**Background**

* Writing a Grant for a Exercise & Nutrition Study
* Interested in a Treatment for Hypertensions (High Blood Pressure)
  + Targeting a decrease in Sodium Intake (which has been shown to produce better health outcomes in general, especially for disadvantaged populations)
  + Implementing a Mobile Phone Application Behavioral intervention to make participants more cognizant of / lower than general Sodium intake
  + Proprietary
* The idea is that making an individual more cognizant of the sodium intake may be able to lower their blood pressure over time
* Systolic BP is more reliable than Diastolic, so this is the primary outcome for this study

**Study Design -- Researcher is interested in a bit of advice on this**

* Blood Pressure Device worn for 24 hours at three different time points
  + Baseline, 4 weeks later, and 12 weeks later
  + The mean BP during this 24hour span is what is recorded for each time point
    - For typical range, defer to paper from PI
  + Activity specifications are not made for the day participants are asked to wear the BP monitoring device
  + Outliers assessed on the basis of what is physically possible
* Initially just interested in a proof of concept
  + *Mainly Interested in the BP difference between baseline & 4 weeks*
  + Wanted longer time point just for data collection purposes & may be interested in this later on
* Primary outcome of Interest: Blood Pressure difference between Baseline and 4 weeks
* Everyone receives roughly the same intervention / notifications from this mobile application
* Ongoing enrollment
  + Will stop enrolling participants when the desired sample size has been met, or when the grant funding runs out after 2 years
  + May be able to expand to recruiting from other clinics if sample size is not met

**Description of the Data**

* Preliminary Data does NOT have any intervention included
* Variables included in Preliminary Data (each are a column)
  + Age (Continuous)
  + Sex (M/F)
  + Systolic BP (at time points 0, 4, and 12 weeks)
  + Proxy Variable for NA+ (Sodium) intake at Baseline
    - This is a Score obtained as a result of summing various survey questions
    - A higher score indicates a higher sodium intake
      * Very rough estimate
* Each row is a participant (good!)
* May see incomplete data as a Loss of Follow-up after the 4 week mark
  + Brainstorm ways of dealing with / mitigating this

**Anticipated Sample Size / Study Population**

* Anticipating 10% Dropout Rate (Conservative Estimate)
  + Occasional issues with reading, but rare enough to not consider in Sample Size Calculations
  + May be able to expend a bit of Energy to lower this drop out rate
* Interested in a Sample Size calculation based on
  + Detectable Difference in Systolic BP: 5 mmHg (millimeters of Mercury -- standard measurement for Blood Pressure)
  + Power: Desire 90% (willing to discuss sample size enrollment)
  + Standard Deviation -- may be able to use the one from the reference paper
  + Alpha = 0.05
  + Maintain a 2-sided study
* Preliminary Data has 315 Subjects
  + Participants will come from the same clinic as the preliminary data subjects
* Everyone has been diagnosed with “mild hypertension”
  + PI will return to us with how this is defined
* Exclusion Criteria: Can’t be on any medications for hypertension, age restriction will be the same as the preliminary data (adults)

**Hypotheses**

The following study questions will be evaluating in this study:

Do Behavioral Health Interventions aimed at lowering an individual’s Sodium intake have ***an effect*** on Systolic Blood pressure over time? If so, ***by how much*** does an individual’s Systolic Blood Pressure change?

* Overall, interested in studying the effects of this app on hypertension
  + Does it decrease over time, and if so, by how much?
  + Interested in the aggregate effect
* Two-Way Test
  + Just want to know the impact of the app on Blood Pressure (increase OR decrease)
* Not interested in the effects of Age & Sex on BP

**Timeline/ Expectations**

* Currently no funding for Statistical Support, but writing this into the grant proposal
* 2 page report
  + Sample Size Calculations
  + Description of Preliminary Data
  + Analysis Plan for the Final Study
  + Sentence or two describing the general relationship with BP over time
    - Accounting for the effects of Behavioral Interventions to lower NA+ intake
  + Visualize Options for the Anticipated Dropout Rate & this effect on Power & Sample Size Calculations
* Want the ability to cut & paste Power & Sample size information direction into the grant
  + In addition to a test that goes with the design of the study

**Long Term Context**

* If there is a relationship between these Behavioral Interventions & lower Systolic Blood Pressure, this would provide grounds for the study long term
* Next Step: Phase 3 Trial
  + Controlled Environment to ultimately determine if this is effective or not
  + Can demonstrate this intervention truly does work
* Eventually may be able to implement as a potential treatment option on the market
* Eventually also want to be able to generalize this