Best Practices for Optimizing Clinical Trials In Physical Activity

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University of Virginia

Public Health and Physical Activity Courses 2023

Introduction

- University of Virginia, B.A.
  - Psychology
- University of Virginia, M.Ed.
  - Exercise physiology
- University of Virginia, M.S.
  - Health evaluation sciences and clinical investigations
- University of Virginia, Ph.D.
  - Exercise physiology
- Pennington Biomedical Research Center (Postdoc)
  - Preventive Medicine

Research interests:

- Exercise training interventions
- Health disparities research
- Weight loss and weight maintenance

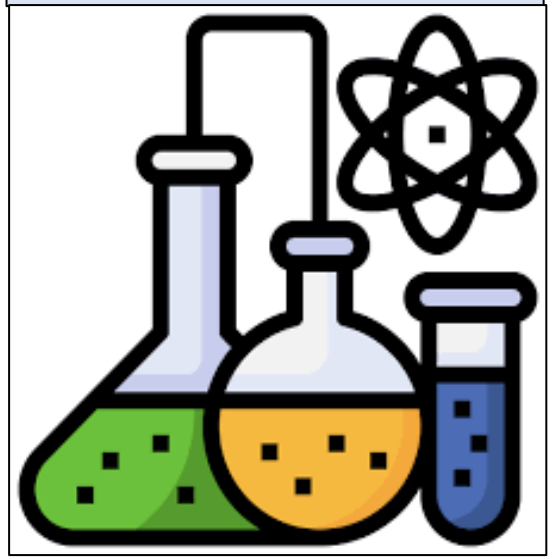
Goal of the Session

- Discuss my trajectory in research
- Discuss ideas on how to optimize various phases of the clinical trial
  - RCT Planning
  - Recruitment
  - Retention
  - Intervention quality
  - Leadership of team
- Discuss early career thoughts

My Story….

What are some accelerators for **research success**?

Leverage pilot data and available databases



Strong research mentors that match you

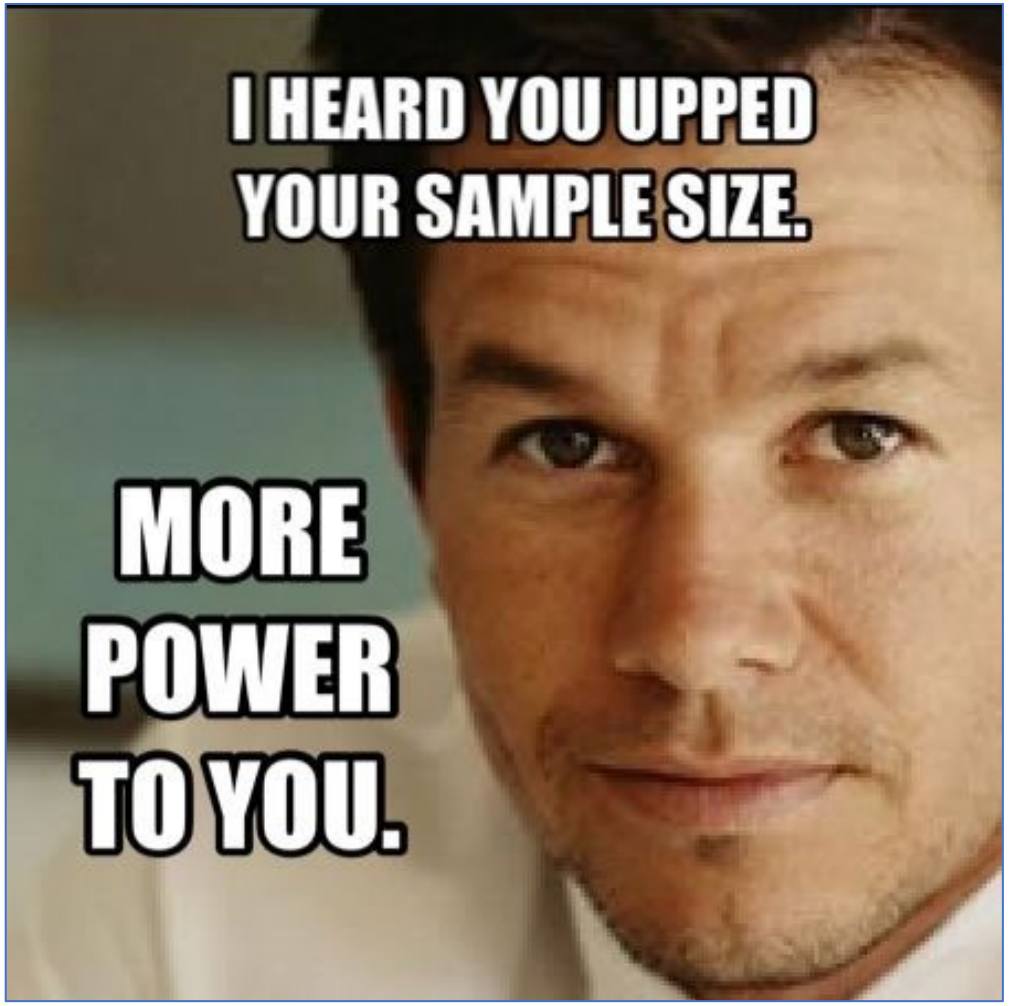
Friends that can tell you "why you're dumb"

Be daring…

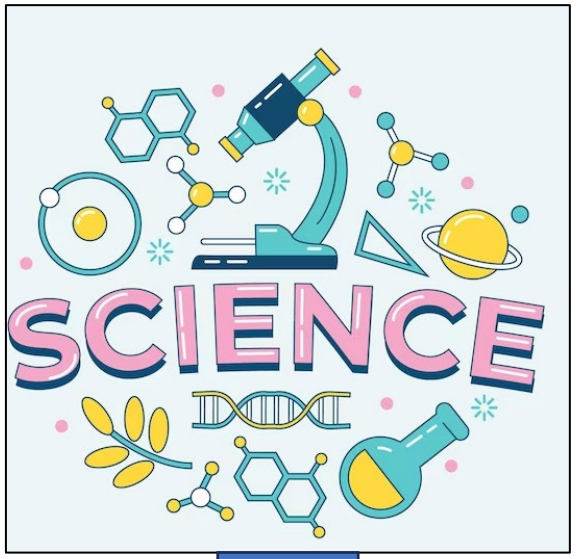
Mix as many metaphors and references as possible!

Planning an RCT in Physical Activity

- Talk to **trusted** mentors, peers, and faculty about your idea and design
- Review their clinical trials sections of the grant to see how specific issues are handled
- Get examples of successful grant applications that have RCTs and **replicate their structure**
- Talk to your **statistician** early in the process as opposed to the last minute:
  - Do your **power analysis** early on the granting side
  - Consult that statistician on analyses plans
  - Discuss randomization procedures



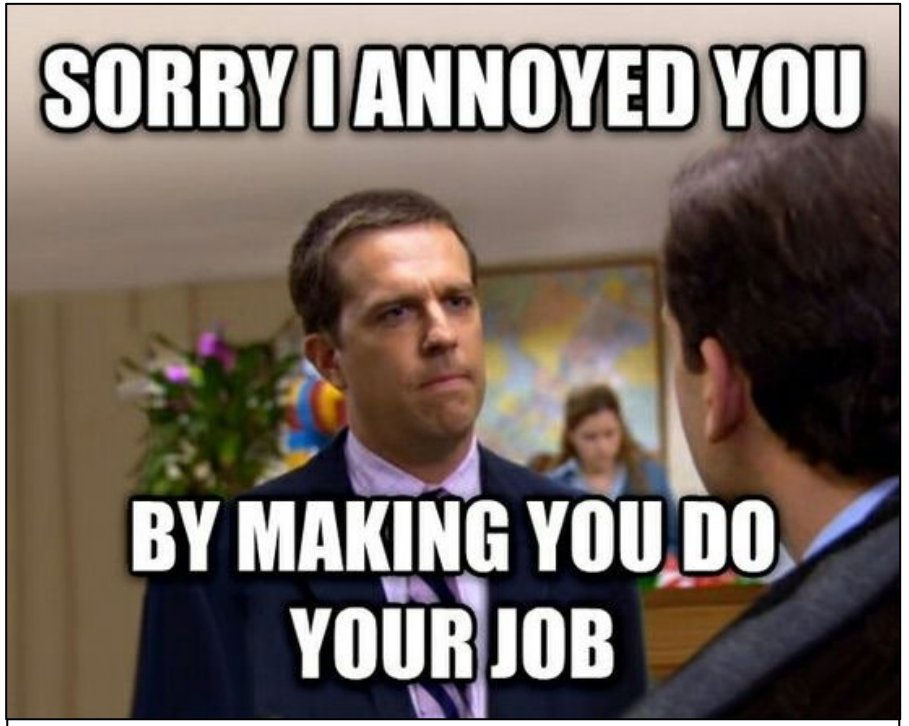
Start-up Phase – Early Career Perspective (Science to Logistics)



- **During start-up initiation:**
  - Talk to as many **senior faculty** as possible and other faculty you trust at your institution
  - Learn institutional procedures and bureaucracy
  - **Discuss with the Do'ers** : They see the trial at a different level and have thinking styles that support logistics
    - Project Coordinators and doctoral students
  - **Determine your timeline (Represented in your grant/clinical trials sections):**
    - Estimate the time needed for:
      - Start-up, MOP, and training of staff
      - Recruitment of needed sample
      - Implementation of the study
      - Data analysis
      - Dissemination of results

Factors that can slow initiation of a trial

- Grant account being set-up: In most cases as soon as you have a notice of award you can set up a grant account
- Getting **staff/faculty** on the grant account
- Software approvals for where there are concerns about PHI or digital data capture
  - Accelerometer programs- Centrepoint, Fitabase
  - Programs where there are digital data collection of information off participants: (these are ones where I had to get clearance for)
    - Digital food frequency questionnaires
    - Quality of life measures
- Setup **Clinical Trials.gov account** for the study



Remember that the people responsible for these actions at your institution may not be on your timeline

Factors that can help mitigate slow start-up

- NOGA
  - As soon as you get NOGA set-up study account. You don’t need to wait for the money to come in
  - Start with purchase of large equipment or software that require approvals
- Discuss and understand the full breadth of institutional factors standing in the way of start-up
- Use faculty mentors and support personal to understand the best methods of pushing through the process
- Start working on the MOP/SOPS and “dress rehearsing” all the visits
- Hit the ground running and preserve as much grant time as possible
- Use your team and do not do it all yourself

During Start-up- MOP

- Develop a **Manual of Procedures (MOP)** which contains the SOPs of your intervention

- The MOP is a **step by step** guide to running all aspects of the clinical trial in extensive detail:

- **Examples of Sections to Discuss:**
  - Recruitment/screening process for participants
  - Detailed directions for conducting each visit
  - Randomization procedures
  - Standard operating procedures for each outcome measure
  - Process for data entry and reporting
  - Process for certifying individuals on a measurement

- Have your research team practice each visit and continue to **problem solve issues** in the MOP and individual SOPs as if it were **a real participant**

- Edit the MOP based on issues discovered when practicing visits

Before the Intervention…

- What are the **"study killers"…** What are things that will dramatically reduce the publishability of your data?
  - Recruitment:
    - What are going to be the difficult cells to access… Put energy into these first
  - Protect your **primary** endpoint:
    - Are all confounders to the endpoint accounted for?
      - Review other papers that have published in this area and see what they have controlled for
    - Standardization approaches for the **primary outcome**:
      - What have you done to ensure that the standardization has been done from a procedural perspective?
        - **Staff level:**
          - How is your team trained around the **primary outcome and secondary outcomes** to insure consistency?
          - SOP and MOPs
          - Certification on outcomes
        - **Participant level:**
          - How are instructions provided?
          - What reminders are necessary?
          - Assessment for how well necessary instructions are followed?

You can write **half** the paper before you have data…
You have everything up to the methods done

Table 1. Demographics

What are key demographic variables?

Are they all accounted for?

Table 2. Key aspects about your intervention

Exercise amount, intensity, compliance

You need a way to track them, which ones would you report in your final paper

What defines success for your physical activity data

Database and variables mapping

Make sure that all the needed variables are mapped to your database and your case report forms

Maximizing your dataset for future papers or analysis

Are there low burden items that you can in your data set that can be a publication?

Can you save blood for later analyses or analyses that you cannot afford currently?

Use a Database for Research Data

- Using excel for research data is **antiquated**

- **Database approaches:**
  - Hire a database manager to build a database (feasible for large grants)
  - Use a database software like Red Cap and develop your database internally

- **Advantages of databases programs like Red Cap compared to excel:**
  - Audit trail for any changes in data
  - Exporting customized data for reports
  - Track progress of students or staff for data entry (exercise intervention data)
  - Comments about data collection can be inserted
  - Data validation reports can be run (check calculations and missing data)
  - Highly customizable for your study purpose

https://www.project-redcap.org/

Advantages of using RedCap

- Available for free at academic institutions
- Only basic database experience needed
- Has survey functions and reminder functions
- Randomization portal
- Survey functionality
- Customizable alerts based on actions within the database
- Cross institution functionality for multi-sites studies
- Continually updating and advancing functionality

https://www.project-redcap.org/

Recruiting

Recruitment- Planning

- **Use historical data to determine whether the plan is feasible (where can you get it?)**
- **Understand the expected recruitment based on a <u>data driven approach</u>**
  - For your typical trials what is your contact to "**randomization ratio**"? This gives you some idea of the amount of participants you need to contact in order to randomize a single participant
  - It starts with "tracking it"
  - Remember that this ratio is affected by the specifics detail of a study. Be realistic about the effect these factors have on recruitment
    - Demographics
    - Participant burden
    - Testing invasiveness
  - The ratio will also be different within populations that you want to recruit (e.g. overweight vs. normal weight, older vs. younger, minority vs. non-minority) and how long you've been recruiting for a trial

- **Participants need an opportunity to be asked to participate?**
  - How does your study recruitment reflect how you are recruiting
  - Are there particular areas in that your community that your recruitment material never reaches?

- **Passive vs. Active recruiting**
- **Under-represented communities and earning trust**
- **Make the best plan at recruitment onset**

Recruitment Planning

- **Recruitment plan**: Think of the amount of time available for recruitment and divide it up into segments (many groups use months or quarters)
  - Take into account holidays and times when recruitment would be slow
  - Plan based on “reality”

- Plan for “**harder to recruit”** participants first:
  - Work on these “cells” and put energy into them earlier as opposed to the end of the trial, when you’re hoping to catch up

- Monitor these stats and update them in study meetings. Think of way to **automate the process in database report** (make it easy to do)
  - Track the overall recruitment
  - Track reasons why people are dropping out at various phases (need it for a consort diagram anyway, so it informs recruitment during the process)
  - Track the sex, racial, and ethnic status to meet grant or RCT recruitment goals

Expanding reach- Making sure participants are being “asked” to participate

- Evaluate your **recruiting tools** and see what demographics they get
  - **Newspaper:** Older populations tend read news paper advertisements
  - Blast to university employees hit specific demographic and educational levels
  - Flyering is dependent on who walks by and is generally inefficient if it isn’t targeted

- What parts of your **local community** and **surrounding areas** are you missing from geographic, socioeconomic, and racial/ethnic perspectives?

Recruitment analogy…

Make sure as many **eligible** participants **"get asked"** to do an intervention

Participants that are available from your study

Make sure you don't lose good participants through the **recruitment process** (and throughout the study)

Ways to expand your recruiting reach and increase population of eligible participants

- Have a **study website**
  - Provides more information than a flyer or other material
  - Links can be shared, forwarded in email and posted
  - Allow initial pre-screen on the study website. This can be done easily through **Red Cap**
- **Do talks on physical activity or health in the community to build trust**
- **Mailers can be targeted (QR codes can be linked to websites)**
- **Social media can be targeted**
- **Call the local news and talk about your research. They can put the news story on social media, which can link to your website or recruitment information**
- **Consider maintaining a database of participants that wish to be contacting about future studies. Participants that have completed a study can participate in a new one.**
- **Community partners and events**

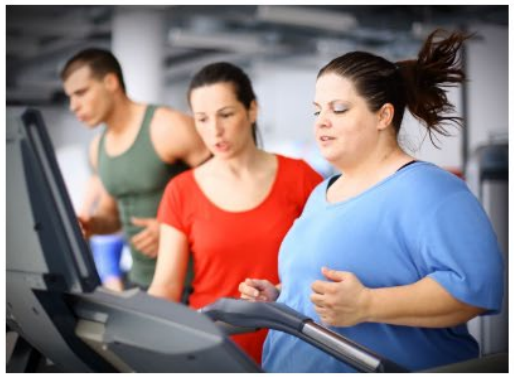
UVA Bariatric Exercise Study

UVA Exercise Training Study Before Bariatric Surgery

BaSE

Home | BaSE Information | Exercise Program | Facilities | Study Staff | Contact Us | Eligibility Survey

Home



Welcome to the **Bariatric Surgery and Exercise (BaSE) Study** website! BaSE is a research study in the University of Virginia (UVA) Kinesiology Department that will evaluate the effects of aerobic exercise on bariatric surgery outcomes. Research indicates that exercise combined with standard pre-bariatric surgery care can improve surgical outcomes, which BaSE aims to further explore.

BaSE is looking for participants between 18-50 years old that plan to undergo bariatric surgery at the UVA Hospital in Charlottesville, VA. Participants must be able to attend in-person, supervised aerobic exercise sessions at UVA 2-4 times a week for 8 weeks before their surgery.

Exercise training will occur at the Student Health and Wellness Building (550 Brandon Ave, Charlottesville, VA 22903). Clinical testing to assess weight and health risk factors will occur at the Student Health and Wellness Building and the Clinical Research Unit (1330 Jefferson Park Ave, Charlottesville, VA 22903).

If you are interested in this study, please complete our eligibility survey or email the study coordinator, Emily Grammer, at erk9nk@virginia.edu. If you want to know more, you can set up appointment with Emily here.

Examples of Study Websites

Get the website **IRB approved** with **recruitment materials**

This can be done with a **simple word press website** and keep information short and simple.

This is relatively easy and can be designed by you or students and available for free at most universities

UVA Bariatric Exercise Study

UVA Exercise Training Study Before Bariatric Surgery

BaSE

Make sure you have a **logo**: Allows participants to identify with the study

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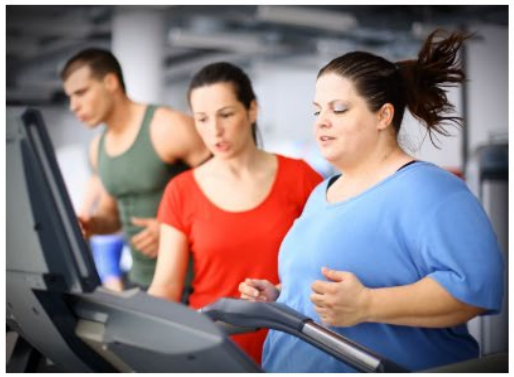
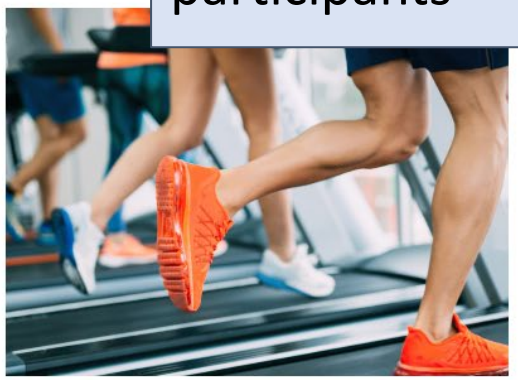
Link to **pre-screener** on every page of the website. Make it **easy to find** for the participants

Home





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WordPress

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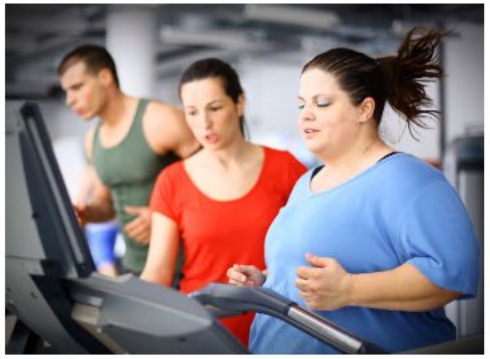

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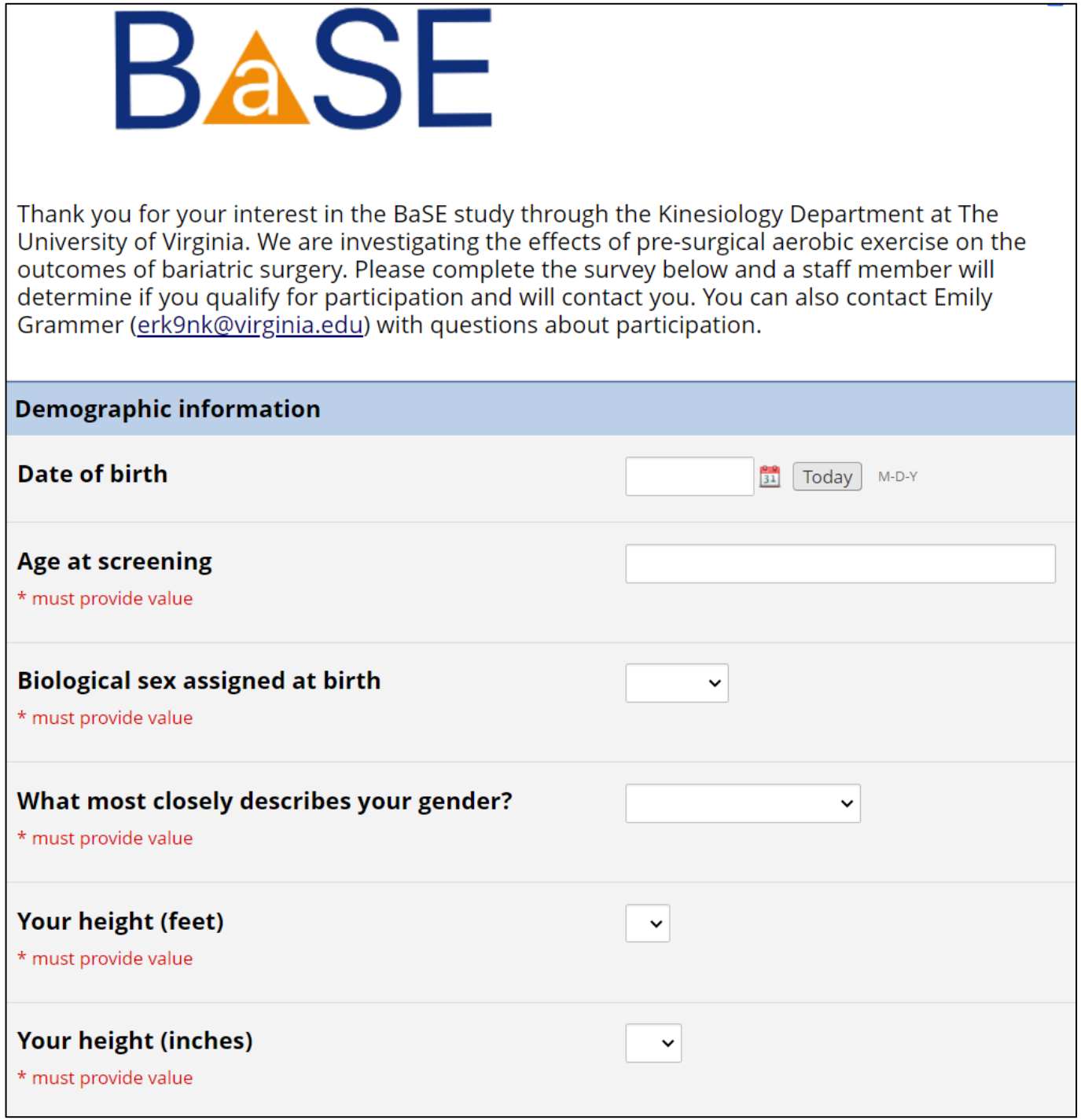
Make the links for **pre-screening** as easy as possible for participants to find and keep in mind "consent form" **level of language and population you are trying to recruit**



- Web-based screening to get participants in the pipeline
- If eligible from the pre-screener study staff can contact them for continued screening
- Using a database within the recruitment process also allows you to track **total contacts** and **consort diagram** issues better than manual methods

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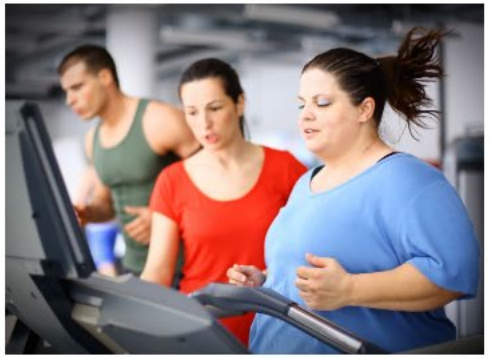

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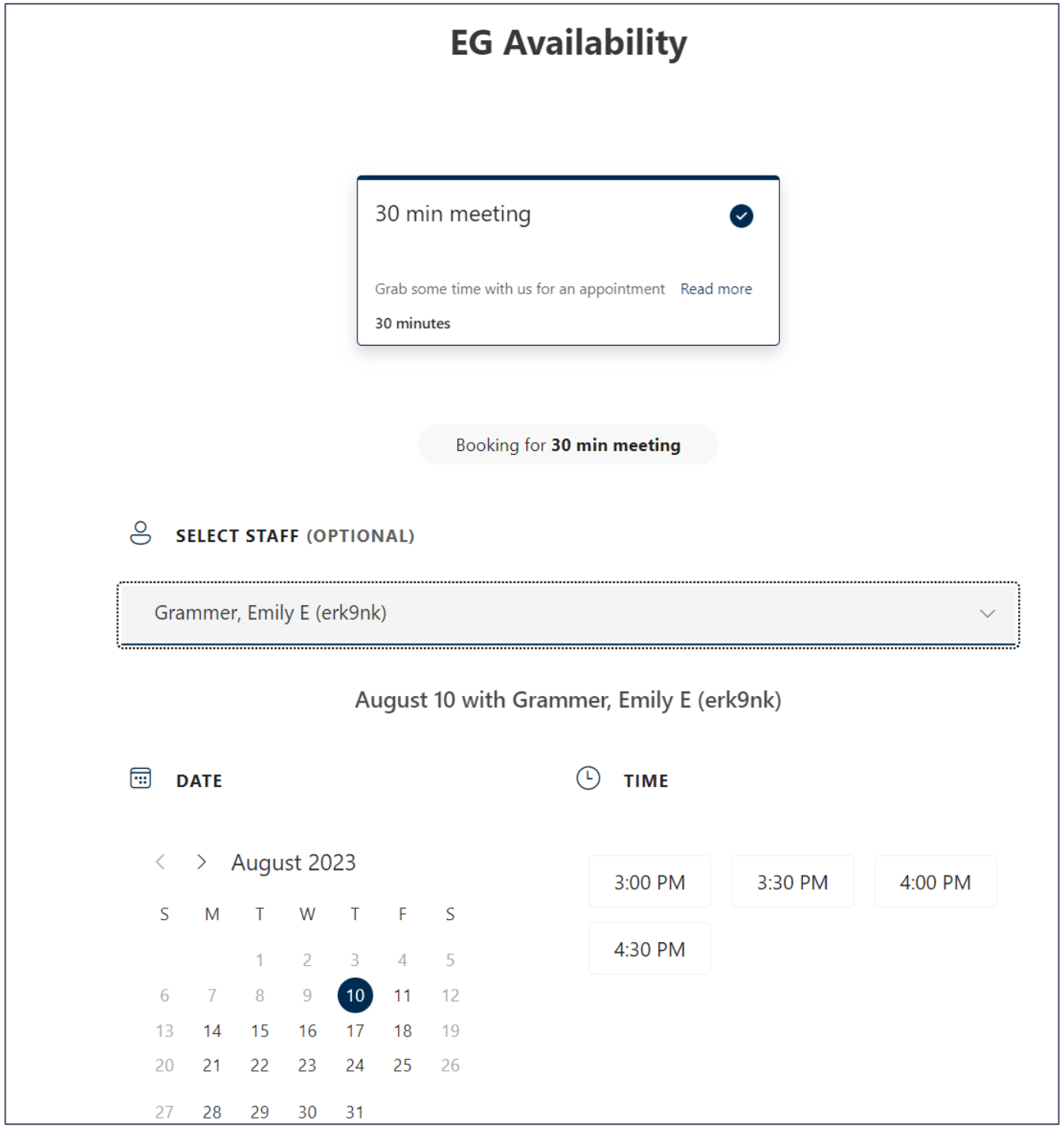
CLICK HERE
to see if you're eligible for the
BaSE study

Bookings

Microsoft Bookings allows participants to schedule with a staff members and put appointments on their calendar

Usually in **Microsoft 365** packages available at most universities

Can designate screening time on the **outlook calendar** of study staff and participants can set up appointments



Participant can schedule their own pre-screening appointment!

Less **burden** on study staff and allows participant to schedule a time that works for them

Might also work well for personality types that do not like to talk on the phone, but would be a a good participant for your study

- Give **potential good participants** as many methods of getting in contact with you as possible:

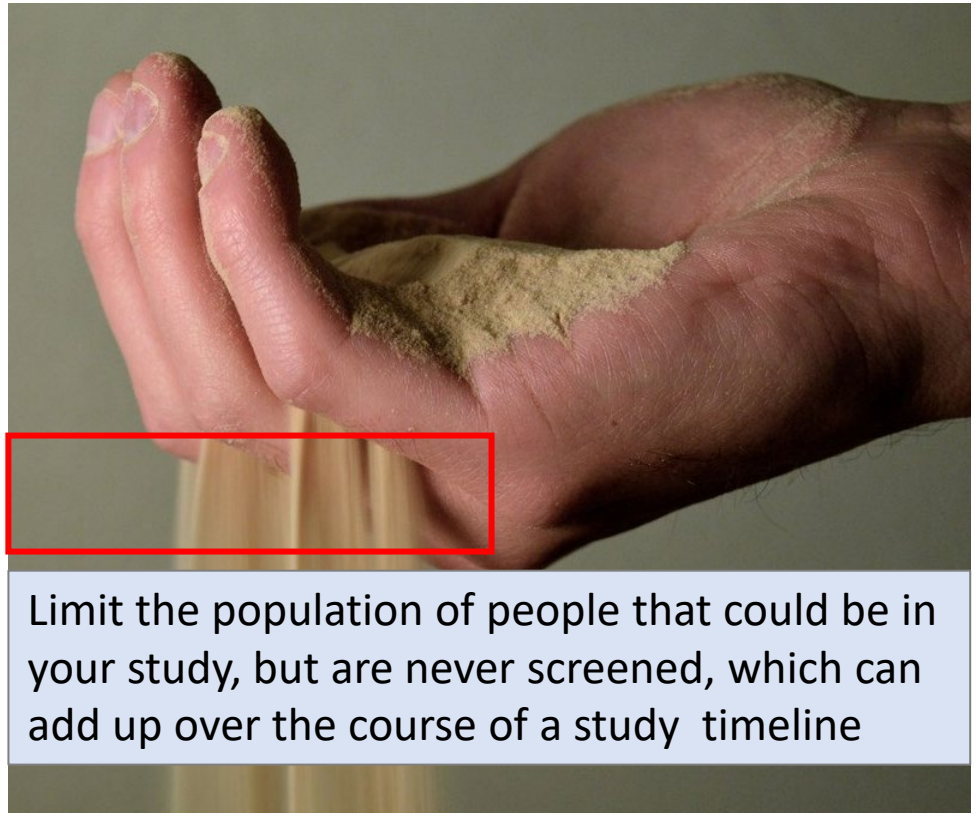
  -Phone call
  -Emailing study staff
  -Filling out a form
  - Scheduling a screening call with a computer system

Other Helpful Hints Regarding Planning Recruitment

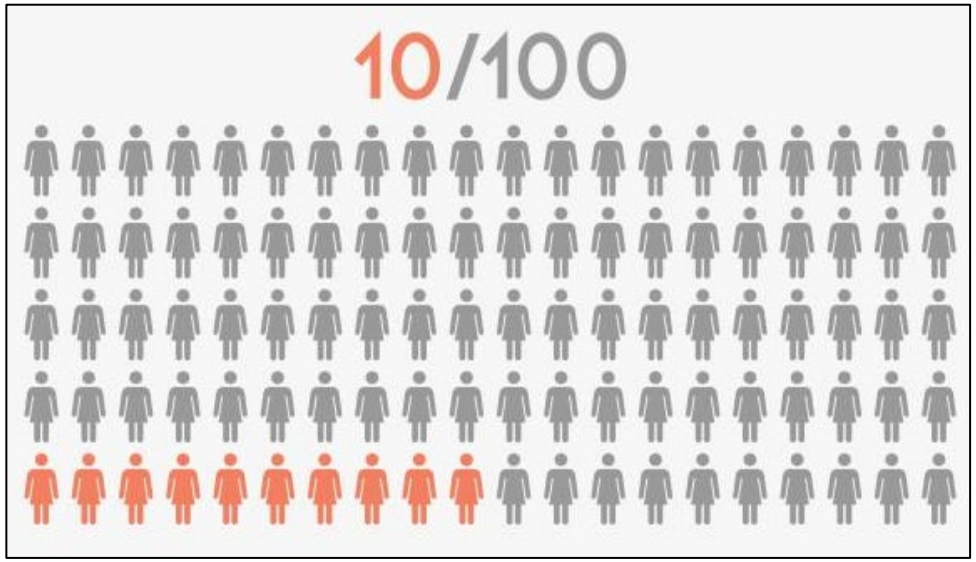
- Thoroughly test all methods of recruitment, plan run throughs with **mock participants** and people unfamiliar with research that **mirror your target population**

- Think through places where participants can be lost:
  - **Phone call messages:**
    - Who is checking them?
    - Who is returning phone calls?
    - When are phone calls being checked?
    - What is the turn-around time for a message to when someone is contacted?
    - Can you allocate some screening time in the evening? Or weekends?
  - **Checking databases and recruitment logistics:**
    - Are there places where participants can get lost?

- You want to get participants when they are most **<u>enthusiastic</u>** about joining the study. Long wait times to be contact can result in loss of participants



Limit the population of people that could be in your study, but are never screened, which can add up over the course of a study timeline



Recruitment in Action

- **Tracking the pipeline:**
  - In staff meetings track the recruitment pipeline at the various levels of the intervention:
    - New contacts
    - Participants in screening
    - Participants in doing baseline Measures
    - Randomizations
  - This might draw attention to times where recruitment is slow or help to identify potential problems

- Understand the **recruitment metrics**:
  - **Contact to randomization ratio** and screening percentages

- Track and adjust to **major screen out percentages**:
  - Update **consort diagram** as you go
  - Run a **report for screen rates** at different levels

- Create recruitment goals and track your progress relative to the goal at each meeting

- **Automate this process** with standardized reports queries from the database
  - (Red Cap has report functions or it can be done with export to statistical software through a custom script)
  - Have a students who has the responsibility of compiling them every week

PREVAIL

All Investigators Meeting, 2-6-19

1. **Pipeline:** Is strong, trying to keep it coming at a reasonable pace, so we can screen folks without them waiting in the pipeline.

   a. **Statistics (Total pipeline)**
      i. 66 Total screens
      ii. 21 total participants in the pipeline
      iii. 6 awaiting phone Screen
      iv. 5 awaiting orientation
      v. 5 currently in run-in
      vi. 2 awaiting baseline testing (2 completing this week)
      vii. 2 complete Baseline

   b. **Major kick outs at web-screen:**
      i. 4.3% Too active
      ii. **60% BMI too high**
      iii. 4.3% Current smoker
      iv. **8.7% weight loss surgery**
      v. **8.7% Other medical conditions**
      vi. 4.3% no email or smartphone
      vii. 4.3% already in weight loss or exercise program

   c. **Demographics of screeners:**
      i. 32% African American, 64% Caucasian **(GOOD)**
      ii. 86% Female **(COULD USE MORE MEN)**
      iii. Orientation obesity class
         1. 0 Overweight
         2. 3 Class I obese
         3. 11 Class II obese
      iv. Trying to get an equal distribution of Class I, Class II and overweight

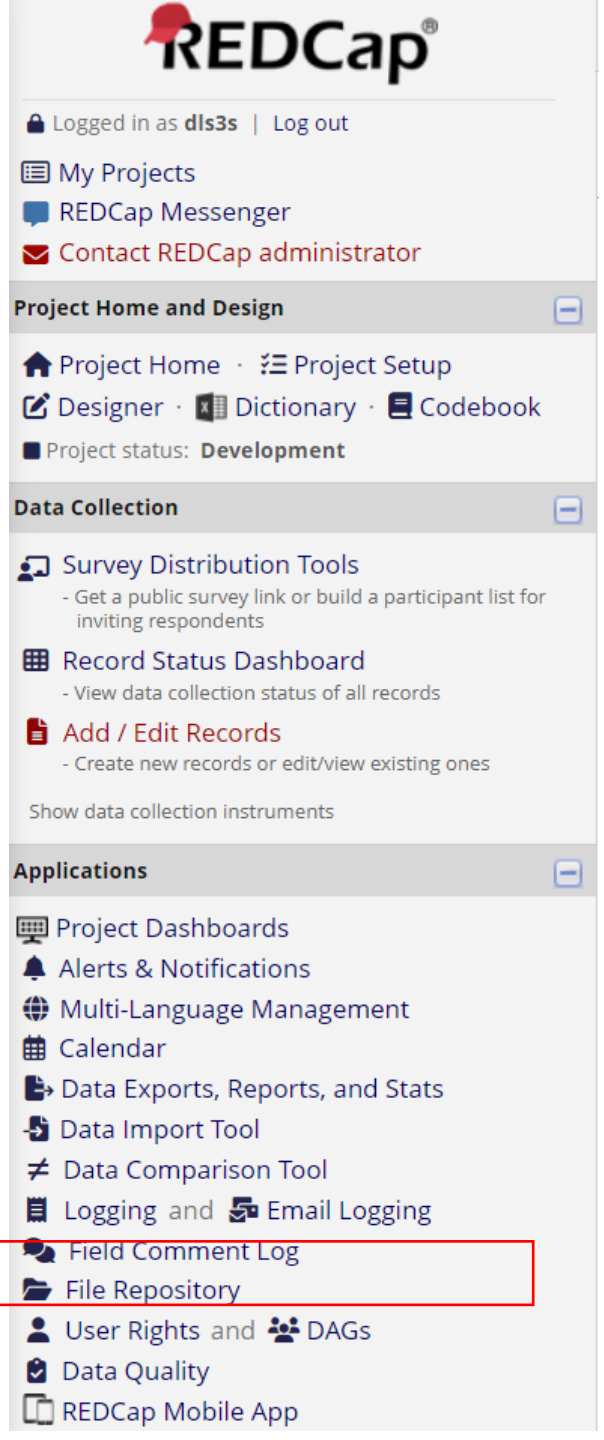
How do you Automate Recruitment Statistics?

- You want to **avoid doing this manually** since that harder it is to do, the less likely they will be run on a regular basis

- **Automation methods**:
  - **Simple: Use Excel**
    - Have pre-programmed calculations
    - Have research assistants enter contacts in the sheet
    - Advantages: Simple, inexpensive, low expertise to create
    - Disadvantages: Very error prone, burdensome to do

  - Use a **report query** from a database:
    - RedCap has a report function which can allow you to pull **specific variable data from recruitment forms**
    - Data pulls directly from data collection instruments
    - Can be customized to your needs
    - Disadvantage: At the current time, you can't incorporate calculations into reports

  - API (**application programming interface)** pull from the database into a **standardized script**



Recruiting **Ethnically Diverse** Individuals for Research

- Recruiting individuals of **racial/ethnic minorities** can be an issue for research trials
- Lower **representation of minorities** in clinical trials reduces the generalizability of results
- Barriers for lower recruitment for racial ethnic minorities:
  - Distrust of medical/researcher personnel
  - Lack of time or financial resources due to other commitments
  - Research information about research studies not reaching them
  - Research "using" ethnic minorities, but not directly benefiting them

Avoid helicopter research

Advice for Recruitment of Racial Ethnic Minorities

- There is no easy fix to bring more minorities into **research studies**
- **Recruitment advice :**
  - Put energy into recruitment for racial ethnic minorities early in the recruitment process instead of the end
  - What does your **recruitment material** look like? Does it look like you're recruiting to include them?
    - Can you create different versions of your materials to include people who are racial/ethnic minorities?
    - Passive forms of recruitment tend to work less well
  - Go to where the target population is
  - Do "service" in those communities even when not asking for them to participate in research
  - Speak to leaders in communities who have connections to help you spread the word about the study
  - Make sure that under-represented minorities in your study have a good experience

NIH Training around Health Disparities

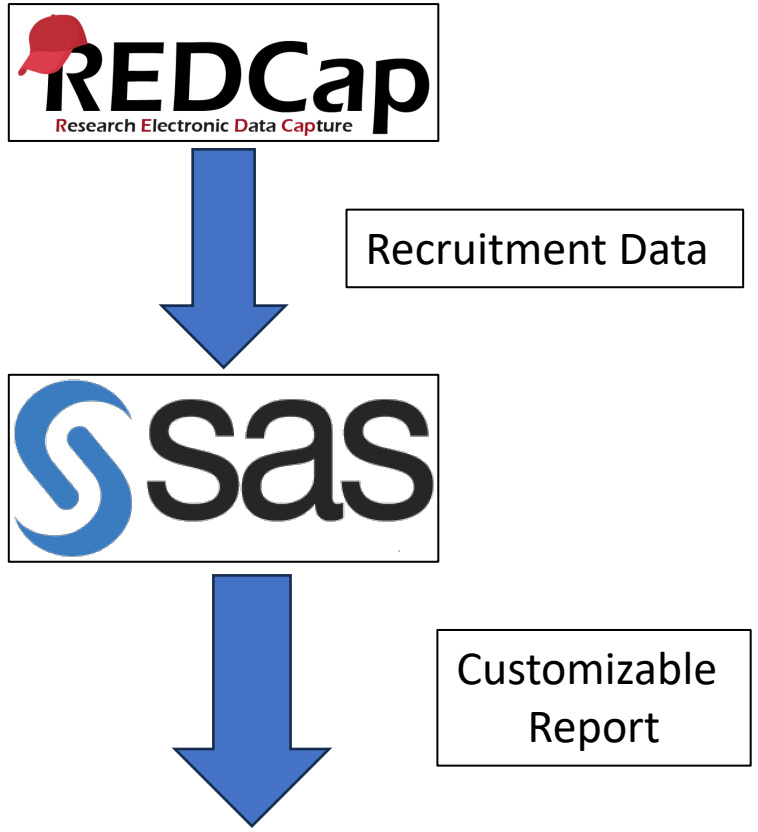
Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE)

The Programs to Increase Diversity among Individuals Engaged in Health-Related Research (PRIDE) is an all-expense-paid Summer Institute, research education, and mentoring initiative sponsored by the National Heart, Lung, and Blood Institute (NHLBI). This initiative addresses the difficulties experienced by junior investigators and transitioning postdoctoral scientists in establishing independent academic research careers and negotiating through the academic ranks.

https://www.nhlbi.nih.gov/grants-and-training/training-and-career-development/diversity/pride

Examples of Tracking the Recruitment Process

- **Application Programming Interface (API)**
  - Recruitment data (or any study data) can be exported directly into a statistical program and **customizable reports** can be created
  - **Advantages:**
    - Customizable reports exactly to your study needs
    - Can be run by the PI, coordinators, or research staff to see real-time statistics
  - **Disadvantages:**
    - Takes some **programing expertise, trouble shooting, and testing**. However, once it is done is saves a lot of time
    - Dependent on how the data is entered in the database and timeliness of data entry



PREVAIL Study: Summarized Locations of Participants

The FREQ Procedure

location	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1. In Screeing	17	47.22	17	47.22
2. Weight Loss Phase	1	2.78	18	50.00
3. Dropped during Weight Loss Phase	1	2.78	19	52.78
4. Did not make Weight	3	8.33	22	61.11
5. Weight Maintenance Phase	14	38.89	36	100.00

Summary of the Recruitment Process

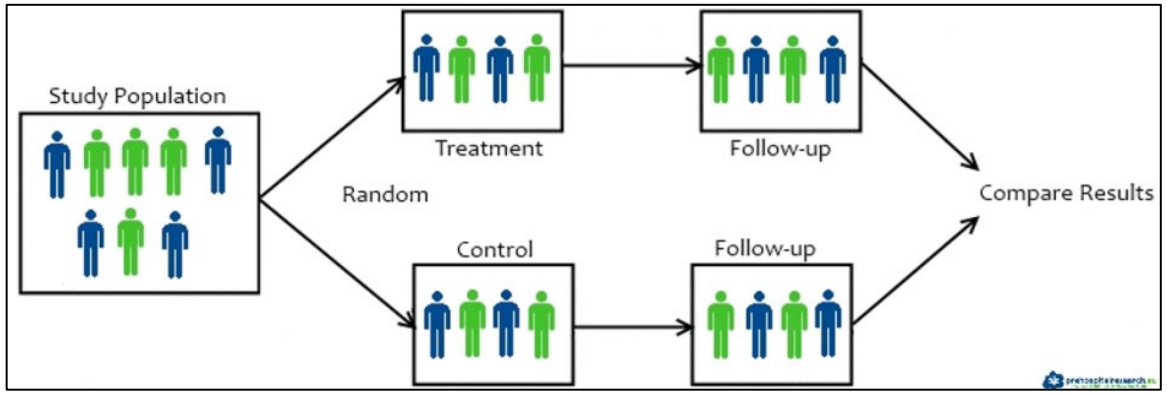
- You need to have a **standing study meeting, where recruitment is discussed on a regular basis**

- **What do you want to track?**
  - How many people are in the pipeline?
  - Ratio of contacts to randomization
  - Distribution of recruitment goals in respect to race, ethnicity (or other aprori study design), and sex

- **What are things you want to analyze?**
  - What are the **bottle necks** in recruitment?
  - How long are people taking to get through the pipeline to get to randomization?
  - Does the recruitment match the goals you outlined in terms of demographics? If not, where are the problems?
  - How is your pace **relative to goals**?

Randomization Process

- Randomization process should be discussed with your **statistician**
- Randomization should occur after the collection of **all outcome measures**
- Blind the **randomization process**:
  - Nobody on the **intervention team** or those assessing **outcome measures** should have advanced knowledge of participant randomization
    - Approaches:
      - Statistician can hold randomization list
      - Person without involvement in the study protocol and randomization request is only given after outcomes measures are completed



Efficacy-based Physical Activity Trials

- In many efficacy-based studies, you are trying to hit specific levels of **compliance** or **adherence** to physical activity level
  - Examples?

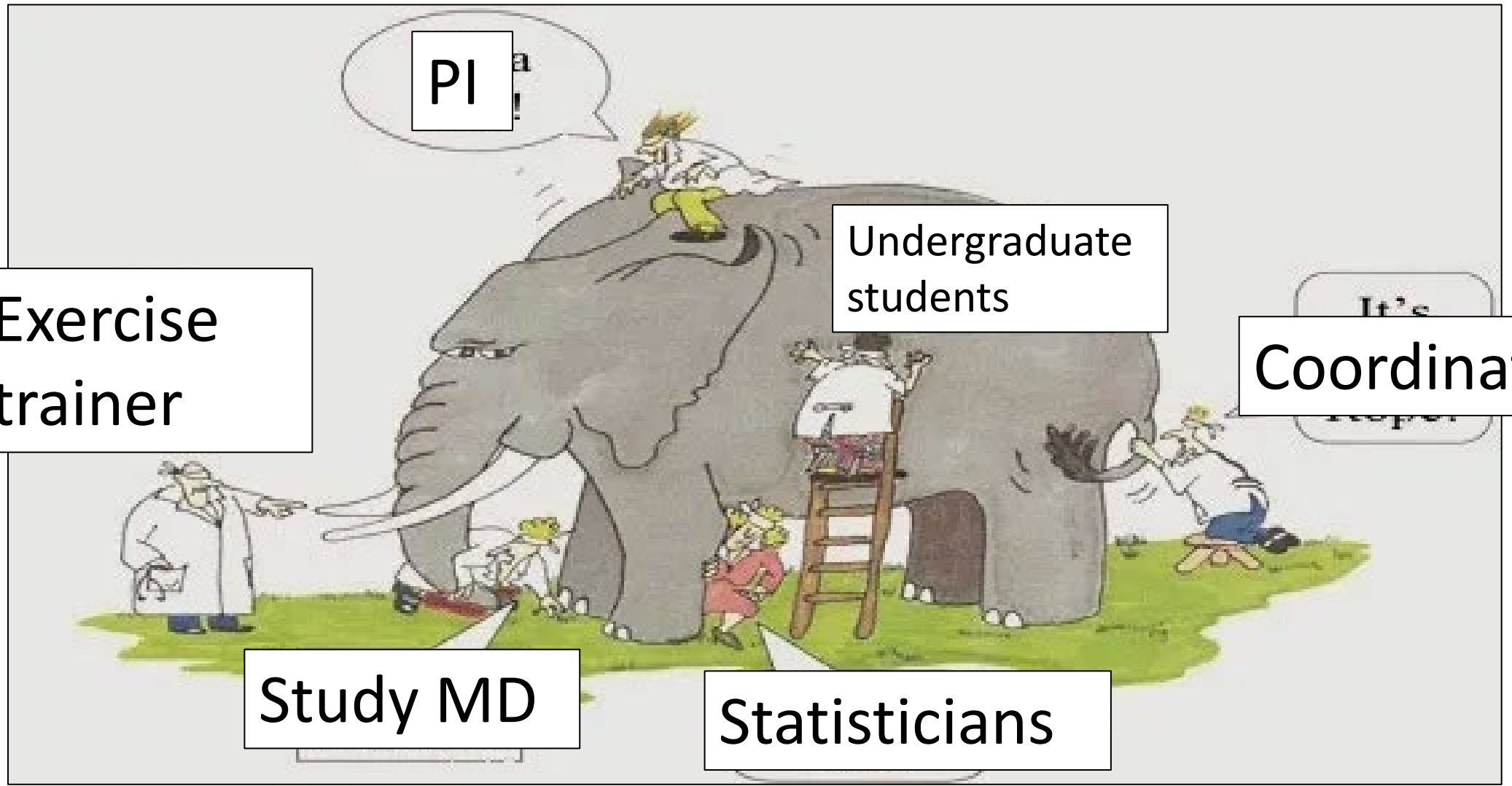
- Tracking and making sure the levels of physical activity during the intervention is critical in making sure participants meet the level needed

- Best practices for efficacy-based physical activity interventions:
  - Be able to quantify the PA levels of participants throughout the intervention
  - Regularly monitor the levels of PA in all participants at study meetings
  - Have contingency plans for when participants do not meet their required amount of physical activity

Advice for Running Clinical Trial Meetings During the Intervention

- It is **critical** to have a weekly staff meeting when running a **physical activity intervention**
- In regard to intervention fidelity, it allows you to:
  - Check the quality of the data
  - Problem-solve specific participant issues
  - Identify participants that might have low adherence level or high drop-out risk and proactively respond
- Create an environment that encourages discussion!

Your Team will See the Study from a Different Perspective…



From those different perspectives, there may be different factors that can inform decision making…

PI		Clinical Coordinators	Study MD
Publishability of data		How feasible is an idea?	How does a decision impact safety?
Future grants		How does this decision affect logistics?	How does a decision impact health measures?
Scientific integrity			
Leadership and team motivation			

If you make a decision without all the information, this will reduce your chance of making the best decision

Management of Physical Activity Intervention Data

- As the PI you need to have your finger on the **pulse** of the intervention
  - When you delegate: “Delegate with supervision”
- In efficacy-based trials, you are trying to obtain **specific goals** for physical activity, so you need to be aware of the participants PA levels throughout
- Think about what you’re going to be **judged on during publication** (e.g., what is in Table 2 intervention statistics) process to determine what variables to track

Table 2. Key aspects about your intervention

Are you trying to control specific variables?

Exercise amount, intensity, compliance

You need a way to track them, which ones would you report in your final paper

What defines success for your physical activity study?

Exercise Trial:
Comparison of 16 weeks of supervised moderate vs. high intensity exercise on insulin sensitivity

What data should we **track** in these participants as we're running the intervention from the database?

Categorically meeting their exercise intensity?

Total exercise time in each groups

HR

Mean Ex Intensity levels

Exercise progression

RPE

Your Topics….

- What are key variables to plan for to insure intervention fidelity…
- What are the factors that your peers will judge you on for publication?

Research Proposal Title
Translational Research to Accelerate Interventions for Fetal Alcohol Spectrum Disorders: Evaluation of Physical Activity at Basic and Clinical Levels
Exploring the influence of identity on adolescent physical activity behavior
Reducing Inactivity, Sedentarism, and Underactivity with Physical Activity Snacks (RISEUP Study)
Does increasing muscular fitness lead to increases in cardiorespiratory fitness in children?
Advancing smoking cessation and physical activity among Latinos

Tracking PA/Exercise in Clinical Trials

- Regular weekly study meetings are essential to monitoring **all phases of the clinical trial**

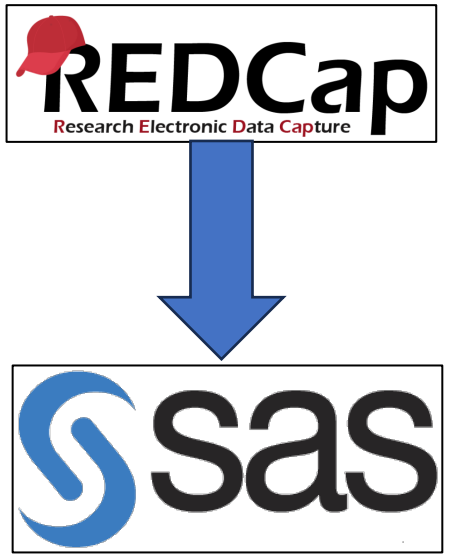
- Dedicate a portion of your meeting to discussing each participant and whether they are meeting specific goals of the intervention:
  - Are they coming in the exercise (Percentage of attendance)
  - What percentage of the PA goals are they meeting (percentage, quantitative)
  - Are they compliant to PA goals from a categorical perspective? Meeting PA guidelines
    - Examples:
      - ≥ 10,000 steps per day (Yes or No)
      - ≥ 150 minutes of moderate PA (Yes or No)

- Look at these variables within **each participant** and the **study overall** and mirror the expected publication table as much as possible

- Find opportunities to **automate** this process within a database, so you can see real-time statistics of participants in the intervention and you're not using staff time

Examples of Tracking from Efficacy based Clinical Trials

- You want to be able to easily track **major intervention quality** data that is associated with your study
- When possible, **exporting and automatically running this data** makes tracking these values easier and reduces staff burden/time
- Running these measures should be a central focus of each intervention meeting
- What does this allow you to do in terms of better managing the trial?



Tracking Example of an Exercise Intensity Trial (High Intensity Group)

ID	Week	ACROSTIC	Attendance (%)	Adherence (%)	Intensity (%VO_2 max)	Compliant to exercise level	Compliant to intensity?
049	5	SWIDA	95.2%	85.0%	72.0%	Yes	Yes
045	6	JOHDA	72.5%	70.1%	70.1%	Yes	Yes
039	6	JAIRA	95.2%	90.1%	68.7%	Yes	Yes
031	8	PENVA	82.5	92.1%	50.7%	Yes	No
026	10	SALVA	96.0%	92.6%	80.2	Yes	Yes
021	11	FREDA	100.0%	100.0%	75.0%	Yes	Yes
017	11	TAVLA	92.0%	92.3%	60.0%	Yes	No
Mean			90.49%	88.89%	68.1%	100.0%	71.4%

Which participants would you offer support to or check with your team about?

Which participants is **meeting compliance levels** that you are nervous about?

ID	Week	ACROSTIC	Attendance (%)	Adherence (%)	Intensity (%VO_2 max)	Compliant to exercise level	Compliant to intensity?
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017	11	TAVLA	92.0%	92.3%	60.0%	Yes	No
Mean			**90.49%**	**88.89%**	**68.1%**	**100.0%**	**71.4%**

Do the mean statistics match what you want to publish on?

If not, what actions can your team do to fix the problems….

Tracking in Trials that are accelerometer based

- Other tracking approaches that may be considered for accelerometer-based trials:
  - Consider at **database program** to make sure you have usable data:
    - Non-wear time (can be done in database system) like CentrePoint
    - Watching to make sure that the data is actually coming in and saved in the system
    - You can also monitor charge status of accelerometers that are in the study
  - If you cannot afford a database program, have a student sum up the percentage of usable data at each study meeting to assure no data loss

Tracking Outcome Measures

- What do you want to track in terms of **outcome measures**?
- What percent of the measurements have you obtained per protocol from a quantitative perspective (%)?
- Are there any ongoing problems that are affecting the:
  - Quality of the data collection
  - Creating bottle necks for participants
  - Causing failure/repeating of outcome measures?
- Loss of acceptable outcome measures can reduce statistical power
- Quantitatively, discussing data allows you not to ignore significant problems affecting study quality

Moderate Intensity Group (N=13)	
Acrostic	Obtained per protocol
Weight	100.0%
DEXA	100.0%
SF-36	100.0%
Flow mediated dilation	**70.2%**
Muscle Biopsy	87.1%
Food Frequency questionnaire	**68.3%**

High Intensity Group (N=14)	
Acrostic	Obtained per protocol
Weight	100.0%
DEXA	97.8%
SF-36	100.0%
Flow mediated dilation	**74.2%**
Muscle Biopsy	92.1%
Food Frequency questionnaire	**66.3%**

Retention Plan for Clinical Trials- What should be in it?

- Think about retention planning from recruitment as opposed to after the participants randomizes

- Maximizing **retention** during the **screening process**
  - Screening for available time to participate in the study
  - For supervised studies,
  - Ask about barriers to meeting study goals
  - Run in period to test participants ability to come to research visits

- Specific plan on what to do if a person is at high risk for drop out:
  - What specific action will your team take if retention falls below a specific level?

High Retention during Trials

- Retention should be **proactive** as opposed to **reactive, and starts with study planning:**
  - Is the PA intervention you're devising feasible?
  - Have you given participants reasonable options and flexibility for completing exercise and the trial
  - What are some planned activities you or your team can do to prevent drop out or compliance?

- During the intervention talk down participants "behavioral status" and identify participants who may need support

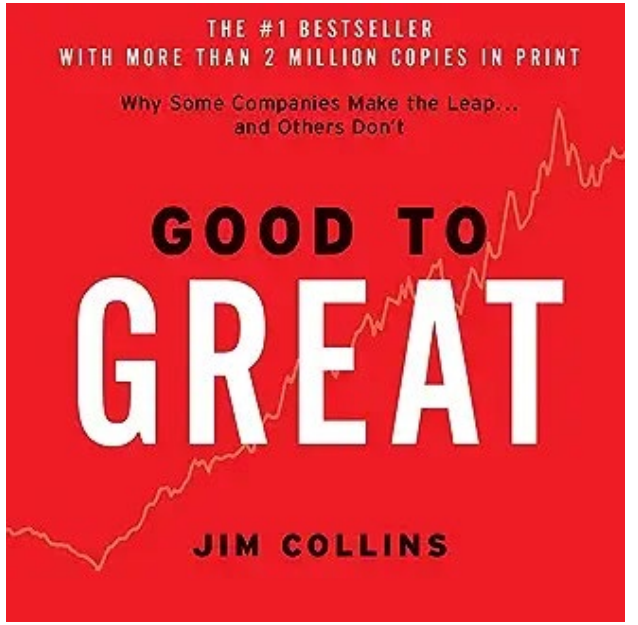
- Remember the "**good**" participants

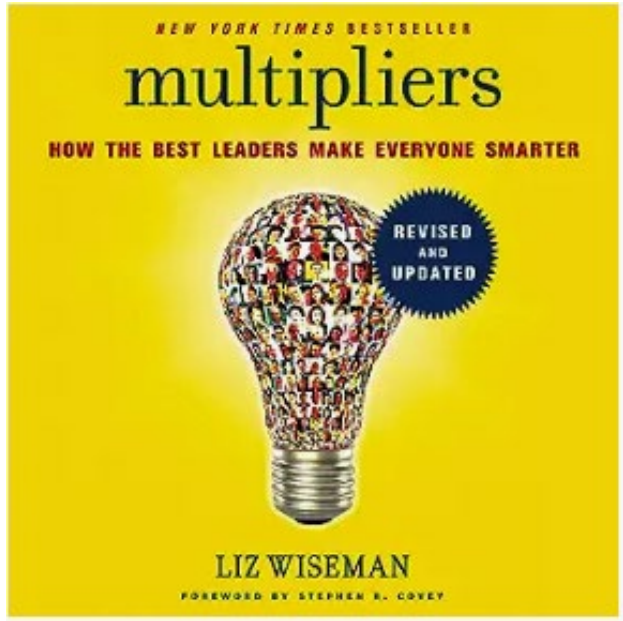
- **Things that we do:**
  - Acknowledge participant birthdays or major life events
  - Intervention games (e.g., staff 2 truths and a lie, trivia)
  - When appropriate show participants their PA data
  - Focus on limiting the time in the fitness center or during clinical visit
  - Small incentive items that show appreciation

Don’t treat your participants like a mouse on a preverbal treadmill

Leadership of Team from an Early Career Perspective

- Learn about **leadership**:
  - There are many good tests about general **business principles of leadership** and **project management:**
  - **My favorites:**
    - Good to Great, Great by Choice (Jim Collins)
    - Multipliers (Greg McKeown and Liz Wiseman)
    - SCRUM (Jeff Sutherland)
    - Entreleadership (Dave Ramsey)
- Observe **good leaders** and see what makes them **successful**





Early Career Training Programs to Increase Clinical Trials and Research Knowledge

- Clinical Trials: NIH Summer Institute on Clinical Trials
- Epidemiology: Ten-Day Seminar on the Epidemiology and Prevention of Cardiovascular Disease and Stroke
- Health Disparities: Programs to Increase Diversity Among Individuals Engaged in Health-Related Research (PRIDE)
- m-Health: m-health Training Institute

- AHA EPI/Lifestyle: Early career Committee and Events
- AHA- Physical Activity Committee- Service opportunities


Questions?