TRIO STUDIO: How to Improve Recruitment Strategies for a Dual-Site Sleep and Circadian Rhythms Study of Adolescents Aged 14 to 17 Years

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Research Assistants: Renjie Li, IIT Institute of Design and Yun Yang, IIT Institute of Design

Attendees:
Sara Polonsky, NorthShore University HealthSystem; Julian Solway, MD, UChicago; Charlene Gamboa, RUMC; Ashley McHugh, Advocate Healthcare; Denise Voskuil- Marre, RUMC; Adrian Melendez, RUMC; Les Cooke, ITM; Raj Shah, MD, RUMC; Ashley Lopez, ITM; Kris Janevski, RUMC; Sabrina Velez, RUMC; and Amanda Kass, ITM.

Summary:
Logan G. Killen, working under the Principal Investigator Stephanie Crowley, PhD, introduced the Studio Topic, How to Improve Recruitment Strategies for a Dual-Site Sleep and Circadian Rhythms Study of Adolescents Aged 14 to 17 Years. The research team is looking for guidance from a TRIO Studio on how to gain more subjects for their study.

Design Thinking Methodology & Quality Science Methodology were used to solve the problem faced by the study team. Many suggestions based, on experiences with different departments, were made.
Top 3 Actions Proposed by the Design Science Studio Participants to Logan:

1. **Collaborate and Form Strong Relationships with Newly Identified Stakeholders** - Establishing relationships with nearby high schools and their nurses, like Whitney Young Magnet High School. Hosting an open house for teens at their lab to spark interest in their research. Collaborating with existing sleep centers at Rush and other Chicagoland clinics and targeting not only teen patients but also their teen sibling is another population to pursue.

2. **Participant Testimonial & Educational Component in REDCap Survey** - Having previous participants give testimonials on their experience with the study can help engage other potential participants. Providing an educational component as to what delayed sleep-wake phase disorder is can help potential participants understand if they perceive their sleeping habits as a problem or not. In REDCap, inviting teens filling out the survey to refer a friend for a chance to win a $25 Amazon gift card.

3. **Change the Goal of the Study** - Revisiting the inclusion/exclusion criteria with Mayo and Rush’s PIs. Talking about the reasoning behind using the diagnostic criteria and see if that or any other part of the screening process can be changed. This would also have to be a conversation with the sponsor.

Top 3 Actions Proposed by the Quality Science Studio Participants to Logan:

1. **Modify the Structure of the Study** - Expand inclusion & exclusion criteria and change the questions presented to potential subjects (e.g. change “Are your sleep problems problematic” to “Do your sleep patterns affect other areas of your life negatively?”)

2. **Update RedCap** - Ask exclusionary questions earlier in the recruitment process (e.g. sex, age, diagnoses, sleep problems). If they still meet the criteria after initial questioning, move on to further questioning and eliminate those who do not meet the initial criteria.

3. **Outreach** - Contact other departments at RUMC for recruitment, such as Pediatrics and Family Medicine.

   Increase social media advertising to sites that potential subjects would view late at night (e.g. Twitter, Reddit, Google Ads, Facebook hashtags).

   Register the study in the New Normal portal and share the flyers with ITM to distribute.
TRIO Studio Problem Description:

Research Assistant Logan G. Killen of Rush University Medical Center (RUMC) presented a current research study, “Teen Night Owl”, where they are experiencing recruitment challenges. They are attempting to recruit subjects between the ages of 14 and 17, with a diagnosis of Delayed Sleep - Wake Phase Disorder (DSWPD). This disorder is characterized by the subject having trouble falling asleep until very late (usually midnight or later), has trouble waking up early in the morning (e.g., on school days), falls asleep easily when bedtime is as late as they want (e.g. weekends, vacations, summer break), school-night sleep onset after midnight 50% or more of the time (from 2-week self-report), and is not currently receiving treatment for sleep (e.g., melatonin). DSWPD has a prevalence of approximately 8% in adolescents.

Potential participants are asked to complete an initial survey, on REDCap, to determine eligibility. If they are eligible, upon completion of the survey, they are asked to complete a sleep log for two weeks and then come in to the lab at Rush to fill out more questionnaires/surveys. The questionnaires/surveys are then sent to the Mayo Clinic PI for a DSWPD diagnosis. If the Mayo Clinic PI gives the subject a diagnosis of DSWP, the subjects then spend two weekends (less than 24-hours each day) in the sleep lab at Rush.

Current recruitment efforts include: distributing flyers at local schools, parks, YMCA’s, & libraries, Facebook, Instagram, and Craigslist advertisements, emailing high school teachers, & posting in the Rush Newsletter.

The Teen Night Owl Study has an extensive application and data collection process, which contributes to their need for improved recruitment strategies. Similarly, many of the potential subjects do not meet the exclusion criteria to participate in the study due to having no diagnosis of DSWPD.

In the first half of a three year grant, they had 500 potential participants fill out the interest form on-line, 150 did the REDCap surveys and only seven subjects were enrolled. Rush’s three year goal is twenty-four subjects enrolled in the study.
Main problem for the studio participants to solve:
What other recruiting strategies can our team use to target this population of late-sleeping teens?

Studio Methodology
Design Science Methodology and Quality Science Methodology were used as part of the TRIO studio to solve the problems.

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)
Design Thinking Based Solutions:

Problem visualized with Insights

The group first discussed the problem and its context yielding the following context diagram:

**Figure 1 Mind Map of Issues**

**Figure 2 Stakeholder Map**
High level insights:
Following the context discussions, insights were generated as follows:

**Barriers**

- 500 applications but only enrolled 7 participants
- 24 need to be enrolled in 3 years
* Must meet all eligibility criteria
* Teenagers may not recognize it’s a problem
* Need to find a way to quantify to show it’s a problem

*Figure 3 Barriers discussed*

*Image 2 Design Science team generating solutions (Left to right: Julian Soloway, MD, Charlene Gamboa, Adrian Melendez, & Kris Janevski)*
Solutions Generated by Design Science Approach Team:

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

1. Collaborate and Form Strong Relationships with Newly Identified Stakeholders - Establishing relationships with nearby high schools and their nurses, like Whitney Young Magnet High School. Hosting an open house for teens at their lab to spark interest in their research. Collaborating with existing sleep centers at Rush and other Chicagoland clinics and targeting not only teen patients but also their teen sibling is another population to pursue.

2. Participant Testimonial and Educational Component in REDCap Survey - Having previous participants give testimonials on their experience with the study can help engage other potential participants. Providing an educational component as to what delayed sleep-wake phase disorder is can help potential participants understand if they perceive their sleeping habits as a problem or not. In REDCap, inviting teens filling out the survey to refer a friend for the chance to win a $25 Amazon Gift Card.

3. Changing the Goal of the Study - Revisiting the inclusion/exclusion criteria with Mayo and Rush’s PIs. Talking about the reasoning behind using the diagnostic criteria and see if that or any other part of the screening proves can be changed. This would also have to be a conversation with the sponsor.

4. Use Fitbit Data for Screener – Having participants use their Fitbit data on sleeping habits will create a better idea of eligibility. Many of those screened are ineligible due to differences in self-reported sleep log and what the activity monitor shows.
Collaborate and form strong relationships with newly identified stakeholders – Establishing relationships with nearby high schools and their nurses, like Whitney Young Magnet High School. Hosting an open house for teens at their lab to spark interest in their research. Collaborating with existing sleep centers at Rush and other Chicagoland clinics and targeting not only teen patients but also their teen sibling is another population to pursue.

Participant testimonial and educational component in REDCap survey – Having previous participants give testimonials on their experience with the study can help engage other potential participants. Providing an educational component as to what delayed sleep-wake phase disorder is can help potential participants understand if they perceive their sleeping habits as a problem or not. In REDCap, inviting teens filling out the survey to refer a friend for a chance to win a $25 Amazon gift card.

Changing the goal of the study – Revisiting the inclusion/exclusion criteria with Mayo and Rush’s PIs. Talking about the reasoning behind using the diagnostic criteria and see if that or any other part of the screening process can be changed. This would also have to be a conversation with the sponsor.

Use Fitbit data for screener – Having participants use their Fitbit data on sleeping habits will create a better idea of eligibility. Many of those screened are ineligible due to differences in self-reported sleep log and what the activity monitor shows.

Figure 4 Design Science solutions discussed.
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)
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Quality Science Based Solutions:

Problems Analyzed to Identify and Define Issues.

Logan’s problem was analyzed and classified into the following table sections.

**Figure 5 Problem Definition**

**Figure 6 Understanding the process**
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Figure 7 Fish Bone Analysis

Image 3  Quality Science team generating solutions (Left to right: Logan Killen, Ashley McHugh, & Les Cooke)
Solutions Generated by Quality Science Approach Team:

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

1. **Modify the Study Structure of the Study** - Expand inclusion criteria to fit more subjects. Reframe the questions (e.g. change the questions from “Are your sleeping habits a problem?” to “Do you have trouble sleeping?” or “Does your sleep pattern interfere with school?”)

2. **Update REDCap** - Change initial questions to exclude ineligible candidates sooner so that resources are not wasted (i.e. based on age, medical history, problems sleeping, etc.) Once participants qualify with the initial questionnaire, a second one can be sent.

3. **Outreach** - Network with other departments at RUMC for recruitment (e.g. Pediatrics, Family Medicine) Utilize other social media advertising (e.g. Twitter, Reddit, Good Advertisements, Facebook hashtags). Register the study in the portal for The New Normal Campaign. Distribute flyers at Grand Rounds.


5. **Prior Participant Outreach** - Ask participants what they liked about the study and ask them to spread the word, of the study, to their friends.

6. **Clinician at Rush** – Add a clinician at Rush on to the study to provide the diagnosis of potential participants with DSWPD.
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<table>
<thead>
<tr>
<th>Figure 8. Quality Science Team Recommended Solutions</th>
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<table>
<thead>
<tr>
<th>Step</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Modify the Study Structure of the Study - Expand inclusion criteria to fit more subjects. Reframe the questions (e.g. change the questions from “Are your sleeping habits a problem?” to “Do you have trouble sleeping?” or “Does your sleep pattern interfere with school?”)</td>
</tr>
<tr>
<td>02</td>
<td>Update REDCap - Change initial questions to exclude ineligible candidates sooner so that resources are not wasted (i.e. based on age, medical history, problems sleeping, etc.) Once participants qualify with the initial questionnaire, a second one can be sent.</td>
</tr>
<tr>
<td>03</td>
<td>Outreach - Network with other departments at RUMC for recruitment (e.g. Pediatrics, Family Medicine) Utilize other social media advertising (e.g. Twitter, Reddit, Good Advertisements, Facebook hashtags). Register the study in the portal for The New Normal Campaign. Distribute flyers at Grand Rounds.</td>
</tr>
<tr>
<td>04</td>
<td>More Rush Branding - Put Rush Logo on advertisements.</td>
</tr>
<tr>
<td>05</td>
<td>Prior Participant Outreach - Ask participants what they liked about the study and ask them to spread the word, of the study, to their friends.</td>
</tr>
<tr>
<td>06</td>
<td>Clinician at Rush – Add a clinician at Rush on to the study to provide the diagnosis of potential participants with DSWPD.</td>
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<End of Document. Thank you.>
Appendix 1.
Slides used

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

- Econmics diagnosis
- Flyers 150
- FB, Ins
- Email to physicians
- Flyers Rush
- eval/Ref

Other comments:
- Study duration (4-6 months)
- Recruitment does not always work
- We need more "friends" at the sites
- Not a lot of adolescent treatment at KU
- Study duration 4-6 months Summer
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NEXT Plan:
- Use PB eligibility → look to apply
- Email teacher 1 by 1, → formal faxes are more likely to apply
- Students families

Solutions:

1. Collaborate with existing sleep center @ RUSH
   - teen→ teenager
   - And target parents and their schools
2. Working with school nurses
   - School based clinic
3. Reach out to new
   - Stakeholders + create collabs
4. Changing the goal for the study
   - GI filled the company
   - Mayo PI + RUSH PI revisit inclusion/exclusion
   - Is something to changed or
   - Participant disheartened in initiation survey
   - Educational component
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4. USE fitbit data for Screener
   • Refer a friend → enter to win $25 amazon in RC survey
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Quality Science

Define the problem

CURRENT STATE

Net missing enrollment goals in first half of 3-year grant.
3-year goal: n=200 at end size
CURRENT n=7

- Who is experiencing the problem?
- PIs
- Research team
- Funding agency
- Sister site - Mayo

- What is the scale of the problem?
- Under
- 500
- 20
- 7
- P0
- P1
- P2
GOAL STATE
n = 28 at each site (by your goal)
Insell adolescents (14-17 year) with first diagnosis
Criteria for Delayed Sleep-Wake Phase Disorder
(DSWPD) into a 3-week behavioral
intervention.

- What is the scale of the problem?
- Why does this problem exist?

- Under-recruiting: Should be n = 12
- 500 applicants
- 20 seen in lab
- 7 on study
- Problem 3m or longer
- Self reported forms (files with lab)
- Sent to Mayo for CV
- 1 wk Sleep Journal
Understanding the process

1. Apply online
   - (Red Cap)
2. Contact the parents
3. Contact the applicants
   - Electronic consent online (in every participant)
4. Sleep log
5. Lab visit
6. Consent form written
   - Lab day
7. Criteria forms completed
   - Sent to Mayo for DX
8. 2 weekend stays
   - (Sat-Sun) lab less than attr.
9. Writeup
10. (20 min)
Why-Why Analysis

- Questionnaires
- Structure of study
- No 1 month, 2 questionnaires
- Can't change questionnaires
- No budget
- No participants
- Need to flush
- Need to recruit a panel

SleepClockLab.org
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[Diagram of analysis process]

- Analysis
- Structure of Study
- Data Collection
- Data Analysis
- Results

SleepClockLab.org
Solutions:

1. Update ReadCap
   - Initial Questions
     - Age
     - Dr.
     - Problems Sleeping
   if quality of initial quest.
   Send forth or questions

2. Study Structure
   - Expand Inclusion Criteria
   - Change Questions
   - Trouble Sleeping

3. Prior Participate Outreach
   Spread the word

4. Outreach
   - Other Dept. @ Rush for Recruitment
     - Fax
     - Family Med.
   - M.D. @ Rush to Rx.
Outreach
- Other Social Media Advertising
  - twitter
  - Reddit
  - Google Ads
  - Facebook hashtags

Outreach
- New Normal | ITM
  - Register Study in
  - Flyer Distribution

More Outreach
- Rush Branding
  - Rush keeps on
Addendum 1 – 30 Day Follow Up
Top 3 Solutions Generated by Design Science Team:

1. **Collaborate and Form Strong Relationships with Newly Identified Stakeholders** - Establishing relationships with nearby high schools and their nurses, like Whitney Young Magnet High School. Hosting an open house for teens at their lab to spark interest in their research. Collaborating with existing sleep centers at Rush and other Chicagoland clinics and targeting not only teen patients but also their teen sibling is another population to pursue.

   **Implementation and results:**

   Since the TRIO Studio, Logan and his team are talking to departments at Rush to see if they can collaborate. They are doing a full marketing campaign with the marketing department at Rush to help with website updates, flyers, photos and testimonials.

2. **Participant Testimonial and Educational Component in REDCap Survey** - Having previous participants give testimonials on their experience with the study can help engage other potential participants. Providing an educational component as to what delayed sleep-wake phase disorder is can help potential participants understand if they perceive their sleeping habits as a problem or not. In REDCap, inviting teens filling out the survey to refer a friend for the chance to win a $25 Amazon Gift Card.

   **Implementation and results:**

   Logan and his team are currently looking at the IRB for direction on testimonials.

3. **Changing the Goal of the Study** - Revisiting the inclusion/exclusion criteria with Mayo and Rush’s PIs. Talking about the reasoning behind using the diagnostic criteria and see if that or any other part of the screening proves can be changed. This would also have to be a conversation with the sponsor.

   **Implementation and results:**

   The team is unable to change the goals of the study as it is a grant funded study.
Top 3 Solutions by Quality Science Team:

1. **Modify the Study Structure** - Expand inclusion criteria to fit more subjects. Reframe the questions (e.g. change the questions from “Are your sleeping habits a problem?” to “Do you have trouble sleeping?” or “Does your sleep pattern interfere with school?”)

   **Implementation and results:**
   
The team is unable to modify the study structure as this is a grant funded study.

2. **Update REDCap** - Change initial questions to exclude ineligible candidates sooner so that resources are not wasted (i.e. based on age, medical history, problems sleeping, etc.) Once participants qualify with the initial questionnaire, a second one can be sent.

   **Implementation and results:**
   
   Since the TRIO Studio, Logan and his team have updated RedCap which included a pre-screener. Once it is IRB approved, they will implement.

3. **Outreach** - Network with other departments at RUMC for recruitment (e.g. Pediatrics, Family Medicine) Utilize other social media advertising (e.g. Twitter, Reddit, Good Advertisements, Facebook hashtags). Register the study in the portal for The New Normal Campaign. Distribute flyers at Grand Rounds.

   **Implementation and results:**
   
   Since the TRIO Studio, Logan and his team are talking to departments at Rush to see if they can collaborate. They are doing a full marketing campaign with the marketing department at Rush to help with website updates, flyers, photos and testimonials.
About the Institute for Translational Medicine (ITM)

The ITM is a partnership between the University of Chicago and Rush in collaboration with Advocate-Aurora 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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