TRIO STUDIO: DBS Outcomes in Parkinson’s Disease
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TRIO STUDIO: DBS Outcomes in Parkinson’s Disease

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Facilitator: Santosh Basapur, IIT Institute of Design

Attendees:
Denise Voskuil-Marre, RUMC; Gian Pal, RUMC; Drew Simon, RUMC; Mary F, UChicago; Ali K., RUMC; Anjan Unni, UChicago; Cynthia Tom Klebba, Loyola; Laura Magda, UChicago; Siqi Zhang, RUMC; Gosia Labno, ITM UChicago; Gerald Stacy, ITM UChicago; and Sherry Robison, ITM UChicago.

Summary
Gian Pal, M.D., M.S., of Rush University Medical Center, introduced his study which is currently funded on a K award. His goal is to predict outcomes after deep brain stimulation for Parkinson’s Disease (PD). He is currently writing an R01 and requests feedback on his aims and which direction to go for his R01, in particular, from a goal of enhancing potential participant recruitment and retention

Design Thinking Methodology approach was used to solve the problems faced by Dr. Pal and his team.

Top 3 Actions Proposed by the Studio Participants to Dr. Pal:

1. **ITM as a Resource**: Attend R Studio, https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers, enter the study in the city wide patient portal, and use Trial Innovative Network if you’re looking for additional sites.

2. **Full Blown Marketing Campaign**: Site testimonials/videos, Facebook, support groups, reach out to manufacturer of the device to see what sites are using the device, and highlight what’s in it for the patient (genotype counseling, etc).

3. **Eliminate Clinic from Recruiting Cycle**: Perform in-person visits and use telehealth for follow-ups.
TRIO Studio Problem Description:

Gian Pal, M.D., M.S., of Rush University Medical Center introduced his study. He explained that the goal is to predict the outcomes after deep brain stimulation (DBS) for Parkinson’s Disease. He gave some background which included GBA mutations are the most common genetic risk factor for Parkinson’s Disease, affecting 5-10% of the patient population. GBA mutations are associated with faster motor and cognitive decline. Subthalamic nucleus (STN)-DBS is the most common type of DBS for Parkinson’s Disease patients. STN-DBS is associated with cognitive decline and approximately 17% of those with STN-DBS are GBA mutation carriers. The hypothesis of his K research project is Parkinson’s Disease GBA mutation carriers with STN-DBS will have greater cognitive decline over time, compared with other groups (STN-DBS – GBA with DBS and Non-GBA with DBS; Non-DBS – GBA without DBS and Non-GBA without DBS).

The study design involves genotyping Parkinson’s Disease subjects undergoing STN-DBS and matched Parkinson’s Disease subjects not undergoing STN-DBS. The primary outcome is Mattis Dementia Rating Scale. Subjects are evaluated at baseline, 1 year and 2 years.

Dr. Pal explained his plan is to recruit 12 subjects in each group. He currently has seven in the GBA with and without DBS, the non-GBA groups are filled and he anticipates completing visits by year four. He preparing to publish results which include GBA decline (n=30) faster versus non-GBA (n=44).

He is doing his study under a K Award and is requesting the TRIO Design Studio audience to provide feedback on his aims for his R01 and provide direction for his R01. His aims are as follows:

Aim 1: Determine survival and time to dementia in GBA mutation carriers and non-mutation carries with STN-DBS. The hypothesis for this aim is: Survival and time to dementia is shortest in the GBA group.

Aim 2: Develop a cognitive risk calculator for Parkinson’s Disease subjects considering STN-DBS. The hypothesis for this aim is: A combination of clinical and genetic factors will provide high sensitivity and specificity to predict cognitive outcomes after STN-DBS.

Aim 3: Develop a DBS risk counseling protocol for Parkinson’s Disease patients considering DBS utilizing intervention mapping. The hypothesis for this aim is: Formal input from key stakeholders will lead to a standardized protocol for counseling of PD patients and families regarding risks and benefits of DBS incorporating clinical and genetic information.
Figure 1. Gian Pal presenting his study
Main problem for the studio participants to solve:
Dr. Pal was awarded a K grant to do his current study. Dr. Pal is requesting the TRIO Design Studio audience to provide feedback on his aims for his R01 and provide direction for his R01, with a lens focused on recruitment and retention of potential participants.

Studio Methodology
Design Science approach was used to solve this problem. The TRIO audience, with experience in recruitment and retention strategies, anticipated the problems for Dr. Pal and discussed how he could incorporate these ideas into his R01 proposal.

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 2 Mind Map of Issues](image-url)
Stakeholder Map

Figure 3 Stakeholder Map
High level insights:
Following the context discussions, insights were generated as follows:

**AIMS**

1. Survival/time to Dementia in GBA
   + Determine the shortest GBA group
   + Get PT from other sites in Chicago to get a bigger sample

2. Cognitive Risk Calculator
   + Include Clinical and Genetic factors
   + What is the risk to dementia?

3. Risk Calculating Protocol-Patients
   + Input from stakeholders
   + Incorporate generic information
   + A tool to counsel patients before surgery

**POTENTIAL OTHER AIDS**

1. Comparing sites of DBS
   + Odds of getting people are bad
   + Ethical issues
   + Follow up of 5-10 years prolongs study

2. Compare people with implantation already done
   + Inherent Bias
   + Not typical targets

3. Other Genotypes
   + LRK 2
   + Odds are even lesser

4. Turning DBS on/off with memory tests and log tests
   + What is the most impactful outcome of 5 yr study?
   + Structure the study in routine care to get larger data
   + PT motivation contributes to the study in terms of recruitment
   + Genetic consulting to PT
   + After DBS, not qualified for many CT but could still contribute to the study
   + Recruitment from other sites
   + PT stop PT med for 12 hours-risk factors
   + Willing to do home visits-3 hours
   + Innovative ways to capture data

5. Diversity and Inclusion

6. GBA - Genetic Risk Factor
   + Age range 40-70 years
   + Average age 55-65 years
   + Age-gender-duration of Dementia
   + Baseline, meet standard criteria
   + Why not secondary research of existing data, why patient?
   + A lot passed, no blood sample
   + 80/150 PT have blood, but lacks genotype data.
   + Rush, Central Dupage, Northwestern/ U Chicago
   + Benefit of the survey to PT
   + Good life quality for 5-10 years
   + Smoother day
   + Reduce med by 50%-70%, but the side effect is nursing homes

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**Figure 3 Insights Generated during Discussion**
Solutions Generated by Design Thinking Approach Team:
Five relatively implementable solutions were created to solve the issues of recruitment. They are as follows:

1. **ITM as a Resource**: Attend R Studio, [https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers](https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers), enter the study in the city-wide patient portal, and use Trial Innovative Network if you’re looking for additional sites.

2. **Full Blown Marketing Campaign**: Site testimonials/videos, Facebook, support groups, reach out to manufacturer of the device to see what sites are using the device, and highlight what’s in it for the patient (genotype counseling, etc.).

3. **Eliminate Clinic from Recruiting Cycle**: Perform in-person visits and use telehealth for follow-ups.

4. **Understand Mechanisms**: Why is the outcome happening? May change aims.

5. **Increase Diversity**: Attend health fairs and explore Rush westside alliance.
Winning solutions

1. **ITM as a Resource (infrastructure)**
   - Patient Portal (city wide);
   - R Studio;
   - Guidance of Counseling;
   - TIN;
   - Accrual to Clinical Trials (ACT);
   - Network at NW.

2. **Full Blown Marketing Campaign**
   - Site with testimonials and videos;
   - Facebook;
   - Support group;
   - Reach out to manufacturers.

3. **No Clinic in Recruiting Cycles**
   - Eliminating doctors from recruiting cycles.
   - In-person visit;
   - Telehealth follow ups.

Other solutions

- Better Highlight What is in it for Patients
  - Genotype Counseling.

- Understand
  - Mechanism of Why
  - The outcome happened - may change aims.

- Increase Diversity
  - Health fair:
  - Rush West Side Alliance.

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*Figure 4 Solutions as visualized on whiteboards*

<End of Document. Thank you.>
Appendix 1.
Slides used by Dr. Pal.

Appendix 2.
Session Pictures
SOLUTIONS

1. Eliminate doctors from recruiting cycle - less health follow-ups
2. Better highlight what's in it for patients - Genotype Counseling
3. ITM as a resource (infrastructure)
   - Patient Portal (Citywide)
   - R Studio - Access to Clinical Trial Network
   - Guidance for Genotyping - Resources
4. Understand mechanism of why the outcome happened.
   - Many change aims
5. Full Blown Marketing Campaign
   - Site, testimonials/videos...
   - FB
   - Support groups
   - Reach out to manufacturers
6. Increase Diversity
   - Health Fair
   - Rust Website, alliances
Addendum 1- 30 Day Follow up

1. **ITM as a Resource**: Attend R Studio, https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers, enter the study in the city-wide patient portal, and use Trial Innovative Network if you’re looking for additional sites.

   **Implementation and Results:**

   Dr. Pal has entered his study on the city-wide patient portal for the New Normal.

   There is another study being done at another institution that is collecting the same data he is looking for with the exception of the genetic data. He has emailed the PI and is awaiting a response to see if he can piggy-back off her study with the exception of also collecting genetic data. Once he receives a response, he will write his grant and attend an R Studio.

2. **Full Blown Marketing Campaign**: Site testimonials/videos, Facebook, support groups, reach out to manufacturer of the device to see what sites are using the device, and highlight what’s in it for the patient (genotype counseling, etc.).

   **Implementation and Results:**

   Dr. Pal has met with a Study Coordinator at Rush to discuss how she set up a Facebook page and the IRB approval process. He is in the process of a marketing campaign for the study.

3. **Eliminate Clinic from Recruiting Cycle**: Perform in-person visits and use telehealth for follow-ups.

   **Implementation and Results:**

   Dr. Pal is currently doing some of the in-person visits and using telehealth, but this will be written and included in his next grant application.
Addendum 2 – 90 Day Follow up

1. **ITM as a Resource**: Attend R Studio, https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers, enter the study in the city-wide patient portal, and use Trial Innovative Network if you’re looking for additional sites.

   **Implementation and Results:**

   At the 30-day follow-up, Dr. Pal entered his study on the city-wide patient portal for the New Normal. There is another study being done at another institution that is collecting the same data he is looking for with the exception of the genetic data. He has emailed the PI and is awaiting a response to see if he can piggy-back off her study with the exception of also collecting genetic data. Once he receives a response, he will write his grant and attend an R Studio.

   Dr. Pal is in contact with the PI at another institution regarding data. Once he receives it, he will analyze and attend an R01 session.

2. **Full Blown Marketing Campaign**: Site testimonials/videos, Facebook, support groups, reach out to manufacturer of the device to see what sites are using the device, and highlight what’s in it for the patient (genotype counseling, etc.).

   **Implementation and Results:**

   At the 30-day follow up, Dr. Pal met with a Study Coordinator at Rush to discuss how she set up a Facebook page and the IRB approval process. He is in the process of a marketing campaign for the study.

   Recruitment goal has been met and Dr. Pal and his team are doing follow up appointments to obtain data. There is no need for a full-blown marketing campaign, at this time.

3. **Eliminate Clinic from Recruiting Cycle**: Perform in-person visits and use telehealth for follow-ups.

   **Implementation and Results:**

   At the 30-day follow-up, Dr. Pal was doing some of the in-person visits and using telehealth, but this will be written and included in his next grant application.

   Dr. Pal will be in touch when he begins writing his grant, for submission in the fall of 2020 to obtain contact information for PIs currently using telehealth. He will incorporate telehealth into his grant application.
4. **Understand Mechanisms:** Why is the outcome happening? May change aims.

   **Implementation and Results:**

   Dr. Pal is currently collecting additional data. Once the data is analyzed, he may need to re-write the aims for his grant application.

5. **Increase Diversity:** Attend health fairs and explore Rush westside alliance.

   **Implementation and Results:**

   Recruitment goal has been met. No need to attend health fairs for recruitment.

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**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](http://chicagoitm.org) and connect with us on Facebook, Twitter, Instagram, YouTube, and LinkedIn @ChicagoITM.

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