TRIO STUDIO: How Do We Increase Recruitment and Retention in Behavioral Chronotype: Impact on Sleep and Metabolism Study?

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TABLE OF CONTENTS

| Topic of Studio: Recruitment and Retention of Research Subjects | 3 |
| Attendees | 3 |
| Summary | 3 |
| Top 3 Actions Proposed by the Studio Participants | 3 |
| Top 3 Actions Proposed by the Quality Science Studio Participants | 4 |
| TRIO Studio Problem Description | 5 |
| Main problem for the studio participants to solve | 8 |

Studio Methodology ........................................................................................................................................ 8
Design Science Method .................................................................................................................................... 8
Quality Science Method .................................................................................................................................. 8
Design Thinking Based Solutions: ...................................................................................................................... 9
Problem visualized with Insights ..................................................................................................................... 9
High level insights: .......................................................................................................................................... 11
Solutions Generated by Design Science Approach Team: .................................................................................. 12
Quality Science Based Solutions: .................................................................................................................... 15
Problems Analyzed to Identify and Define Issues. ............................................................................................ 15
Solutions Generated by Quality Science Approach Team: ................................................................................ 17
Appendix 1 ....................................................................................................................................................... 20
Appendix 2 ....................................................................................................................................................... 20
Addendum 1 – 30 Day Follow up ..................................................................................................................... 28
Addendum 2 – 90 Day Follow up ..................................................................................................................... 30
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Summary
Stephanie Sintetas and Wajdey Nesheiwat, Research Coordinators at the University of Chicago, introduced the problem to the studio participants. Stephanie and Wajdey are looking to increase recruitment and retention of research subjects in their study.

Design Science Methodology and Quality Science Methodology were both used to solve the problem faced by Stephanie and Wajdey. Many suggestions, based on experiences within different departments were made.

Top 3 Actions Proposed by the Studio Participants to Stephanie and Wajdey:

1. Targeting senior centers around Chicago – Dedicating visits and advertisement placement in locations that retired adults or seniors frequent, such as libraries, The Cliff Dwellers, The Metropolitan Club, Chicago Architecture Center, Chicago Cultural Center, etc. Participants should be regarded as “citizen scientists” and made to feel that their participation is a contribution to the advancement of science of sleep.

2. Testimonials and Informative advertisement material on multiple platforms – Custom flyers targeted to different adult demographics can help bring a broader participant pool. Video message from the Principal Investigator and reading testimonials from previous study participants can also help engage those interested. Have social networking site advertisements embedded with an influencer will also be a good idea.

3. Give participants a personal report on sleep and food habits – For the participants that are not solely motivated by the monetary incentive, the educational portion of the study and learning something new about themselves can become a more desirable reason to participate. So enable a "sleep” report that can be given to participants along with a thank you note.
Top 3 Actions Proposed by the Quality Science Studio Participants to Stephanie and Wajdey:

1. **Broader Distribution of Advertisements** - Broaden the distribution of advertisements to employment facilities, ITM institutions, clinics, health clubs and fitness centers, community centers, church groups and coffee shops.

2. **Create Ambassadors** - Create ambassadors of prior participants to help recruit for the study. They can assist by making potential participants aware of the study and what it entails.

3. **Lower the Age** - Lower the age of potential participants to 25 - 75. The current age group of 35-75 may include individuals who are just starting a family or have young children which would make it difficult to participate. Lowering the age group may get a younger group of participants and someone who can sacrifice their time a little easier to participate.
TRIO Studio Problem Description:

Stephanie and Wajdey explained the goal of their study which is to investigate the misalignment of central and peripheral circadian rhythms and how they impact glucose metabolism and blood pressure regulation. The specific aims are:

- Cross-Sectional analysis of habitual circadian alignment and cardiometabolic (CM) function
- Testing the impact of extending the overnight fast and shifting an individual’s caloric intake within the daytime period, early distribution versus late distribution results in better CM and sleep outcomes.

Pre-Eligibility Criteria includes inclusion criteria:

- Healthy, overweight or obese individuals (BMI: 25-45)
- 35-75 years old
- Sleep 6.5 – 9 hours per night
- Eat at least 2 meals per day

Exclusion criteria:

- Sleep Disorders
- Psychiatric Disorders
- Weight loss program within 1 year
- Smokers
- Shift Workers
- Undergone bariatric surgery
- Serious health conditions/disorders
- Certain medications

The study involves a screening phase which includes the consent process, completing a home food log, a sleep study to make sure participants do not have sleep apnea and screening. If subjects qualify for the study they will complete a sleep and food log for seven to nine days at home and a six-day lab session which includes...
TRIO STUDIO: How Do We Increase Recruitment and Retention in Behavioral Chronotype: Impact on Sleep and Metabolism Study?

overnight stays in the sleep lab. Subjects will then participate in the intervention session which will involve seven overnight stays in the sleep lab and various blood draws.

An example of a study calendar is:

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Ambulatory Session: At home only
Baseline Session: Half at home, half in the laboratory
Intervention Session: Half at home, half in the laboratory
EOF: 48h in the laboratory only.

Current problems involve recruiting individuals that fit within the inclusion/exclusion criteria and who are willing to complete the full study. There is a loss of participants at each stage of scrutiny that is affecting overall numbers in terms of throughput.
Current recruitment efforts include Craigslist ad, Facebook, Research and Me, IRB approved flyers, and university/hospital monitors. Once a patient is consented, the research coordinators are in constant communication with the subjects to insure they understand the study, know what is involved, and understand what they need to do at each point.

Stephanie and Wajdey asked the studio audience to assist them in determining how they can recruit more eligible participants and once they are consented, how can they keep the subjects in the study.
Main problem for the studio participants to solve:
How can the study team recruit more eligible participants and once they are consented, how can they keep the participants in the study to completion?

Studio Methodology
Design Science approach as well as Quality Science approach were used as part of the studio to solve the problem.

Design Science Method
We used the Design Science approach with five steps:

1. Created a free form mind map of the problem and identification of issues – Mind Mapping technique
2. Actionable insights were identified
3. Generated ideas to address issues
4. Synthesized solutions from the smaller ideas – Creative integration of smaller ideas led by Design Thinking Expert facilitator was done using white boards.
5. Solutions were proposed and were rated by the team on implement-ability (0-4 scale)

Quality Science Method
The Six Sigma Quality Science approach was used which consisted of five steps:

1. Problem definition and mapping of actual structure of the process
2. Identify issues and analyze causality using Fishbone analysis
3. Generated ideas to address to issues – Brainstormed using SCAMPER method
4. Merged smaller ideas and scale ideas to create bigger solutions
5. Actionable insights and solutions were proposed and solutions were rated by the team on implement-ability (0-4 scale)
Design Thinking Based Solutions:
Problem visualized with Insights
The group first discussed the problem and its context yielding the following context diagram as well as the stakeholder map:

Figure 1 Mind Map of Issues with context
Figure 2 Stakeholder Map
High level insights:
Following the context discussions, insights were generated as follows:

**Problem Reframing**

01. Research is not a problem

02. No on the ground recruit efforts

03. Restricted income needs disincentive retirees (nothing more than 600 dollars)

04. 1500 Dollars is not much

05. How to make people engage in this research as contributors?

06. How to advertise in right ways? (Flyers)

07. No out reach efforts of PIs

08. How to find enough people to finish questionnaires?
Solutions Generated by Design Science Approach Team:
Nine relatively implementable solutions were created to solve the issues. The ideas were discussed to be of importance and deeper impact and hence made into these solutions.

The solutions are as follows:

1. **Targeting senior centers around Chicago** – Dedicating visits and advertisement placement in locations that retired adults or seniors frequent, such as libraries, The Cliff Dwellers, The Metropolitan Club, Chicago Architecture Center, Chicago Cultural Center, etc. Participants would be regarded as “citizen scientists” to feel their participation is a contribution to the advancement of science.

2. **Informative advertisement material** – Flyers targeted to different adult demographics can help bring a broader participant pool. Video message from the Principal Investigator and reading testimonials from previous study participants can help engage those interested. Have social networking site advertisements embedded with an influencer.
3. **Give participants a personal report on sleep and food habits** – For the participants that are not solely motivated by the monetary incentive, the educational portion of the study and learning about themselves can become a more desirable reason to participate.

4. **Change incentive to make IRS compliant** - Participants may be hesitant to become involved due to IRS income restrictions. Change incentives to accommodate their needs, whether through gift cards, split payments or goods.

5. **Re-evaluate inclusion/exclusion criteria and see if there is room for tweaks, or adjusting disqualification, which is high** – Currently the study team would have to reach out to 1,800 individuals to find 24 participants to complete the study. Adjusting the criteria to capture the relatively healthier individuals could help study recruitment success. This would need to be reviewed by the PI and team.

6. **Analyze previous success with onerous studies** - Conduct a literature review on other onerous studies and find solutions that may be replicated and tailored to this specific study.

7. **Ideal study for TRIO to happen before their protocol development** – Having a TRIO studio prior to protocol development including PIs, coordinators and potential participants to design best method of recruitment and defining attainable goals.

8. **Capturing the existing workforce population through annual wellness program** - Advertise study at annual wellness programs at U of C to capture employee population.

9. **Make weekend option available** – Making weekends an option for the two 24-hour inpatient stays required in this study can help the 35-50-year-old range of the targeted population participate. Most participants within this range are employed and/or have kids.
Solutions Design Approach

01 Targeting senior centers, libraries around Chicago, making senior citizen scientist. Dedicated visits to social clubs.

02 Informative advertisement material (flyers)

03 Give people a personal report on sleep and food habits

04 Change incentive to make compliant

05 Reevaluate inclusion/exclusion criteria and see if there is room for tweaks, or adjusting qualification which is high

06 Analyze success with onerous studies, find solutions to replicate

07 Ideal study for TRIO to happen before protocol development

08 Capturing the existing workforce population through annual wellness program

09 Make weekends option available
Quality Science Based Solutions:

Problems Analyzed to Identify and Define Issues.
Stephanie and Wajdey’s problem was analyzed and classified into the following table sections.

![Figure 5 Problem Definition](image-url)
TRIO STUDIO: How Do We Increase Recruitment and Retention in Behavioral Chronotype: Impact on Sleep and Metabolism Study?

Understanding the Process

Figure 6 Understanding the Process

Fish Bone Analysis

Figure 7 Fishbone Analysis to Figure Out Causality of Problems
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Image: Quality Science team generating solutions.

Solutions Generated by Quality Science Team:

Seven solutions were created to solve the issue of recruitment and retention of research participants in the study. They are as follows in the list below and the diagram digitized from whiteboard:

1. **Broader Distribution of Advertisements** - Broaden the distribution of advertisements to employment facilities, ITM institutions, clinics, health clubs and fitness centers, community centers, church groups and coffee shops.

2. **Create Ambassadors** - Create ambassadors of prior participants to help recruit for the study. They can assist by making potential participants aware of the study and what it entails.

3. **Lower the Age** - Lower the age of potential participants to 25 - 75. The current age group of 35-75 may include individuals who are just starting a family or have young children which would make it difficult to participate. Lowering the age group may get a younger group of participants and someone who can sacrifice their time a little easier to participate.

4. **Create a Newsletter** - Create and distribute a newsletter to distribute to physicians and past participants to let them know about the study, any preliminary results and the recruitment efforts.
5. **Change the 24-hour Sessions to Weekends** – Changing the 24-hour sessions to weekends will allow for participants who work full-time positions and their schedule doesn’t permit them to participate during the week.

6. **Trinkets for Participants** – Create some type of trinkets for participants such as certificates, stickers or provide consultations to educate participants on healthy habits.

Solutions: Quality Science Approach

01 Distribute Advertisements
   - Employ Facilities
   - ITM Institutions
   - Clinics
   - Health Clubs/Fitness Centers
   - Community Centers
   - Coffee Shops

02 Ambassadors
   - Prior Participants

03 Newsletter
   - Distribute to physical Participants

04 Trinkets for Participants
   - Post
   - Sticker
   - Consultation of healthy habits

05 New Normal Launch

06 Lower Age to 25-75

07 Change 24hr Sessions to weekend

Figure 8 Quality Science Team Recommended Solutions

<End of Document. Thank you.>
Appendix 1.
Slides used by Stephanie Sintetas and Wajdey Nesheiwat.

Appendix 2.
Actual pictures of white board from the studio session.

Design Science
Stakeholder Map.

- Investigators
- UChicago
- Northwestern University
- Clinical research center
- Research nurse
- PIs coordinator
- Clinical staff
- Recruiter
- Participants
- Family (kids)
- People not meet criteria
- Senior center
- Place gym
- Work
- Social media
- Hospital
- People drop off
- EPIC
Reframe Problems.

1. Reach is not a problem (huge drop outs)
2. No on the ground recruit efforts
3. Restricted income needs disincentivize attractions [Nothing more]
4. $1500 is not much
5. How to make people engage in this research as contributors?
6. How to advertise in right ways? (flyers)
7. No out reach efforts from PIs
   How to
8. Find enough people to finish questionnaires
   (Make it an interesting study)
Solutions

7. Lead Study for TRIO to happen before this Studio.
   - Coordinator, P.I.s, Possible People

6. Analyze how success with numerous studies
   - Find Solution to Replicate Libraries, Chicago Architecture

5. Targeting Senior Centers around Chicago
   - Making seniors citizen scientists

4. Make weekend option available (Lower ranking)

3. Give people a personal report on sleep and food habits.

2. Informative Advertisement Material (Flyers)
   - Embedded all inclusive

1. Dedicated visits to social clubs (Coffee, Social, Metropolitan clubs)

2. Capturing the existing workforce population through annual wellness program.

5. Reevaluate inclusion/exclusion criteria and see if there is room for tweaking, or adjusting disqualification (reaching out to 1800 to have 24 completed)
TRIO STUDIO: How Do We Increase Recruitment and Retention in Behavioral Chronotype: Impact on Sleep and Metabolism Study?

Quality Science

**DEFINE THE PROBLEM**
- Recruiting individuals that fit within the inclusion criteria.
- Individuals willing to complete the full study.

**WHO IS EXPERIENCING THE PROBLEM?**
- Study team
- Patients (35-75)
- Funding agency
- Employees
- Clinical research.

**GOAL STATE**
- Recruit 30 subjects
- Retain subjects in study.

**WHAT IS THE SCALE OF THE PROBLEM?**
- Recruiting 5 yrs. broad
- Between 3-6 subjects complete.
- 2 sessions (act. iv. n)
- Flexibility
- Operational restrictions
- 24 x 7

**WHY DOES THE PROBLEM EXIST?**
- Lack of understanding about the study.
- Patients and medical centers of participation.

**CAUSAL ANALYSIS**
- Factors affecting recruitment.
- Factors affecting retention.
SOLUTIONS:

- Reach of flyers
  - New locations such as community centers
  - Partnerships
    - Clinics
    - Research centers

- Smokers and coffee drinkers
  - Explained in the R&D

- Feedback/Communication
  - Newsletter 1
    - Certificate of completion/sticker
    - Results of the study
  - Newsletters explained
    - Contained at home under sleep conditions
    - Let participants know earlier about following steps

- Extra recruiter

- Health advisor (session?)
  - Pre
  - Post

- Partnerships benefits for participants
Solutions

1. **Broader**
   - Distribute Advertisements
     - Employ Facilities
     - ITM Institutions
     - Clinics
     - Health Clubs/Fitness Gyms
     - Community Centers
     - Veteran Groups
     - Coffee Shops
   - Ambassadors
     - For participants
     - Trinkets for part.
     - Pen.
     - Sticker
     - T-shirts Re: breaking habits
   - New Normal Launch

2. **Newsletter**
   - Distribute to potential participants

3. **Lower Age to 25-75**

   - Change Att-lc Session to Weekend
Addendum 1 – 30 Day Follow up
Top 3 Actions proposed by Design Science team:

1. **Targeting senior centers around Chicago** – Dedicating visits and advertisement placement in locations that retired adults or seniors frequent, such as libraries, The Cliff Dwellers, The Metropolitan Club, Chicago Architecture Center, Chicago Cultural Center, etc. Participants would be regarded as “citizen scientists” to feel their participation is a contribution to the advancement of science.

   **Implementation and results:**

   At the 30 day follow up, Stephanie and Wajdey posted flyers at the YMCA, at coffee shops and gyms. They feel like these efforts have increased interested responses to the research study. Stephanie stated she changed her view of research participants and is referring to them as “citizen scientist”.

2. **Informative advertisement material** – Flyers targeted to different adult demographics can help bring a broader participant pool. Video message from the Principal Investigator and reading testimonials from previous study participants can help engage those interested. Have social networking site advertisements embedded with an influencer.

   **Implementation and results:**

   At the 30 day follow up, Stephanie and Wajdey are looking to TRIO for help with re-designing their study flyer. They will work with TRIO to create a targeted flyer for specific demographics.

3. **Give participants a personal report on sleep and food habits** – For the participants that are not solely motivated by the monetary incentive, the educational portion of the study and learning about themselves can become a more desirable reason to participate.

   **Implementation and results:**

   Stephanie and Wajdey reached out to Jennifer, CRC Dietitian, who will work with participants, if they’re interested, and get them a personalized evaluation of their eating habits and make suggestions on how to improve them. This will be IRB approved prior to utilizing.
Top 3 Actions proposed by Quality Science team:

1. **Broader Distribution of Advertisements** - Broaden the distribution of advertisements to employment facilities, ITM institutions, clinics, health clubs and fitness centers, community centers, church groups and coffee shops.

   **Implementation and results:**

   At the 30 day follow up, Stephanie and Wajdey posted flyers at the YMCA, at coffee shops and gyms. TRIO has also distributed the flyers to all the ITM institutions.

2. **Create Ambassadors** - Create ambassadors of prior participants to help recruit for the study. They can assist by making potential participants aware of the study and what it entails.

   **Implementation and results:**

   Stephanie and Wajdey are speaking with their participants to reach out to any family or friends who may be interested. They hope that word of mouth, from previous participants, will spark the interest of other people enrolling in the study.

3. **Lower the Age** - Lower the age of potential participants to 25 - 75. The current age group of 35-75 may include individuals who are just starting a family or have young children which would make it difficult to participate. Lowering the age group may get a younger group of participants and someone who can sacrifice their time a little easier to participate.

   **Implementation and results:**

   The study cannot be amended to lower the age of participants as it’s a federal funded aging study.

**Misc.**

Before TRIO Studio, the research team had approximately 33 participants consented and 4 had completed the study. They are seeing increased responses of participants saying they found out about the study through posted flyers. They currently have 5 subjects that have completed the study. CRC previously approved them to have one subject on study a week. They reached out to CRC to see if they can have two subjects a week on the study. CRC has approved this change, and they currently have one or two subjects scheduled for the next several weeks.
Addendum 2 – 90 Day Follow up
Actions proposed by Design Science Team:

1. **Targeting senior centers around Chicago** – Dedicating visits and advertisement placement in locations that retired adults or seniors frequent, such as libraries, The Cliff Dwellers, The Metropolitan Club, Chicago Architecture Center, Chicago Cultural Center, etc. Participants would be regarded as “citizen scientists” to feel their participation is a contribution to the advancement of science.

Implementation and results:

At the 90 Day follow up, Stephanie and Wajdey revised their Craigslist ad to express a more inclusive approach to research for potential participants. Instead of using “volunteers needed”, the team used words akin to “please help us find out why . . .”. They are continuing to post flyers at the YMCA and coffee shops.

2. **Informative advertisement material** – Flyers targeted to different adult demographics can help bring a broader participant pool. Video message from the Principal Investigator and reading testimonials from previous study participants can help engage those interested. Have social networking site advertisements embedded with an influencer.

Implementation and results:

Stephanie and Wajdey are awaiting IRB approval for their new flyers. They created flyers with QR codes (includes instructions on how to use), different language (such as the use of BMI and overweight on separate flyers), and changed the images used, to attract mid-to-older adults.

3. **Give participants a personal report on sleep and food habits** – For the participants that are not solely motivated by the monetary incentive, the educational portion of the study and learning about themselves can become a more desirable reason to participate.

Implementation and results:

At the 90 day follow up the CRC Dietitian, works with patients who are interested in receiving tips on how to improve eating habits to obtain a more complete diet. IRB approval is not needed for this since the CRC dietitian is already working with patients regarding food logs.
4. **Change incentive to make IRS compliant** - Participants may be hesitant to become involved due to IRS income restrictions. Change incentives to accommodate their needs, whether through gift cards, split payments or goods.

**Implementation and results:**

The study team reports that participants are not required to report compensation received from this study to the IRS. They must fill out a W-9 Tax form, however, the participants decide if they want to report it. The study confirmed this with the IRB and the IRS.

5. **Re-evaluate inclusion/exclusion criteria and see if there is room for tweaks, or adjusting disqualification, which is high** – Currently the study team would have to reach out to 1,800 individuals to find 24 participants to complete the study. Adjusting the criteria to capture the relatively healthier individuals could help study recruitment success. This would need to be reviewed by the PI and team.

**Implementation and results:**

The study cannot be amended to lower the age of participants as it’s a federally funded aging study. However, Northwestern is doing a similar study and has increased their apnea-hypopnea index (AHI) from 15 to 30. The team at UChicago may also amend their protocol. Stephanie and Wajdey report that while this may help eligibility, those interested have multiple issues/comorbidities that make them ineligible.

6. **Analyze previous success with onerous studies** - Conduct a literature review on other onerous studies and find solutions that may be replicated and tailored to this specific study.

**Implementation and results:**

At the 90 day follow up, Stephanie and Wajdey have talked to others study coordinators. While helpful, those coordinators have similar techniques on promoting their projects.

7. **Ideal study for TRIO to happen before their protocol development** – Having a TRIO studio prior to protocol development including PIs, coordinators and potential participants to design best method of recruitment and defining attainable goals.
Implementation and results:

Stephanie and Wajdey’s project is funded through the National Institute on Aging and is structured based on their guidelines. They require overweight but healthy individuals. They have a goal of enrolling 80 participants to complete the entire study session. They currently have 10.

8. Capturing the existing workforce population through annual wellness program - Advertise study at annual wellness programs at U of C to capture employee population.

Implementation and results:

Stephanie and Wajdey will post flyers during the annual wellness program at UChicago. This program usually lasts for 10 weeks and promotes exercising daily for UChicago employees. The team will also post flyers inside of UChicago’s Student Health Center.

9. Make weekend option available – Making weekends an option for the two 24-hour inpatient stays required in this study can help the 35-50-year-old range of the targeted population participate. Most participants within this range are employed and/or have kids.

Implementation and results:

The Clinical Research Center is only open Monday through Friday. Participants can come to the sleep lab over the weekend but would have to start their sleep session on a Sunday in order to have the nurses in the CRC obtain their blood samples.
Solutions Generated by Quality Science Team:

1. **Broader Distribution of Advertisements** - Broaden the distribution of advertisements to employment facilities, ITM institutions, clinics, health clubs and fitness centers, community centers, church groups and coffee shops.

   **Implementation and results:**
   At the 90 Day follow up, Stephanie and Wajdey are continuing to post flyers around the YMCA and coffee shops, especially in Hyde Park. They also started posting flyers at parking lots and by elevators.

2. **Create Ambassadors** - Create ambassadors of prior participants to help recruit for the study. They can assist by making potential participants aware of the study and what it entails.

   **Implementation and results:**
   Stephanie and Wajdey continue to encourage participants to reach out to their contacts about the study. They have seen a slight increase in applications that are referred by others but none have been eligible at this point.

3. **Lower the Age** - Lower the age of potential participants to 25 - 75. The current age group of 35-75 may include individuals who are just starting a family or have young children which would make it difficult to participate. Lowering the age group may get a younger group of participants and someone who can sacrifice their time a little easier to participate.

   **Implementation and results:**
   The study cannot be amended to lower the age of participants as it is a federally funded aging study.

4. **Create a Newsletter** - Create and distribute a newsletter to distribute to physicians and past participants to let them know about the study, any preliminary results and the recruitment efforts.

   **Implementation and results:**
   The study team has not created a newsletter to promote their study but Northwestern (a partner institution for a similar study) is discussing potential advertisement in the RedEye and Chicago Tribune. They hope to create an advertisement for this study, if budget permits.
5. **Change the 24-hour Sessions to Weekends** – Changing the 24-hour sessions to weekends will allow for participants who work full-time positions and their schedule doesn’t permit them to participate during the week.

**Implementation and results:**

The Clinical Research Center is only open Monday through Friday. The Sleep lab has weekend coverage, enabling participants to start their 24-hour session on Sundays but would need the Clinical Research Center to help with blood draws. Additionally, the Clinical Research Center prefers blood draws to be in the middle of the week.

6. **Trinkets for Participants** – Create some type of trinkets for participants such as certificates, stickers or provide consultations to educate participants on healthy habits.

**Implementation and results:**

Stephanie and Wajdey have constant communication with study participants via follow up calls, asking for feedback throughout different steps of the study. They are now giving study participants a booklet of when to expect follow up calls.


**Implementation and results:**

The study team has entered the study in the portal and are anxiously awaiting the New Normal launch.

**Misc.** Before TRIO Studio, the research team had approximately 33 participants consented and 4 had completed the study. At the 90 day follow up, they consented 41 participants; 31 screen failed and 10 completed the study.
About the Institute for Translational Medicine (ITM)

The ITM is a partnership between the University of Chicago and Rush in collaboration with Advocate Health Care, the Illinois Institute of Technology (Illinois Tech), Loyola University Chicago, and NorthShore University HealthSystem that’s fueled by about $35 million in grants from the National Center for Advancing Translational Sciences at the National Institutes of Health through its Clinical and Translational Science Awards (CTSA) Program.

We’re part of a network of more than 55 CTSA Program-supported hubs across the country working to slash the time it takes to develop and share new treatments and health approaches. We work with you and for you to make participating in health research easy, so that together we improve health care for all.

Join the movement and learn more about how we help researchers, physicians, community members, industry, government organizations, and others. Visit us at chicagoitm.org and connect with us on Facebook, Twitter, Instagram, YouTube, and LinkedIn @ChicagoITM.

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