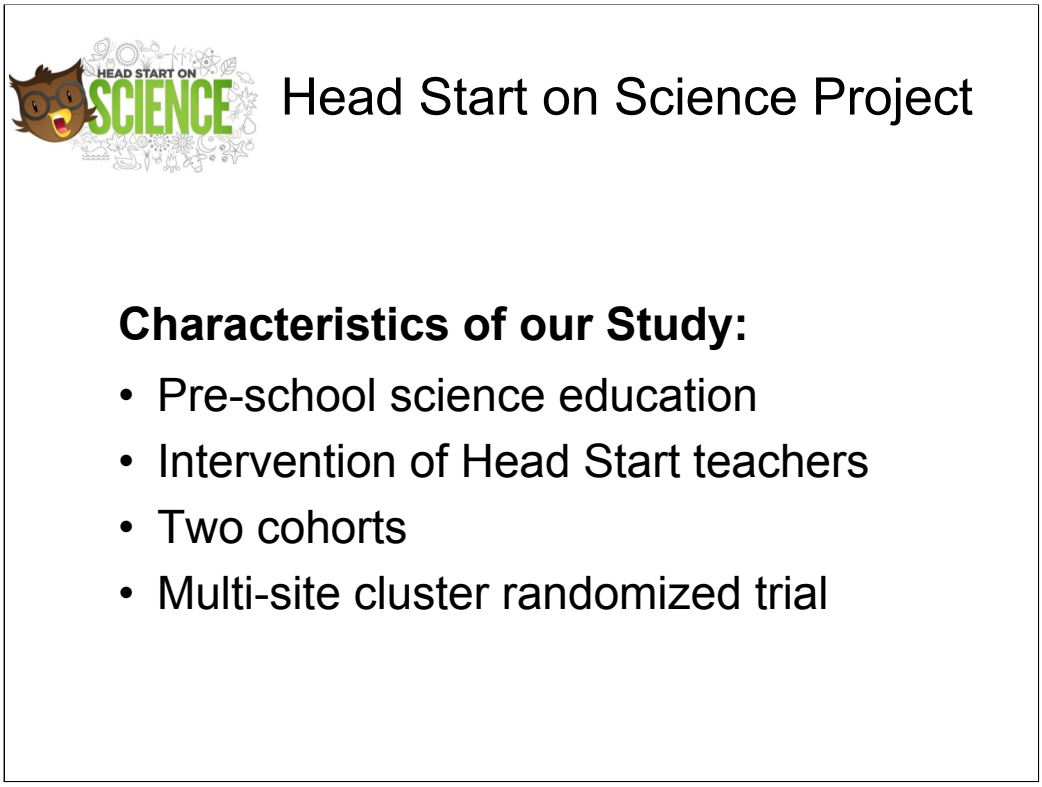


I will be presenting a method that we used in the Head Start on Science project.
The method is called Minimization, and it is an alternative to pure randomization. (Is the Gold Standard always the best? Are there other options?)
In the presentation I will go over some of the background regarding the project. Then I will go into issues with which we were confronted with and our approach to deal with them. And, finally I will demonstrate how this method was implemented with the chosen software.

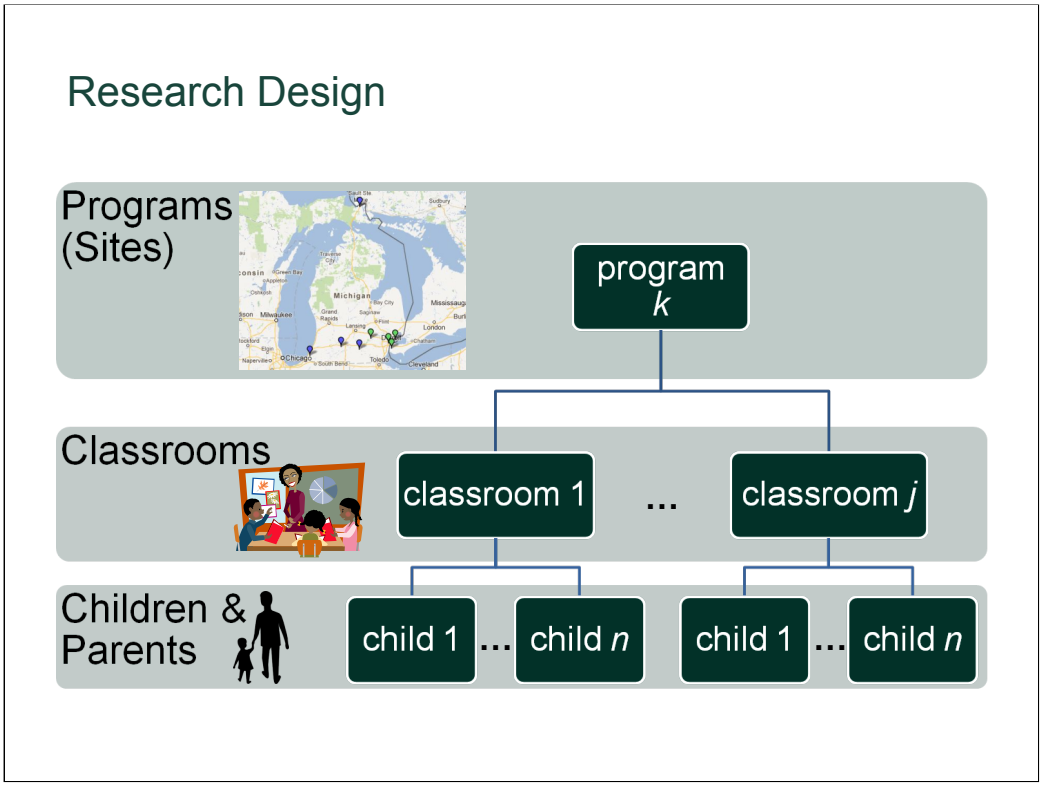


The following are a few characteristics of our study. Each of these characteristics (among others that we will be discussing later in the presentation) influenced the selection of the method used in the allocation of classrooms into the two groups: Intervention and Control.

-The project is an intervention of Head Start teachers to improve science education.
-The sample will consist of two cohorts. Each of the cohorts will contain one-half of the total sample.
-The study design is a multi-site cluster randomized trial. More on these on the next slide.

We started our task with two questions:
1. What is the best research design for our study?
Is there a naturally embedded structure in our study.
2. How can we create balanced groups? (i.e., Intervention & Control)
Balanced allocation considering the research design and the research question of interest.

Why are these important?
a. Understand the task at hand. Provides the bigger picture.
b. Identify models for analyses.
c. Ability to attribute the results to the impact of the intervention.
d. Better chance at avoiding competing explanations to our results.
e. Want to avoid any confounding variables that we might not be aware of and might become a nuisance to our study and our conclusions.
f. The properties of well balanced groups provide us with an opportunity to get as close as possible to causal inference regarding the effects of the teacher intervention.

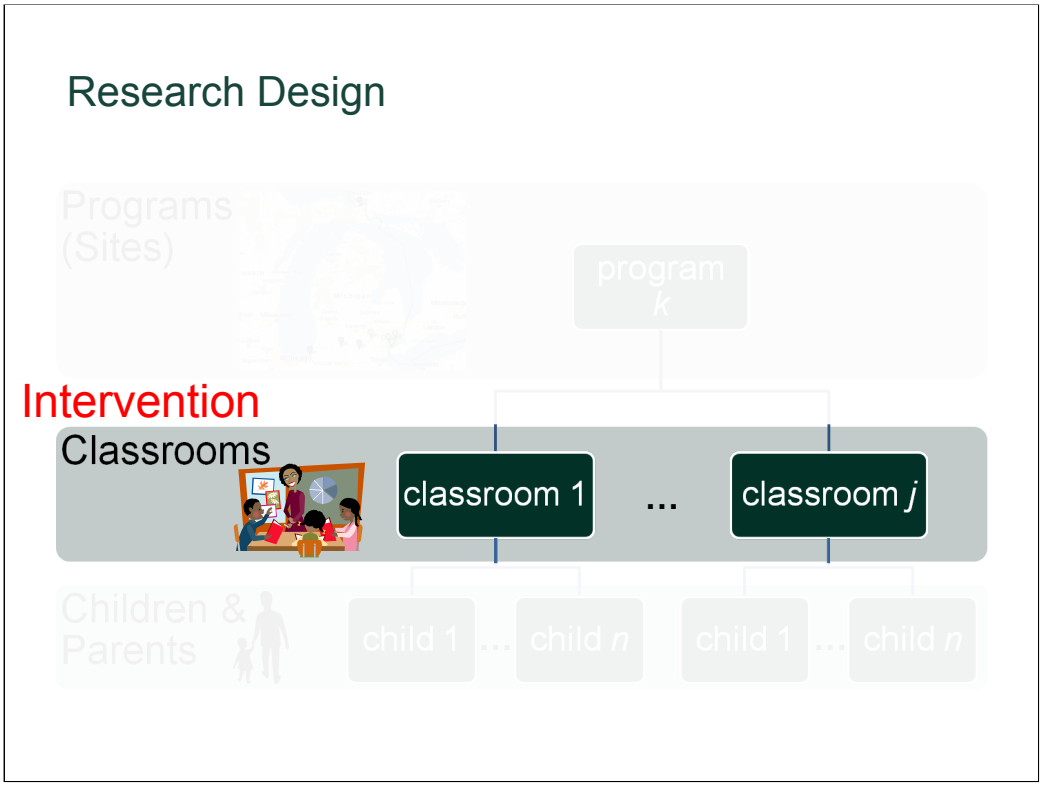


Our study has a multilevel structure with programs (sites) that contain classrooms, and classrooms (clusters) that contain students.

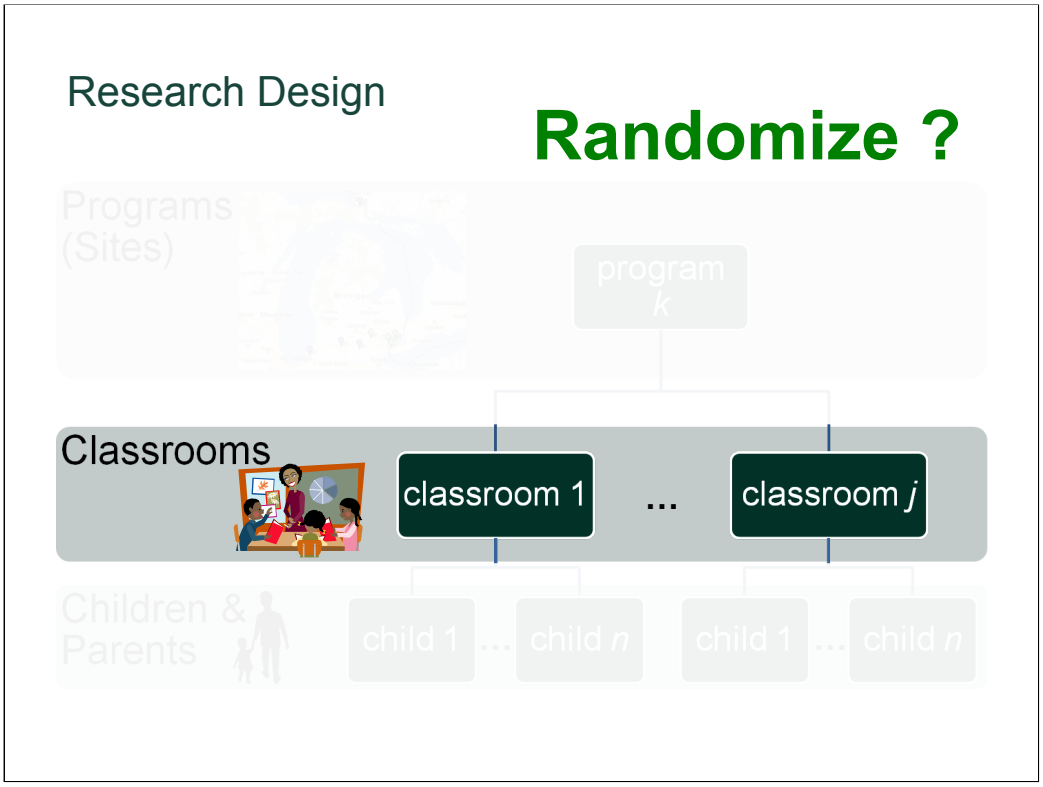
It is important to point out that the intervention is at level 2. But the study is gathering information from teachers, students and parents. That is, The study will be gathering, studying, and analyzing effects at the teacher level and the child level.

We are using multiple sites in our study for each of the following reasons:

1. One program would not have enough classrooms for our study.
2. Multiple programs allow us to sample areas with different demographics.
3. It will give us a stronger argument to generalize our results.



The intervention in our study happens at the classroom level, since it is a teacher intervention.
This informs us that we should think about the best way to allocate teachers into our two groups: Intervention and Control.
How can we do this?
What options do we have?
What is the best method to use?



Should we randomize? This is the gold standard.
If we had the money and personnel then we could use a large sample in our study. For example, we could take a sample of 100 programs and 1000 classrooms (ten classrooms per program), this is just an example. By randomly allocating classrooms to intervention/control group, flipping a 50/50 coin, this would probably balance out the two groups, that is, the two groups would be quite similar in important characteristics. This would be an ideal situation, but in most studies this is not the case.
What do we have in our study? SMALL SAMPLE
Before we go over the sample size of our study.

Let us think about a simple example of why common randomization is NOT a good method for small samples.
If we just randomly assign classrooms, then many things could happen regarding the intervention/control groups.
Let us think about what can go wrong when we are working with small samples.
EXAMPLE: If we have 3 classrooms in one program, then we would have 8 possible group assignments (each classroom has two possibilities). And, two of these possibilities assign all three classrooms to the same group (all intervention or all control). So, in this case we have a 25% probability that all classrooms in the program would be allocated to the same group.
Why is this a problem? We would not be able to compare the intervention and control groups for this program (the one with all classrooms having the same allocation). We would not be able to conclude that the intervention had the same effect in this program as in the rest of the programs. There could be some special characteristics about this program that would be confounded in our results, and this could present obstacles to our results at the conclusion of our study.
NOT GOOD

Head Start on Science Project

Each cohort:

- 4 programs
- 9 classrooms (per program)
- Students in the classroom

Total per cohort:

- 36 classrooms

What do we have in our study?
AND
What do we do?

Based on a power analysis performed, we had that each cohort would have 4 programs.
And, that each program would have 9 classrooms (on the average).
Assuming that the study would have a balanced design. Of course, this is thinking that everything works out perfectly in real life.

What can we do with small samples?
Before we go further, we should ask ourselves the following questions:
1. What is the primary goal of the study/project?
2. What are the constrains/limitations with which we are going to be confronted with?

NOTE: This implies that you need to talk to your colleagues involved in the project. And, that statistics is not a magical tool that you can use blindly (one method that works all the time).

Primary Research Goal:

Compare outcomes between the classrooms in the intervention group and control group

This is based on the broader view of the main research question of the study and also based on our research design.

Based on this goal and discussions from the project team, we identified important features that we should attempt to have in our allocation method. (What are these?)

Is there more to the research question?

Primary Research Goal:

Compare outcomes between the classrooms in the intervention group and control group, while accounting for:

- Potential program-level variation
- Correlated data associated with the multi-level design

There is, in the analyses we want to be able to account for variation and correlations embedded in our design.

Are there any other desired characteristics that we would like for our allocation?

Desired key features for the allocation method:

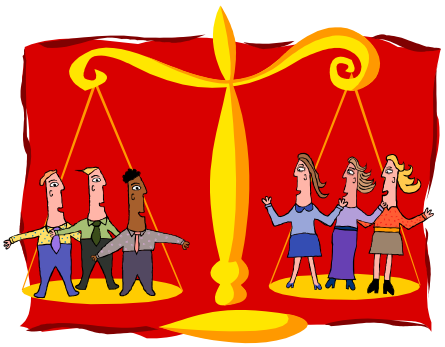
Equal number:

- Overall
- By Program

After team discussions we identified the following seven features that we wanted our allocation method to have.

1. This feature increases statistical power to detect intervention effects.
2. To measure the effect of the intervention at the program level, and to assess the stability of the intervention effects across programs.

Desired key features for the allocation method:

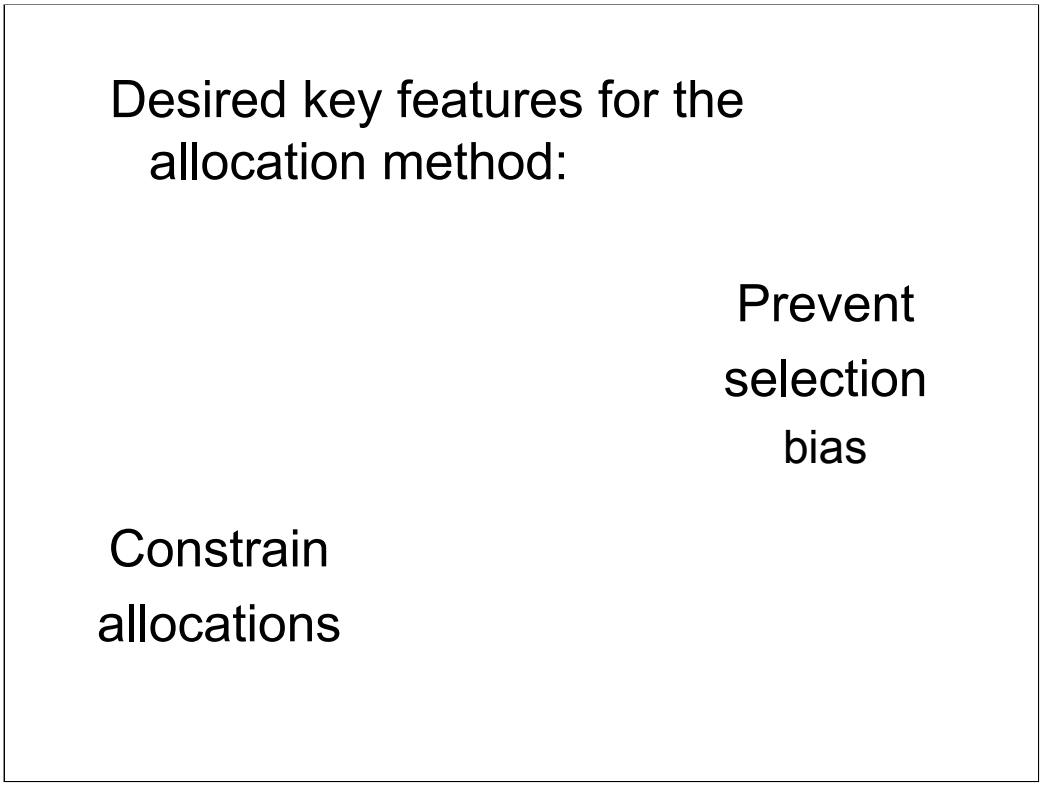


Balance on:

- Variables
- Characteristics

We want our allocation to provide balanced groups on important characteristics.

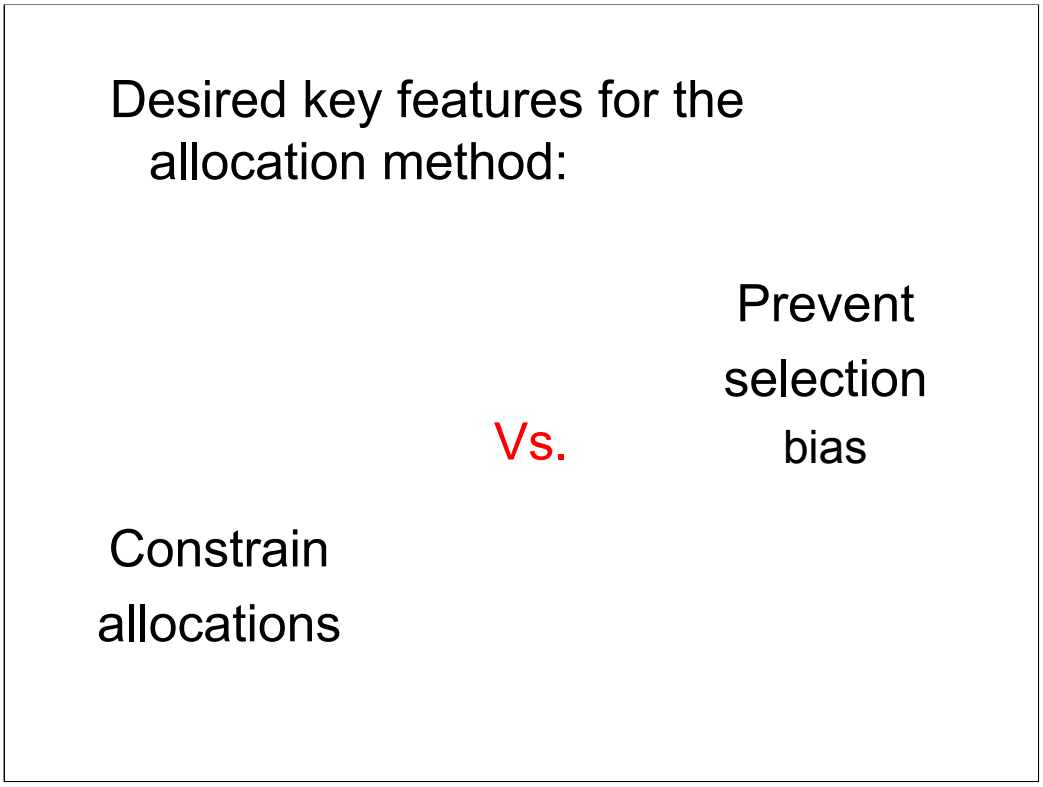
Note:
The covariates (variables) were informed by research. These covariates are related to target outcomes, because having comparable groups at baseline allows for stronger inferences about intervention effects.



We would like to have a method that does not create a biased allocation. (Selection bias refers to the bias arising from being able to predict the group to which a classroom would be allocated.)

And

We would like to be able to constrain allocations. What does this mean? In our case, this refers to the following: classrooms in the same building should be allocated to the same group, to prevent spill-over (contamination between intervention and control classrooms).



These are two competing features. Is this possible? We might need a few trade-offs to (partially) satisfy these features.

Desired key features for the allocation method:

- Allow sequential assignment.
- Method consistent with the Consolidated Standards for Reporting Trials (CONSORT).

Sequential Assignment:

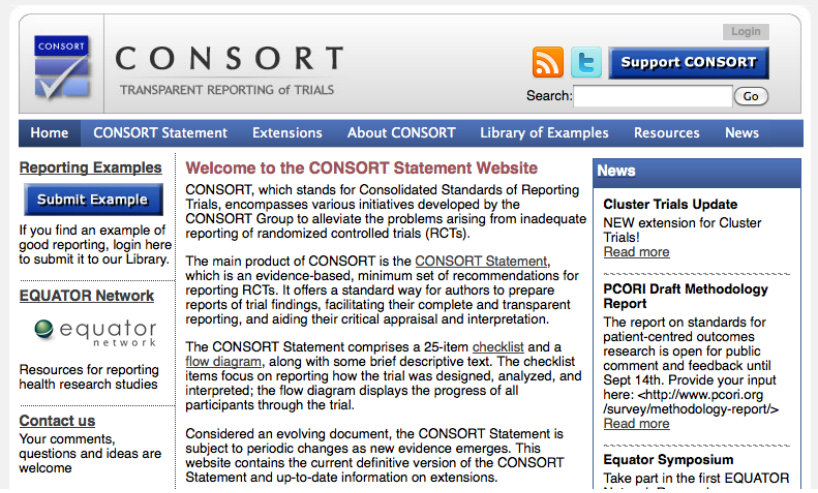
We wanted to have the option of replacing classrooms. In the case of high attrition. (The power analysis accounted for attrition, so small attrition would not be a problem.)

CONSORT:

We wanted our method to be within the accepted practices for conducting randomized controlled trials described in the consolidated standards for reporting trials (CONSORT) statement.

Before going into our allocation method. Let us explain what CONSORT is and where you can find more information.

Consolidated Standards of Reporting Trials (CONSORT)



Source: http://www.consort-statement.org/

These standards were developed to improve the implementation and reporting of randomized controlled trials within the medical community.

Allocation Method:

Biased Coin Minimization Algorithm

(Scott, McPherson, Ramsay, Campbell 2002; Taves 2010)

MinimPy software

(Saghaei, Saghaei 2011)

IMPORTANT:
Selected allocation method that made appropriate trade-offs.
And
Software that allowed us to control and implement all the desired features.

Vs.

True Randomization	Minimization
Requires large samples to balance groups in: • Group size • Covariates	• Deterministic • Explicitly balances group size • Explicitly balances on covariates (Scott et. al 2002; Torgerson, Torgerson 2007)

How does this method compare to the "Gold Standard".

Remember, true randomization (and most methods) only work for large samples

(to guarantee

equal group sizes and

good covariate balance).

MINIMIZATION:
Deterministic (Trade-off / Bad Feature):
How do we deal with this?
(We selected a Biased Coin minimization procedure to deal with the deterministic feature of the algorithm.)

How does minimization work?

Principles of Minimization:

- The first classroom is allocated to a group at random.
- For each subsequent classroom we determine which group allocation would lead to better balance between the groups in the variables of interest.

What are the big concepts associated with Minimization?
The method follows the two given principles.
1. It randomly assigns the first classroom. (Flip of a 50/50 coin.)
2. It creates a score for each group based on currently allocations, and based on this score it determines which assignment for the subsequent classroom would provide the best balance.

This has two consequences:
1. The order in which the classrooms are allocated matters.
2. Once the order is determined then the allocation is deterministic.

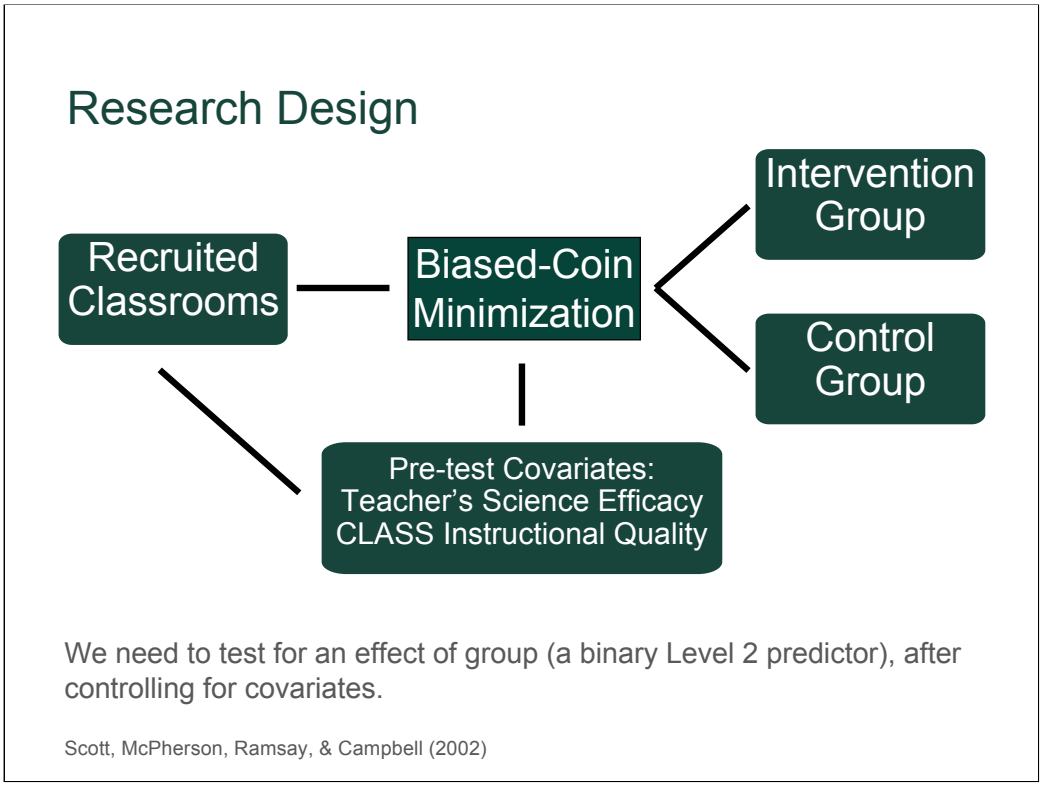
How can this be modified (or implemented) to get a better allocation (based on our desired) features?

Principles of Minimization:

- The first participant is allocated a treatment at random.
  - The order is randomized.
- For each subsequent participant we determine which group allocation would lead to better balance between the groups in the variables of interest.
  - Introduce a biased coin.

What did we do to deal with this?
1.We randomly assigned the order.
2.We used a biased coin.

Did we satisfy our seven desired features?
First, we should mention that this method is consistent with CONSORT.
We will go over the other desired features as we go through the software implementation.



The overall implementation is illustrated by this diagram:

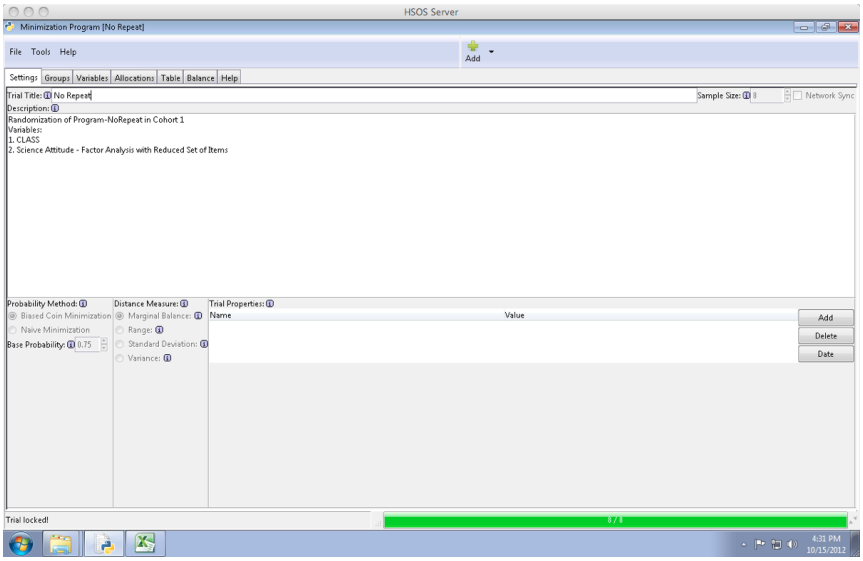
1. We recruit classrooms.
2. We obtain some baseline data, and use this data to obtain our covariates.
3. Take the list of classrooms and the covariates, and we put them into the allocation algorithm.
4. Obtain the two groups: Intervention & control.

Covariates

- Teacher's Science Efficacy
  - Measure obtained from teacher surveys, these surveys were completed during recruitment.
- CLASS Instructional Quality
  - Measure obtained from classroom observation during recruitment.

The covariates (variables) were informed by research. These covariates are related to target outcomes, because having comparable groups at baseline allows for stronger inferences about intervention effects.

MinimPy software: Settings

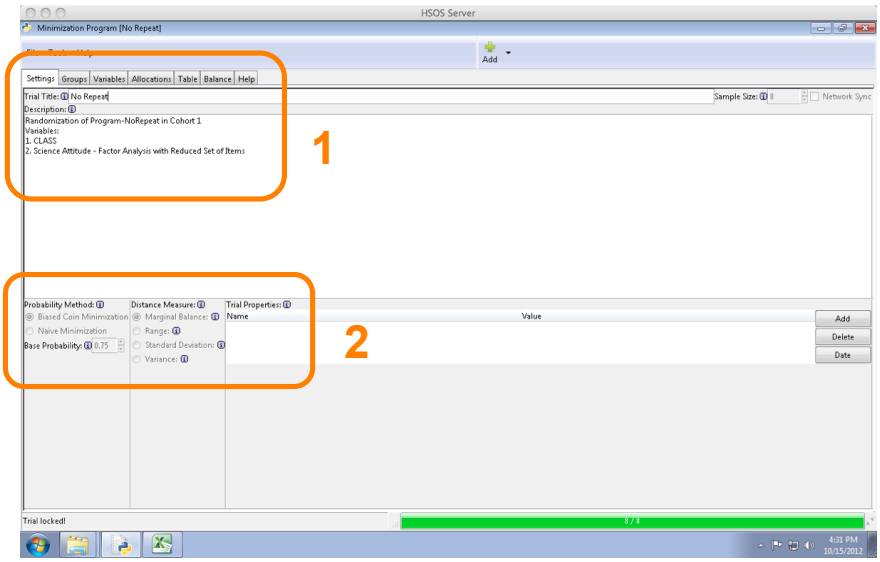


So how did we implement this algorithm and what does the software allow us to do?

Note:

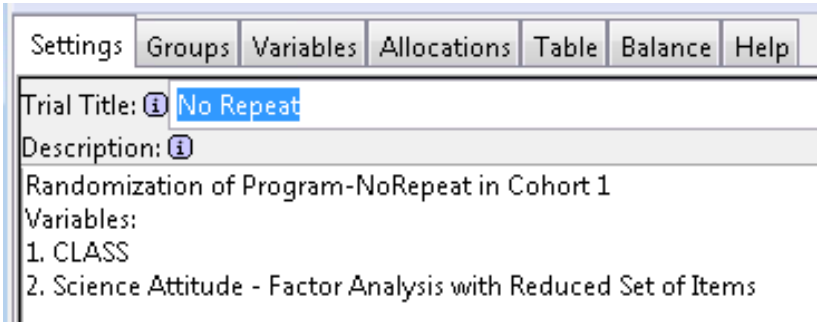
We applied the algorithm to each program separately.

MinimPy software: Settings



Since the fonts are small we will be focusing on these two areas of the screen.

MinimPy software: Settings

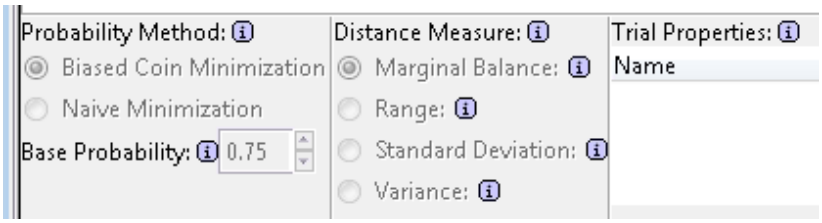


1

On the top you can see that the software has multiple tabs. We will be going over each one of these during the demonstration.

This area allows you to enter any type of descriptions that will be useful later on, in case we have to go back and look at our process. This will remind us of what we did in the process.

MinimPy software: Settings



2

This section allows us to select the probability of the biased-coin. The number we chose was based on previous research.

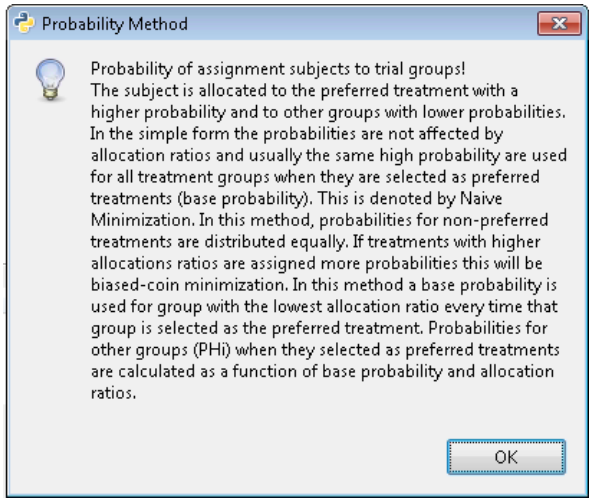
And, we can also select the desired distance measure. With this option we are selecting the formula that will be creating scores for the groups, and that will be used to balance the groups (Minimization).

Note:
We can see that the screen has many i's encapsulated in circles. What are these? Let us see at the one next to "Probability Method".

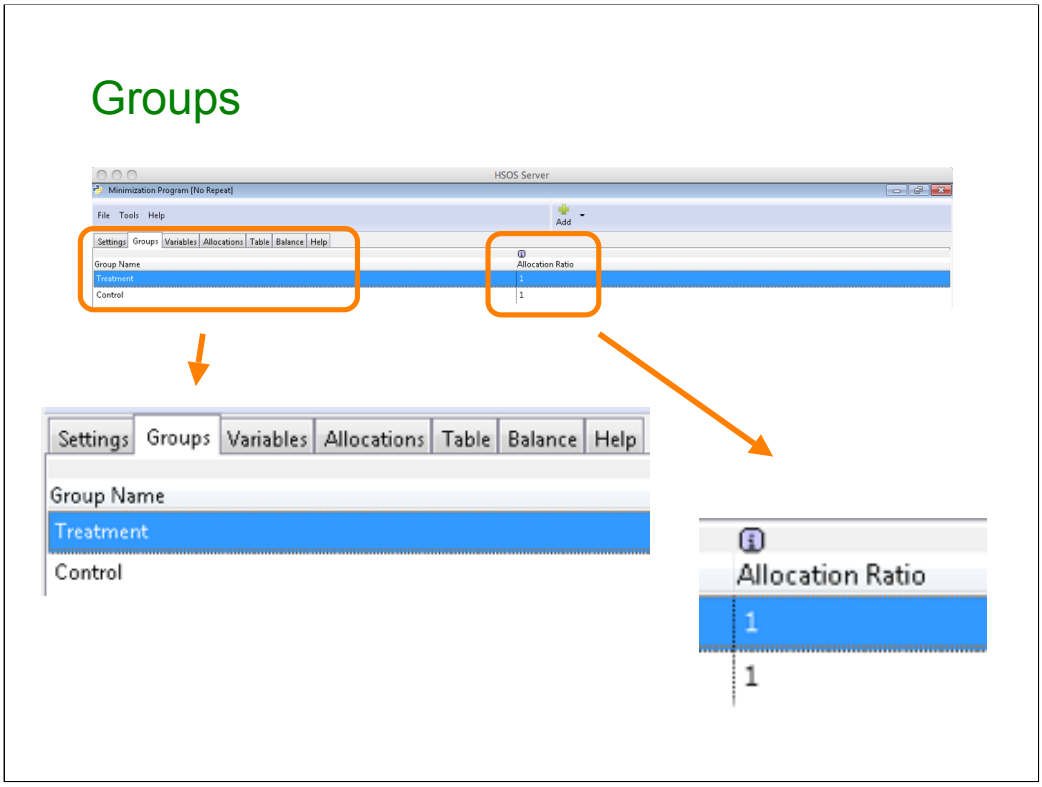
Related to our desired features:

We used the biased coin variation of the minimization algorithm. It prioritizes the balancing allocation, but still adds some uncertainty to the allocation process.

MinimPy software: Settings



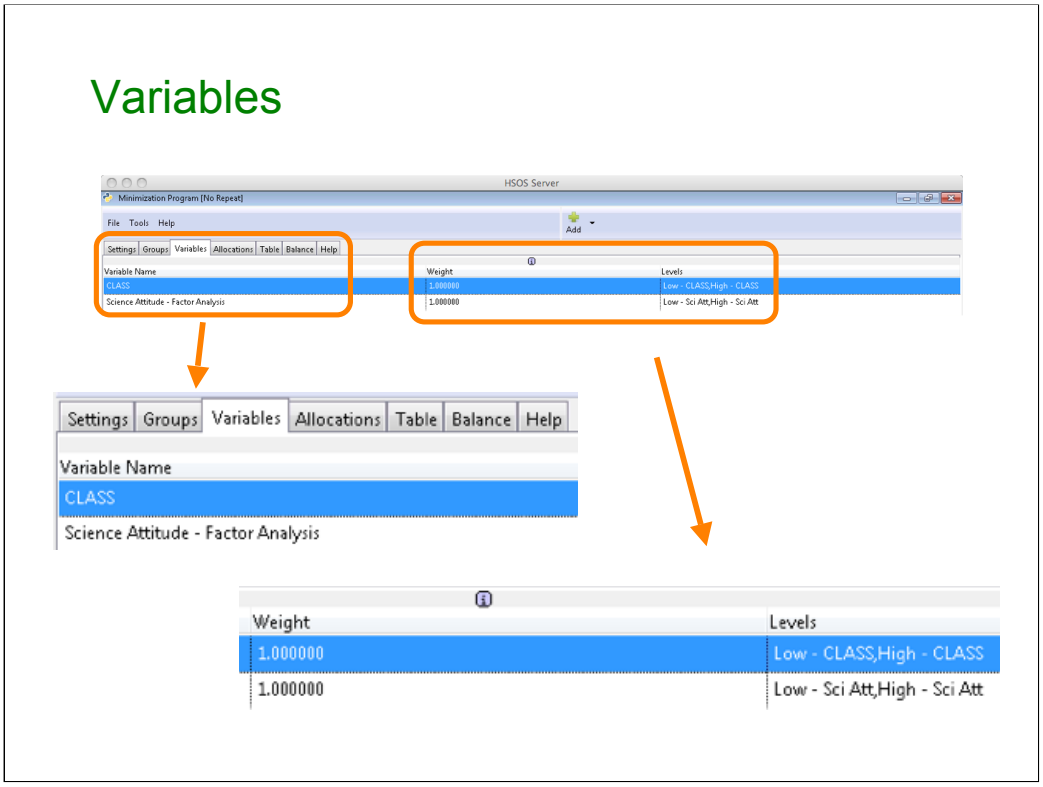
The software provides information regarding the options provided help us select the best options for our study.



On the next tab, "Groups":
We assign names to our groups and provide the desired allocation ratio.

Related to our desired features:

1. This provides the desired balance in size (both groups will have similar number of classrooms).
2. Used the algorithm in each of the programs. So the balance in size applies to each program, and also overall.

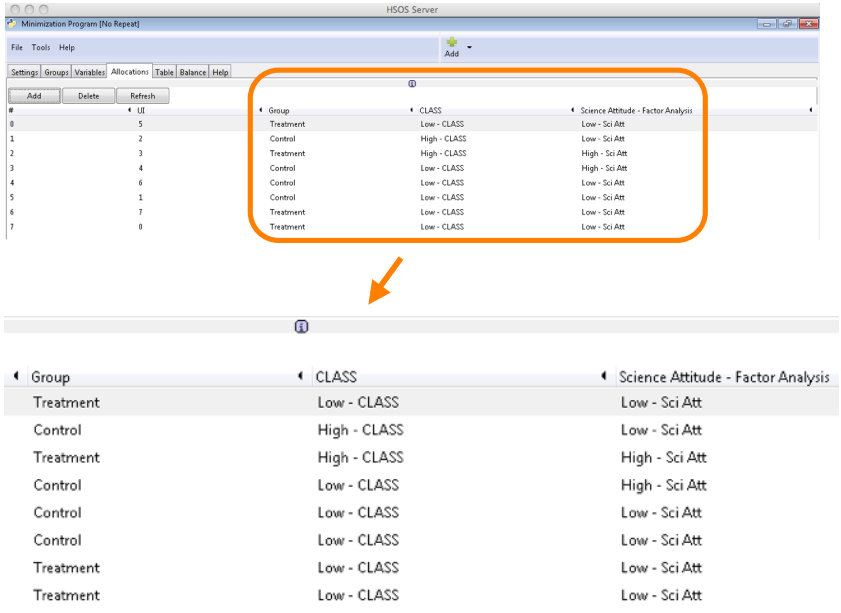


The next tab, “Variables”:
Here we can enter our covariates and the acceptable values for each of them.
Important: You also have the option to assign weights to each of the covariates, this provides an opportunity to rank the importance of each them if needed (or desired).

Related to our desired features:

1. The covariates were used as balancing criteria.

Allocations



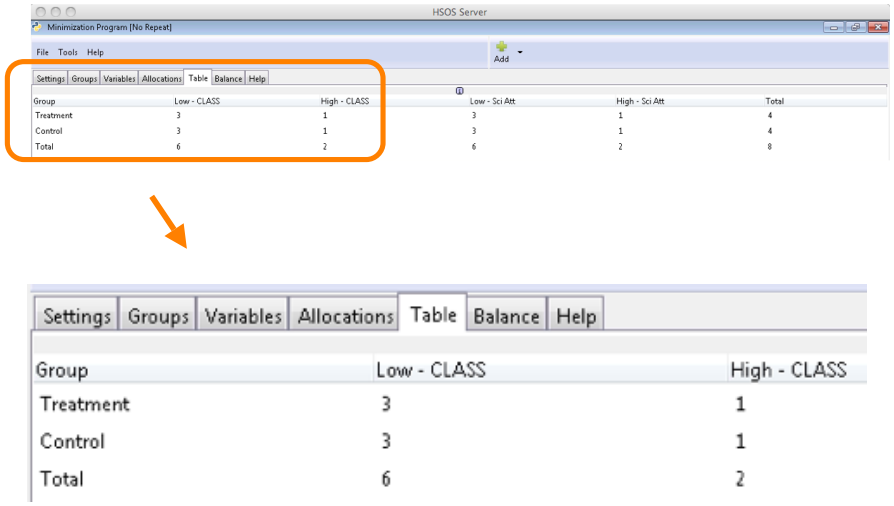
The “Allocation” tab:

We can see the allocation of the classrooms that have already been entered. This current allocations are used to determine the allocation for the next entered classroom.

Related to our desired features:

1. The software allows us to force the allocation (override if needed), and then based on the current groups the next classroom should be allocated following the algorithm.
2. The algorithm works in a sequential manner.

Table



On this tab, "Table":
We obtain a breakdown of our covariates by group.

Table

Settings | Groups | Variables | Allocations | Table | Balance | Help

Group	Low - CLASS	High - CLASS
Treatment	3	1
Control	4	0
Total	7	1

Balance

Settings | Groups | Variables | Allocations | Table | Balance | Help

Variable/Level	Marginal Balance	Range	Variance	SD
⊟ CLASS	0.571429	1.000000	0.500000	0.707107
Low - CLASS	0.142857	1.000000	0.500000	0.707107
High - CLASS	1.000000	1.000000	0.500000	0.707107
⊟ Science Attitude - Factor Analysis	0.266667	1.000000	0.500000	0.707107
Low - Sci Att	0.333333	1.000000	0.500000	0.707107
High - Sci Att	0.200000	1.000000	0.500000	0.707107
Mean	0.419048	1.000000	0.500000	0.707107
Max	1.000000	1.000000	0.500000	0.707107

This is a different example, in this program the variable did not balance out perfectly (due to randomness and the number of classrooms with values in each of the covariates).

On the “Balance” tab, we can see the results of the “Marginal Balance” minimization formulas.

Sample Descriptive Characteristics (Cohort 1)

	Intervention N (%)	Control N (%)	Total N (%)
Classrooms	18 (51)	17 (49)	35 (100)
Teachers	35 (51)	34 (49)	69 (100)
Teacher type			
Lead teacher	18 (51)	17 (50)	35 (51)
Teaching assistant	17 (49)	17 (50)	34 (49)
Gender			
Female	34 (97)	33 (97)	67 (97)
Male	1 (3)	1 (3)	12 (3)
Race			
African American	6 (17)	7 (21)	13 (19)
White	24 (69)	21 (62)	45 (65)
Other	4 (11)	5 (15)	9 (13)
Missing	1 (3)	1 (3)	2 (3)
Education			
Master's degree	3 (9)	1 (3)	4 (6)
Bachelor's degree	11 (31)	13 (38)	24 (35)
Associate degree	13 (37)	7 (21)	20 (29)
High school degree/GED	8 (23)	13 (38)	21 (30)
	***M* (*SD*)**	***M* (*SD*)**	***M* (*SD*)**
Experience in early childhood programs (years)	9.9 (6.6)	11.4 (8.6)	10.6 (7.6)

This table illustrates what happened to all the other variables we were not controlling for in the minimization algorithm.

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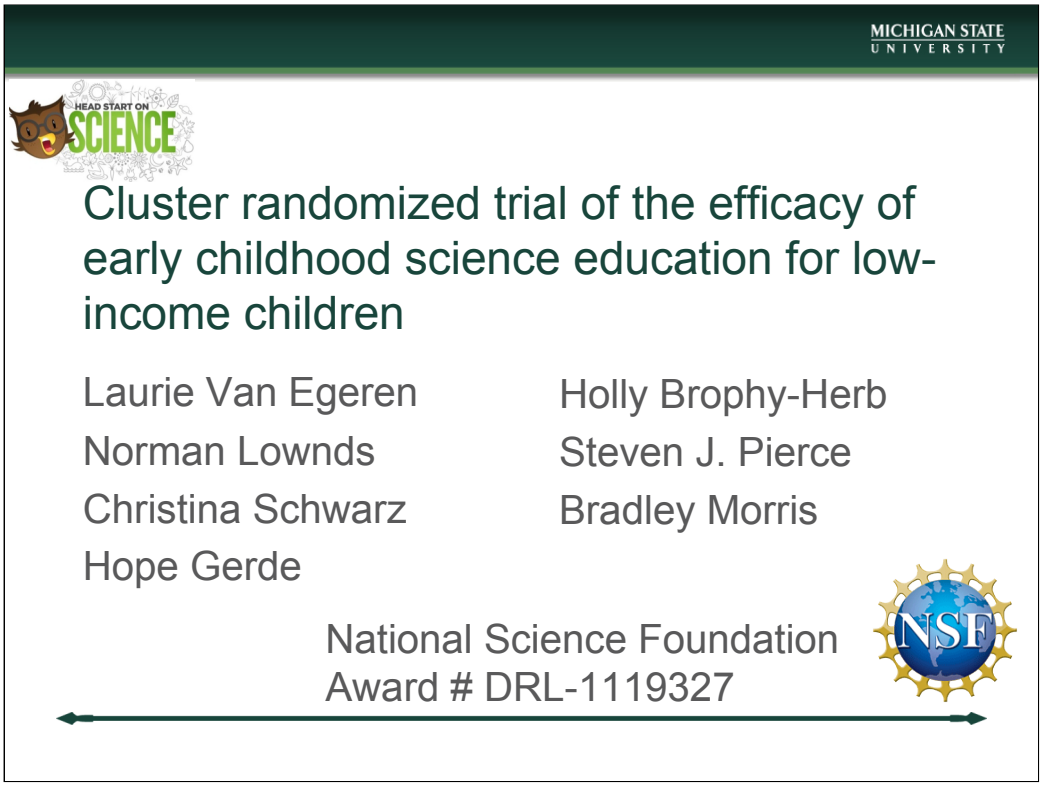
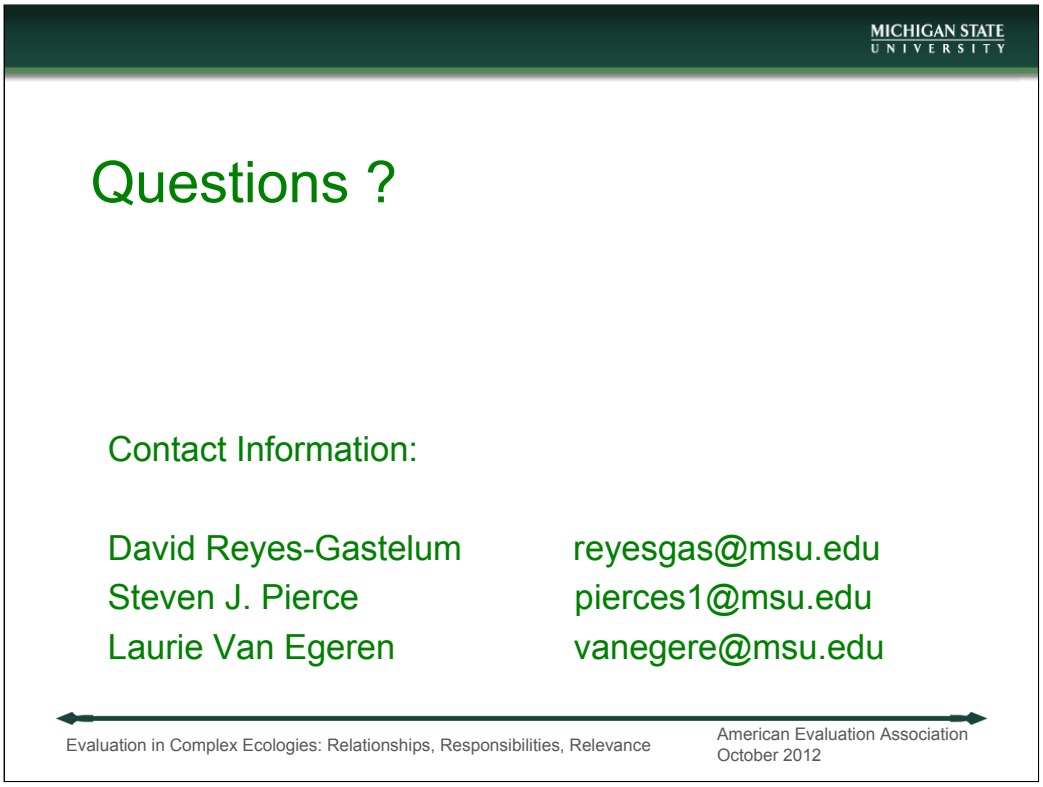


Co-PIs and project information.



Contact Information.