Micro-Randomized Study Design Example (With Results)

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

ClinicalTrials.gov Identifier: NCT00055672

Recruitment Status: Completed
First Posted: January 2, 2018
Results First Posted: August 31, 2019
Last Update Posted: August 31, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

The Maryland Alcohol-Dependent Moms Abstinence (MAMA) Study is a micro-randomized optimization trial (MRT) conducted to gather evidence about the effectiveness of a just-in-time adaptive intervention (JITAI) to reduce risky drinking among pregnant women during the first trimester.

Condition or disease	Intervention/treatment	Phase
Alcohol Abuse Pregnancy Trimester, First	Behavioral: MAMA Intervention (Push Component: Stress Management Prompts) Behavioral: MAMA Intervention (Pull Component, Active: Easing Distress) Behavioral: MAMA Intervention (Pull Component, Active: Web Links)	Not Applicable

	Behavioral: MAMA Intervention (Pull Component, Active: Frequently Asked Questions) Behavioral: MAMA Intervention (Pull Component, Active: Instant Library) Behavioral: MAMA Intervention (Pull Component, Active: Personal Stories) Behavioral: MAMA Intervention (Pull Component, Active: Discussion Groups) Behavioral: MAMA Intervention (Pull Component, Passive: Daily Abstinence Counter)	

Detailed Description:

The MAMA Study is designed to test the effectiveness of JITAI strategies to reduce drinking in pregnant women with risky drinking behavior. Risky drinking behavior will be determined using the AUDIT (US) screening tool (score range of 0 - 46 points; higher scores indicate more risky behavior). Women who score between 8 and 19 and who are still in the first trimester of pregnancy will be eligible to enroll in the study for a period of 37 days.

The MAMA intervention will be delivered to participants through the Addiction-Comprehensive Health Support System (A-CHESS) app, which will be available on a study-provided mobile phone. The intervention will include a single “push” component which will be responsive to the participant’s level of stress. Participants will be required to wear a wristband stress sensor that monitors electrodermal activity (EDA) to detect stress events. If a stress event is detected in the 10 minutes prior to a decision point, a message (or no message) will be sent to encourage the use of coping strategies in the A-CHESS app and to consider attending a support group meeting. Alternatively, if stress levels are not elevated during this period, participants will receive a message (or no message) of encouragement to remain stress-free. Participants will be asked to define a 13-hour period each day during which they will be awake and available for either monitoring (during the baseline period) or monitoring and receiving messages (during the intervention period) at decision points once every hour at the top of the hour, for a total of 13 points during each 24-hour period.

The intervention will also include several “pull” components that will always be available to participants through the A-CHESS app and that participants can choose to access or use themselves, with the exception of the daily abstinence counter. The daily abstinence counter will prompt participants daily to record the number of drinks they consumed that day and the time of day they were consumed.

Study Design

Study Type:	Interventional
Actual Enrollment:	63 participants
Allocation:	Randomized
Intervention Model:	Single Group Assignment
Intervention Model Description:	Micro-Randomized Trial (MRT)
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Maryland Alcohol-Dependent Moms Abstinence (MAMA) Study
Actual Study Start Date:	January 1, 2018
Actual Primary Completion Date:	December 31, 2018
Actual Study Completion Date:	December 31, 2018

Arms and Interventions

Arm	Intervention/treatment
Experimental: Alcohol-Dependent Moms The MAMA intervention was delivered through the A-CHESS app, which was available to each participant on her study-provided mobile phone. The intervention included a single "push" component, which was responsive to a participant's level of stress and sent messages (or no messages) to each participant via the A-CHESS app according to a decision rule. A-CHESS randomized delivery of the push component with a probability of 0.2 for receiving a message and a probability of 0.8 for receiving no message at each decision point when participants were available for the intervention.	Behavioral: MAMA Intervention (Push Component: Stress Management Prompts) Messages prompted participants to manage their stress by using coping mechanisms or to maintain their current affect, depending on whether the wristband stress sensor detected a stress event in the 10 minutes prior to a decision point. If participants experienced a stress event during this period, they were encouraged to access coping strategies in the A-CHESS app and to consider attending a support group meeting. If they did not experience a stress event during this period, they received a message of encouragement to remain stress-free.

Arm	Intervention/treatment
The intervention also included several "pull" components that were always available to participants through the A-CHESS app. Participants could choose to access or use these intervention components themselves, with the exception of the daily abstinence counter, which prompted participants daily to record the number of drinks they consumed that day and the time of day they were consumed.	Behavioral: MAMA Intervention (Pull Component, Active: Easing Distress) A computerized cognitive-behavioral therapy program designed to help women cope with inaccurate thoughts that hinder their efforts to remain abstinent. The program helped assess logical errors, attributional mistakes, and the tendency to amplify distress, and it offered exercises to sharpen problem-solving skills. Behavioral: MAMA Intervention (Pull Component, Active: Web Links) Links to evidence-based addiction-related websites and specific pages within those sites, including Alcoholics Anonymous resources Behavioral: MAMA Intervention (Pull Component, Active: Frequently Asked Questions) Brief and encouraging answers to questions about addiction, such as "How do I deal with cravings for alcohol?" The responses included links to information and services for more support. Behavioral: MAMA Intervention (Pull Component, Active: Instant Library)

Arm	Intervention/treatment
	Summaries of articles, chapters, and other publications on addiction management for women Behavioral: MAMA Intervention (Pull Component, Active: Personal Stories) Professionally produced text and videos of abstinence stories from other mothers, focusing on ways to manage addiction and cope with challenges Behavioral: MAMA Intervention (Pull Component, Active: Discussion Groups) Participants could chat online anonymously with others in the MAMA Study to receive instant support Behavioral: MAMA Intervention (Pull Component, Passive: Daily Abstinence Counter) The counter and graph of days abstinent appeared on the home page of the app to remind participants of their days of abstinence. Participants recorded their number of drinks per day by time of day in the A-CHESS app for the duration of the study.

Outcome Measures

Primary Outcome Measure:

1. Proportion of Decision Points Followed by a Stress Event - Proximal (Short-Term) Outcome [Time Frame: For 1 hour after each decision point, over the 30-day intervention period]

   Participants were asked to define a 13-hour period each day during which they would be awake and available for monitoring and receiving messages. The same 13-hour period defined for each participant in the baseline period was used for the intervention period. Decision points occurred once every hour at the top of the hour. Participants were monitored for a stress event in the subsequent hour after each decision point. To determine the effect of messaging on stress, the proportion of decision points followed by a stress event in the subsequent hour for participants who received a stress-management message was compared to the proportion of decision points followed by a stress event in the subsequent hour for participants who received no message. Proportions were determined for each participant, then averaged across participants. There were up to 390 decision points (13 per day x 30 days) per participant for the intervention period.

Secondary Outcome Measures:

1. Number of Drinks Within the Hour Following a Decision Point - Proximal (Short-Term) Outcome [Time Frame: For 1 hour after each decision point, over the 30-day intervention period]

   Short-term alcohol consumption was defined as the number of drinks consumed within the hour following a decision point. This was recorded in the A-CHESS app daily via the daily abstinence pull intervention component. The A-CHESS app asked two questions to assess a participant's abstinence or level of alcohol consumption daily throughout the intervention: "How many drinks did you have today?" and "When did you have those drinks?" If participants had one or more drinks within the hour after a decision point, then those drinks were assigned to that decision point. To determine the effect of messaging on short term alcohol consumption, the number of drinks in the hour following decision points during which participants received a stress-management message was compared to the number of drinks in the hour following decision points during which participants received no message. The number of drinks per decision point was determined for each participant, then averaged across participants.

Other Outcome Measures:

1. Number of Drinks Per Woman Throughout the Intervention Period – Distal (Long-Term) Outcome [Time Frame: 30-day intervention period]

   Long-term alcohol consumption was defined as the average number of drinks consumed per woman throughout the 30-day intervention period.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)
Sexes Eligible for Study: Female

Gender Based Eligibility: No
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Alcohol use in the first trimester of pregnancy
- AUDIT (US) score between 8 and 19

Exclusion Criteria:

- Second or third trimester of pregnancy
- High-risk pregnancy requiring bed rest
- Use of any other teratogenic substances except for alcohol
- Unable to use a cell phone or no cellular service at home

Contacts and Locations

Locations

United States, Virginia

Virginia University's School of Medicine
Alexandria, Virginia, United States, 22304

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] December 1, 2017

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055672
Other Study ID Numbers:	TTTMicroRandomizedR
First Posted:	January 2, 2018
Results First Posted:	August 31, 2019
Last Update Posted:	August 31, 2019

Last Verified: August 2019

Human Subjects Protection Review Board Status: Approved
Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Study Results

Participant Flow

Recruitment Details	76 pregnant women were assessed for eligibility, and 10 were found ineligible: 3 had high-risk pregnancies, 4 were diagnosed with alcohol use disorder, and 3 had no cellular service at home. Therefore, a total of 66 participants were eligible and offered enrollment, of which 63 signed informed consent forms and enrolled in the study.
Pre-assignment Details	

Arm/Group Title	Alcohol-Dependent Moms
Arm/Group Description	The MAMA intervention was delivered through the A-CHESS app, which was available to each participant on her study-provided mobile phone. The intervention included a single “push” component, which was responsive to a participant’s level of stress and sent messages (or no messages) to each participant via the A-CHESS app according to a decision rule. A-CHESS randomized delivery of the push component with a probability of 0.2 for receiving a message and a probability of 0.8 for receiving no message at each decision point when participants were available for the intervention. There were 13 possible decision points per day per participant, for a total of ≤ 91 decision points per participant in the 7-day baseline period and ≤ 390 decision points per participant in the 30-day intervention period. The intervention also included several “pull” components that were always available to participants through the A-CHESS app. Participants could choose to access or use these intervention components themselves, with the

	exception of the daily abstinence counter, which prompted participants daily to record the number of drinks they consumed that day and the time of day they were consumed.
Period Title: **Overall Study**	
Started	63
Completed	50
Not Completed	13
Reason Not Completed	
Withdrawal by Subject	4
Lost to Follow-up	9

Baseline Characteristics

Arm/Group Title	Alcohol-Dependent Moms
Arm/Group Description	The MAMA ntervention was delivered through the A-CHESS app, which was available to each participant on her study-provided mobile phone. The intervention included a single “push” component, which was responsive to a participant’s level of stress and sent messages (or no messages) to each participant via the A-CHESS app according to a decision rule. A-CHESS randomized delivery of the push component with a probability of 0.2 for receiving a message and a probability of 0.8 for receiving no message at each decision point when participants were available for the intervention. There were 13 possible decision points per day per participant, for a total of ≤ 91 decision points per participant in the 7-day baseline

		period and ≤ 390 decision points per participant in the 30-day intervention period. The intervention also included several “pull” components that were always available to participants through the A-CHESS app. Participants could choose to access or use these intervention components themselves, with the exception of the daily abstinence counter, which prompted participants daily to record the number of drinks they consumed that day and the time of day they were consumed.
Overall Number of Baseline Participants		63
Baseline Analysis Population Description		[Not Specified]
Age, Continuous Mean (Standard Deviation) Unit of measure: years		
	Number Analyzed	63 participants
		23.7 (1.7)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants		
	Number Analyzed	63 participants
	Female	63 100.0%
	Male	0 0.0%
Ethnicity (NIH/OMB) Measure Type: Count of Participants		

Unit of measure: Participants		
	Number Analyzed	63 participants
	Hispanic or Latino	9 14.3%
	Not Hispanic or Latino	54 85.7%
	Unknown or Not Reported	0 0.0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants		
	Number Analyzed	63 participants
	American Indian or Alaska Native	0 0.0%
	Asian	5 7.9%
	Native Hawaiian or Other Pacific Islander	0 0.0%
	Black or African American	18 28.6%
	White	40 63.5%
	More than one race	0 0%
	Unknown or Not Reported	0 0%
Region of Enrollment (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants		

United States	Number Analyzed	63 participants
		63 100.0%
AUDIT (US) Score [1] Mean (Standard Deviation) Unit of measure: units on a scale		
	Number Analyzed	63 participants
		15.4 (2.3)
		[1] Measure Description: The AUDIT (US) is a 10-item instrument that asks questions about alcohol consumption during the past year, symptoms of alcohol dependence, and alcohol-related problems or harm. Questions 1-3 have seven possible answers, scored from low risk (0) to high risk (6). Questions 4-10 have answer options that vary by question but range from low risk (0) to high risk (4). Scores are summed for a total ranging from 0 to 46, with higher scores indicating worse outcomes. Scores of 8-15 suggest drinking in excess of screening guidelines, and scores of 16-19 might indicate additional alcohol-related harm.
Proportion of Decision Points Followed by a Stress Event [1] [2] Mean (Standard Deviation) Unit of measure: proportion of decision points		
	Number Analyzed	50 participants
		0.56 (0.08)
		[1] Measure Description: Participants were asked to define a 13-hour period each day during which

		they would be awake and available for monitoring. Decision points occurred once every hour at the top of the hour. For each decision point for which a participant was available, the occurrence of a stress event in the subsequent hour was monitored to establish the proportion of decision points followed by a stress event. Proportions were determined for each participant, then averaged across participants. [2] Measure Analysis Population Description: Assessed for the outcome measure analysis population during the 7-day baseline period; participants were available during 3,668 of a total of 4,550 possible decision points (50 participants x 91 decision points per participant).
Number of Drinks within the Hour Following a Decision Point [1] [2] Mean (Standard Deviation) Unit of measure: drinks per decision point		
	Number Analyzed	50 participants
		0.24 (0.04)
		[1] Measure Description: The number of drinks within the following hour was measured for each decision point for which a participant was available. Participants documented their alcohol use for each baseline day, including an approximation of the time of day they consumed each drink. If participants had one or more drinks within the hour after a decision point, then those drinks were assigned to that decision point. The number of drinks per decision point was determined for each participant, then averaged across participants.

	[2] Measure Analysis Population Description: Assessed for the outcome measure analysis population during the 7-day baseline period; participants were available during 3,668 of a total of 4,550 possible decision points (50 participants x 91 decision points per participant).

Outcome Measures

1. Primary Outcome

Title	Proportion of Decision Points Followed by a Stress Event - Proximal (Short-Term) Outcome
Description	Participants were asked to define a 13-hour period each day during which they would be awake and available for monitoring and receiving messages. The same 13-hour period defined for each participant in the baseline period was used for the intervention period. Decision points occurred once every hour at the top of the hour. Participants were monitored for a stress event in the subsequent hour after each decision point. To determine the effect of messaging on stress, the proportion of decision points followed by a stress event in the subsequent hour for participants who received a stress-management message was compared to the proportion of decision points followed by a stress event in the subsequent hour for participants who received no message. Proportions were determined for each participant, then averaged across participants. There were up to 390 decision points (13 per day x 30 days) per participant for the intervention period.
Time Frame	For 1 hour after each decision point, over the 30-day intervention period

Outcome Measure Data

Analysis Population Description
All participants who completed the study and all decision points for which those participants were available to receive the intervention. Participants were available for the intervention during 15,586 of a total of 19,500 possible decision points (50 participants x 390 decision points per participant).

Arm/Group Title	No Message	Stress-Management Message
Arm/Group Description:	Participants were randomized by A-CHESS to receive no message during these decision points.	Participants were randomized by A-CHESS to receive a message during these decision points. If participants experienced a stress event in the 10 minutes prior to a decision point, they were encouraged to access coping strategies in the A-CHESS app and to consider attending a support group meeting. If they did not experience a stress event during this 10 minute period, they received a message of encouragement to remain stress-free.
Overall Number of Participants Analyzed	50	50
Overall Number of Units Analyzed Type of Units Analyzed: decision points	12530	3056
Mean (Standard Deviation) Unit of Measure: proportion of decision points	0.58 (0.07)	0.55 (0.09)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	We designed the study to have 80% power to detect a small effect size of relative risk (RR = 1.05) in the probability of experiencing stress in the hour after a decision point with 5% type I error

		control. In conducting a simulation-based sample size calculation, we assume that participants are available for 70% of the 390 (13 x 30) decision points. Our study sample of 50 participants exceeded the minimum sample size of 49.
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.017
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	-4.9
	Estimation Comments	Percentage change (calculated as 100% * [e^-0.05 - 1], where -0.05 is the fitted coefficient) in the probability of experiencing a stress event in the subsequent hour if a participant received a message, compared to no message

Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.155
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect

Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	-0.3
	Estimation Comments	Percentage change (calculated as 100% * [1 - e^0.003], where 0.003 is the fitted coefficient) in EMEE of messages for each additional day in the study

Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.054
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	6.1
	Estimation Comments	Percentage change (calculated as 100% * [e^-(-0.059) - 1], where -0.059 is the fitted coefficient) in EMEE of messages if the participant was prior-stressed (experienced a stress event in the 10 minutes prior to a decision point) vs. not

2. Secondary Outcome

Title	Number of Drinks Within the Hour Following a Decision Point - Proximal (Short-Term) Outcome
Description	Short-term alcohol consumption was defined as the number of drinks consumed within the hour following a decision point. This was recorded in the A-CHESS app daily via the

	daily abstinence pull intervention component. The A-CHESS app asked two questions to assess a participant's abstinence or level of alcohol consumption daily throughout the intervention: "How many drinks did you have today?" and "When did you have those drinks?" If participants had one or more drinks within the hour after a decision point, then those drinks were assigned to that decision point. To determine the effect of messaging on short term alcohol consumption, the number of drinks in the hour following decision points during which participants received a stress-management message was compared to the number of drinks in the hour following decision points during which participants received no message. The number of drinks per decision point was determined for each participant, then averaged across participants.
Time Frame	For 1 hour after each decision point, over the 30-day intervention period

Outcome Measure Data

Analysis Population Description
All participants who completed the study and all decision points for which those participants were available to receive the intervention. Participants were available for the intervention during 15,586 of a total of 19,500 possible decision points (50 participants x 390 decision points per participant).

Arm/Group Title	No Message	Stress-Management Message
Arm/Group Description:	Participants were randomized by A-CHESS to receive no message during these decision points.	Participants were randomized by A-CHESS to receive a message during these decision points. If participants experienced a stress event in the 10 minutes prior to a decision point, they were encouraged to access coping strategies in the A-CHESS app and to consider attending a support group meeting. If they did not experience a stress event during this 10 minute period, they received a message of

		encouragement to remain stress-free.
Overall Number of Participants Analyzed	50	50
Overall Number of Units Analyzed Type of Units Analyzed: decision points	12530	3056
Mean (Standard Deviation) Unit of Measure: drinks per decision point	0.22 (0.02)	0.21 (0.04)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.004
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	-6.0
	Estimation Comments	Percentage change (calculated as 100% * [e^-0.062 - 1], where -0.062 is the fitted coefficient) in the number of drinks consumed following a stress event if a participant received a message, compared to no message

Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.447
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	-0.2
	Estimation Comments	Percentage change (calculated as 100% * [1 - e^0.002], where 0.002 is the fitted coefficient) in EMEE of messages for each additional day in the study

Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.091
	Comments	[Not specified]
	Method	Other [EMEE]
	Comments	Estimator for marginal excursion effect
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	8.2

	Estimation Comments	Percentage change (calculated as 100% * [e^-(-0.079) - 1], where -0.079 is the fitted coefficient) in EMEE of messages if the participant was prior-stressed (experienced a stress event in the 10 minutes prior to a decision point), vs. not

Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	No Message, Stress-Management Message
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.242
	Comments	[Not specified]
	Method	Other [GEE]
	Comments	Generalized estimating equation
Method of Estimation	Estimation Parameter	Other [Percentage Change]
	Estimated Value	2.0
	Estimation Comments	Percentage change (calculated as 100% * [e^0.02 - 1], where 0.02 is the fitted coefficient) in number of drinks following a stress event if the participant experienced stress in the subsequent hour after a decision point

3. Other Pre-specified Outcome

Title	Number of Drinks Per Woman Throughout the Intervention Period – Distal (Long-Term) Outcome
Description	Long-term alcohol consumption was defined as the average number of drinks consumed per woman throughout the 30-day intervention period.
Time Frame	30-day intervention period

Outcome Measure Data Not Reported

Adverse Events

Time Frame	From time of enrollment through 2 days after participation ended (approximately 39 days)
Adverse Event Reporting Description	Adverse events were monitored in all enrolled participants.
Source Vocabulary Name for Table Default	[Not specified]
Collection Approach for Table Default	Systematic Assessment
Arm/Group Title	Alcohol-Dependent Moms
Arm/Group Description	The MAMA Intervention was delivered through the A-CHESS app, which was available to each participant on her study-provided mobile phone. The intervention included a single “push” component, which was responsive to a participant’s level of stress and sent messages (or no messages) to each participant via the A-CHESS app according to a decision rule. A-CHESS randomized delivery of the push component with a probability of 0.2 for receiving a message and a probability of 0.8 for receiving no message at each decision point when participants were available for the intervention. There were 13 possible decision points per day per participant, for a total of ≤ 91 decision points per participant in the 7-day baseline period and ≤ 390 decision points per participant in the 30-day intervention period. The intervention also included several “pull” components that were always available to participants through the A-CHESS app. Participants

	could choose to access or use these intervention components themselves, with the exception of the daily abstinence counter, which prompted participants daily to record the number of drinks they consumed that day and the time of day they were consumed.

All-Cause Mortality

	Alcohol-Dependent Moms
	Affected / at Risk (%)
Total	0/63 (0%)

Serious Adverse Events

	Alcohol-Dependent Moms
	Affected / at Risk (%)
Total	5/63 (7.94%)
Psychiatric disorders	
Hospitalization †[1]	1/63 (1.59%)
Major Depressive Disorder †	2/63 (3.17%)
Substance Use Disorder †	2/63 (3.17%)

† Indicates events were collected by systematic assessment

[1] Hospitalization for substance use disorder

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

	Alcohol-Dependent Moms
	Affected / at Risk (%)
Total	4/63 (6.35%)
Cardiac disorders	
Hypertension †	2/63 (3.17%)
Vascular disorders	
Leg Edema †	2/63 (3.17%)

† Indicates events were collected by systematic assessment

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

Name/Title:	PRS Training Lead
Organization:	PRS Results Training
Phone:	555-555-5555
Email:	register@clinicaltrials.gov

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055672
Other Study ID Numbers:	TTTMicroRandomizedR
First Submitted:	December 28, 2017
First Posted:	January 2, 2018
Results First Submitted:	August 1, 2019
Results First Posted:	August 31, 2019
Last Update Posted:	August 31, 2019