TRIO STUDIO: Recruitment and Successful Intervention in the US POINTER Chicagoland Site

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TRIO STUDIO: Recruitment and Successful Intervention in the US POINTER Chicagoland Site

by Martha Clare Morris, Sc.D.
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Quality Science Team: Evelyn Torres, Advocate-Aurora Health; Allecia Harley, RUMC; ERIC Beyer, UChicago; Lainie Ross, UChicago; Lisa Guay-Woodford, EAB Chair; Gerald Moose Stacy, ITM; Rachelle Paul-Brutus, Chicago Dept. of Health; Darren Gitelman, Advocate-Aurora Health; Mary Harris, UChicago; Drew Simon, RUMC; and Tony Solomondies, NorthShore University HealthSystem.

Summary
Martha Clare Morris, Sc.D., Rush University Medical Center, introduced the US POINTER clinical trial to be conducted in the Chicagoland region by Rush and Advocate-Aurora sites. She gave background information and introduced the perceived recruitment challenges to the studio.

Martha Clare Morris, Sc.D. and Darren Gitelman, M.D. are looking for suggestions for improving the recruitment and retention strategy in the US POINTER study.

Design Science Methodology and Quality Science Methodology were both used to solve the problems faced by Chicagoland site PI’s, Dr. Martha Clare Morris and Dr. Darren Gitelman and their teams at Rush University Medical Center and Advocate-Aurora. Many suggestions, based on experiences at different institutions, were made.
Top 3 Actions Proposed by the Design Science Studio Participants to Dr. Martha Clare Morris and Dr. Darren Gitelman:

1. Going beyond the current network of YMCAs to other similar organizations (such as park district programs, churches and other community based organizations).

2. Targeting pre-retirement people: 65-79 age group has a lot of variability. Target more pre-retired people so that they qualify for the study (minimal physical activity criteria).

3. Develop clinicians as study ambassadors.

Top 3 Actions Proposed by the Quality Science Studio Participants to Dr. Martha Clare Morris and Dr. Darren Gitelman:

1. Informatics consultation early on for solutions.

2. Engage more than YMCAs to remove constraints - churches and community organizations.

3. Structure the "funnel": Work back through the recruitment funnel and consider the resources needed for each step.
TRIO Studio Problem Description:

Martha Clare Morris explained the goal is to recruit and successfully conduct a multi-modal lifestyle intervention with 400 older community participants from the Chicagoland region. She gave some background for the study which is designed to include 2,000 cognitively normal older adults aged 60-79 years who are at increased risk for cognitive decline due to sedentary lifestyle, poor diet, suboptimum cardiovascular health status, and/or a first degree family history of significant memory impairment. The primary aim is to assess effects of random assignment to a Self-Guided vs. Structured Lifestyle Intervention focused on increasing aerobic exercise, adherence to the MIND diet, cognitive and social stimulation, and guideline-based health coaching to manage cardiometabolic risk factors on a two-year cognitive trajectory (based on a global cognitive composite outcome).

The study is a two-year multi-domain intervention of diet, exercise, cognitive training, and vascular risk monitoring versus control to prevent cognitive decline in at-risk elderly people. Subjects will be randomized into one of two groups: (1) a multi-domain Intervention consisting of nutrition, exercise, cognitive training and vascular risk monitoring or (2) a Self-Guided Lifestyle Intervention. The Self-Guided Lifestyle Intervention group will have group meetings two to three times per year to provide tangible resources and encouragement to support self-selected plans. They will receive annual physical exams and blood tests. The Structured Lifestyle Intervention group will exercise four times a week primarily at a YMCA, follow a MIND diet (modified Mediterranean), receive cognitive stimulation which consists of computer cognitive training (BrainHQ), regular group meetings to encourage social/intellectual challenge and will receive guideline-based health coaching which includes frequent exams, blood tests, and goal setting. Subjects will be followed for two years and the interpretation is that findings from this large, long-term, randomized controlled trial suggest that a multi-domain intervention could improve cognitive functioning in at-risk enderly people from the general population.

This study is being done all across the country and similar studies also are launching in Mexico, Argentina, Germany, Spain, Italy, Netherlands, India and Japan. The study is a partnership between local academic and medical institutions, local Alzheimer Association Chapter and local YMCAs. Chicagoland sites are Rush University Medical Center and Advocate–Aurora Health along with key current partners at the Alzheimer’s Association Illinois Chapter, McGaw YMCA, and West Cook YMCA. Other YMCAs will also be added in the future. The Chicagoland site POINTER study will be done at Rush University Medical Center and Advocate-Aurora Health. Rush will recruit and perform outcomes assessments on 200 subjects and interventions on all 400. Advocate-Aurora will recruit and perform outcomes assessments on 200 subjects.

Recruitment will consist of electronic medical record (EMR) searches to identify potential candidates. Eligible candidates will be mailed a letter assessing interest and questionnaires to identify those who are sedentary,
consume a poor diet, and have a first degree family history of memory impairment. Eligible candidates then complete a telephone cognitive assessment to exclude prevalent cognitive impairment. Subjects must live within five miles of a targeted YMCA.

Potential problems include:

1. Is the EMR sufficient to recruit eligible patients within five miles of a targeted YMCA?
2. Would other types of recruitment/advertising increase the response from EMR outreach.
3. Potential overlap in EMR patient recruitment.

Current efforts including contacting multiple YMCAs close to either Rush/Oak Park or Advocate-Aurora/Park Ridge, plans for community advertising, and enlisting the ITM community engagement coordinator to assist in recruitment beyond the EMR.

Potential plans for supplementary recruitment efforts include a Rush/Advocate-Aurora newsletter, partnering YMCA newsletter, Alzheimer Association newsletter, ITM trial website, local churches and other community organizations.
TRIO STUDIO: Recruitment and Successful Intervention in the US POINTER
Chicagoland Site

Image: Design Science Team

Image: Quality Science Team

Image: TRIO Studio in Session at IIT Institute of Design
Main problem for the studio participants to solve:
Does the TRIO studio audience have suggestions for improving the recruitment and retention strategy for the Chicagoland region launch of the US POINTER clinical trial?

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 four 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.

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 four 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

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:

Figure 3. Insights for current flow.
Solutions Generated by Design Science Approach Team:
Four relatively implementable solutions were created to solve the issues. They are as follows:

1. **Go beyond the YMCA network:** Investigators need to expand the pool of participants radically by going beyond the targeted YMCAs and reaching out to community organizations, Alzheimers centers, Parkinsons centers, Churches, Park District based and other independent Senior Citizen Centers.

2. **Target Pre-retirement:** People are active after retirement so try to target a bit more sedentary pre-retirement population.

3. **Clinicians as Ambassadors:** Try to recruit the power recruiters by turning to clinicians as your study ambassadors. They are the trusted voice for this population so their buy in will tremendously help achieve participation and retention.

4. **Corporate Partnerships:** Partner with Uber/Lyft for rides, partner with HomeChef/ Hello Fresh/ food-to-home companies as well as park district and other community organizations to create enough buzz and incentive to make participation very attractive. Barrier to participation needs to be reduced using these critical partnerships.

### Solutions

<table>
<thead>
<tr>
<th>SELECTED SOLUTIONS</th>
<th>OTHER SOLUTIONS</th>
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<tr>
<td>1. GOING BEYOND THE CURRENT NETWORK</td>
<td>GO BEYOND THE 5 MILE</td>
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<td>2. TARGET PRE-RETIREMENT</td>
<td>STUDY TEAM FLIGHTS OUT</td>
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<td>3. CLINICIANS AS STUDY AMBASSADORS</td>
<td>FACEBOOK ADS &amp; GOOGLE ADWORDS</td>
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<tr>
<td>4. CORPORATE PARTNERSHIPS</td>
<td>CARE GIVERS</td>
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<tr>
<td>5. EXPANDING COMMUNICATION CHANNELS</td>
<td>TRANSPORTATION IN THE WINTER</td>
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Figure 4. Top 5 solutions along with other solutions discussed.

Other solutions included

1. Facebook advertisements and google ad words purchase
2. Increase catchment area from 5 miles to much more. Make it travel time based instead of distance based
3. Study team flies out to Florida to make sure data is gotten during winter months of Chicago (most appealing idea for the coordinators)
4. Care givers should be targeted to target the 70-75+ population
5. Transportation is provided in winter months so ease pain of participation
Quality Science Based Solutions:
Problems Analysed to Identify and Define Issues.

Define the Problem

Figure 5. Problem Definition
Understanding the Process

EMR Search

What if I’m not with Rush or Advocate?

No in person approaches

Search is not sophisticated: Candidates lost due to lack of I2B2 to work with Trineics and cohort discovery tools

No location based searches

Screening 1: EMR Search

Identify Candidate

Losing people from EPIC-institutional change not connected with EMR

Couples cannot participate together-lost family members

Screening 2: Mailed questionnaire

Interest, lifestyle, family history

What is consent? What kind of information is given?

Social isolation is not addressed - losing people on interest

What about hearing impairment? Could we do it in person?

Screening 3: Telephone interview

Complete cognitive assessment to exclude prevalent cognitive impairment

Dropping out at this point is very disappointing for participants

Do we inform participants of cognitive impairment, if found?

SUCCESSFUL RECRUITMENT

Figure 6. Flow analysis and problem occurrence location identification

Analysis of Issues and Causes
The EMR is not enough for recruitment for the US POINTER study in the Chicagoland area. That issue was analyzed as a group and causality of the problem assessed and insights discussed. Causes for the issues found in step one were discussed as a group. Here is the summary of that discussion:

1. EMR targets only known patients of the clinics. Need to reach beyond immediate areas covered by clinics.
2. EMR based recruitment is not connected to the community. It will lead to ineffective communication.
3. EMR is not set up for such kind of work. May not capture key criteria for inclusion or exclusion.
4. Community based recruitment is harder when the whole approach is EMR based versus people to people based.
5. Can there be proxy markers for weight and BP so that exclusion criteria is not so harsh. Can we broaden inclusion criteria using proxy markers.

Ssolutions Generated by Quality Science Approach Team:
Top 3 solutions were created to solve the issues of getting a study started. Other solutions were discussed as well. They are as follows in the list below and the diagram digitized from whiteboard:

1. **Informatics Consultation**: Informatics consultation early on to make sure the EMR is capable of providing a sophisticated enough search to yield a small enough pool of potential recruits.

2. **Engage more YMCAs** to remove constraints – Engage with churches and community organizations as well to increase reach.

3. **Structure the funnel**: Work back through the funnel diagrammed in Figure 6 keeping in mind the resources available to the study. Start with the number needed to recruit and work backwards based on anticipated loss of persons at each stage. Choose recruitment methods that align with available resources to reduce loss at each stage.

Figure 8. Solutions created and discussed
Other solutions include:

1. Look at other neighborhood centers where communities get together (not just exercise based places)
2. Simplify screening process
3. EMR analysis to screen for participants
4. Medicare records scanning for participants?
5. Address social isolation as motivation in this population
6. Remove the constraints of churches – assisted living?
7. Focus on community in immediate vicinity of the targeted Y
8. Iterative approach for screening
9. Flexiblity in recruitment funds
10. Structure the funnel in the format that is useful – process design so that coordinators can easily manage the flow of participants without loosing too much at each screening.

<End of Document. Thank you.>
Appendix 1.
Slides used by Martha Clare Morris, Rush University Medical Center for the studio kick off.

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

Design Science
Quality Science
SOLUTIONS

1. INFORMANTS
   - CONSULTATION EARLY (ADN)
   → FOR SOLUTIONS

2. MORE Ys by C:
   → STRUCTURE THE FUNNEL
   → WORKING OFF
   - THROUGH PROGRAMS
   → WITH RESOURCES

3. CHURCHES A/V IN 5 MILES
   → ENGAGE COMMUNITY ORGANIZATIONS

4. ADDRESS SOCIAL
   - ISOLATION IN Ys
   → MOTIVATION

5. LOOK AT OTHER
   - OPTIONS THAN
   → Y TO OFFER
   → ANCHOR SERVICES

6. SITYLIZE PROCESS
   - BY SOLUTION
   → OCR MAIL ACCOUNT

7. USE CURRENT EMAIL
   → ANALYSIS

8. MEET WITH OTHER
   - RECRUITMENT FROM X Y
   → TO NONE

9. STRUCTURE THE KINKEL
   → IN 2 TIMES UN DAILY

10. FOCUS IN COMMUNITY NEXT
    → T TO Y

11. START 0/ITERATIVE APPROACH
    → FOR SCREENING PIVOT QUICKLY

12. FLEXIBILITY IN RECRUITMENT
    → FUNDS
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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