Biofeedback Pilot Data Report and Recommendations

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About the Pilot

- Participants of the pilot used the Heartmath app for approximately 5 minutes on up to 3 occasions, between November 4, 2019 and December 19, 2019.
- Participants completed a survey 3 timepoints.
- Data were recorded for 10 Participants at baseline (11/4/2019), 6 participants at midpoint (11/18/2019 or 11/26/19) and 2 participants at endpoint (12/19/2019).
- Additionally, 2 of focus groups were conducted before the pilot started, 1 focus group was conducted during the pilot, and 1 focus group was conducted at the end of the pilot.

Background

Goal of Pilot: To assess the feasibility of implementing a biofeedback breathing program in the setting of a local county jail.

Reason for Pilot: The goal of the pilot was to take proven, evidence-based technology that has been shown to improve the health of clients autonomic nervous systems, and test how feasible it is to successfully use this technology to create access for people who are currently incarcerated in our local county detention center. This technology has never before been offered in this setting before.

Hypothesis: We believe that providing biofeedback breathing training for people currently incarcerated in the Edgecombe County Detention Center will lead to a measurable improvement in the health of the autonomic nervous systems of the participants, which will lead to less stress and anxiety, and a more balanced nervous system.

Description of Participants:

- All of the participants were men between the ages of 27 and 56 (average age: 36.7).
- The overall population of the Edgecombe County Detention Center is on average over 90% male

Background

History of Edgecombe County: Our community has a long history of resilience and justice and this pilot sought to build on these long-standing assets. Our county is home to first town (Princeville) that was settled by freed slaves after the Civil War and is the first place that Dr. Martin Luther King Jr. delivered his famous “I Have A Dream” speech. We are inspired by the leaders who have been, are here, and will continue to be here, who fight for healing & connection, instead of punishment & isolation.

Pilot Setting: Biofeedback was identified as an intervention that can help strengthen people’s autonomic nervous system, which can become impacted through overexposure to toxic stress & trauma. Our community identified trauma/ACEs as a root cause of:

1) poor health outcomes (98 out of 100 NC counties, Health Outcomes)*
2) high risk behaviors (95 out of 100 NC counties, Juvenile Detention Admission Ranking)**
3) high poverty and hopelessness (99 out of 100 NC counties, Social & Economic Factors)*

*source: Robert Wood Johnson Foundation 2017 County Health Rankings
**source: Roadmap of Need 2018 PSF of NC

Quantitative Data Measurements

- **Normalized Coherence** (the state in which heart rate variability, blood pressure rhythm, and respiration rhythm are in sync)
- **Mean Heart Rate**
- **# of RR intervals** (The RR interval is the time between heart beats)
- **Mean Inter Beat Interval** (Average time interval between consecutive heart beats)
- **SDNN** (Standard deviation of inter beat intervals of normal sinus beats; a measure of variability in heart rate)
- **RMSSD** (Root mean square of successive differences between normal heartbeats; reflects beat-to-beat variance in heart rate)
- Heart Rate oscillations are divided into frequency bands including:
  - **Very Low Frequency** (HR rhythms with periods between 25 and 300 seconds)
  - **Low Frequency** (HR rhythms with periods between 7 and 25 seconds affected by breathing from ~3 to 9 bpm)
  - **High Frequency** (HR rhythms affected by breathing from 9 to 25 bpm
- **Low Frequency/High Frequency Ratio** (Estimates the ratio between the sympathetic and parasympathetic nervous system activity under controlled conditions)
- **Total Power** (The sum of energy for the Very Low Frequency, Low Frequency, and High Frequency for the recording)

Movement in Quantitative Data Measurements

- Due to the low sample size, we found no clear trend in many of the quantitative data measures.

- We did see movement in the data measurements below, though it is very important to remember, that due to the small sample size, this could be due to random chance. Measures that showed movement:

    1. # of RR Intervals, increased from baseline to endpoint
    2. SDNN, increased from baseline to endpoint
    3. Measure: RMSSD, increased from baseline to endpoint
    4. Very Low Frequency (VLF), decreased from baseline to endpoint

- These measures are explained in more detail over the following four slides.

Movement in Quantitative Data Measurements

1. Measure: # of RR Intervals

   Change: Increased from baseline to endpoint

   Explanation of Measure: This measure depicts the space between the heart beat. An increase of space between heartbeats signals to our autonomic nervous system that we are safe, can let our guard down, and begin to “rest and digest.”

   Impact: A calmer, more relaxed person, who has less stress chemicals (adrenaline, cortisol) pumping through their body.

of RR Intervals

Including All Participants

Baseline Average (n=10): 386.3; sd=50.94

Midpoint Average (n=6): 379.6; sd=46.36

Endpoint Average (n=2): 416; sd=49.50

Interpretation: **Measures increased from baseline to endpoint, but this could be due to random chance**

*sd = standard deviation

Participants Who Completed All Measures (n=2)

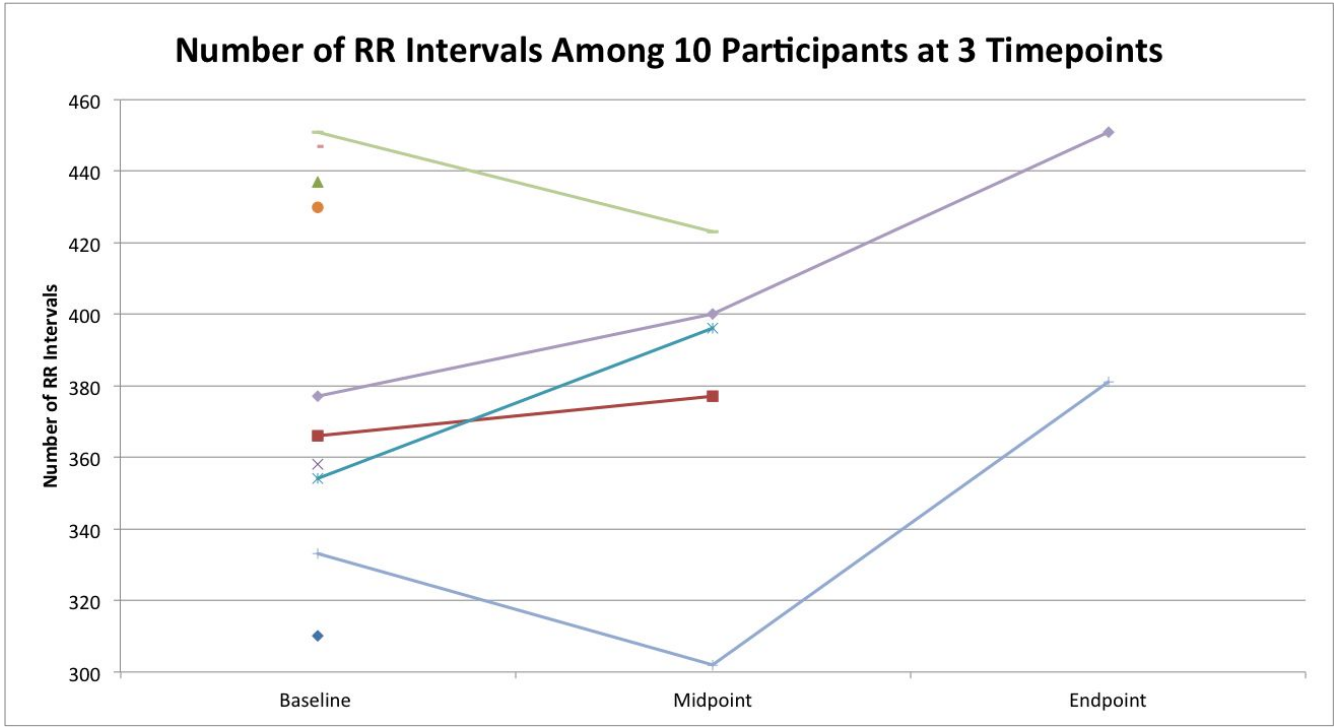
Baseline Average: 355; sd=31.11

Midpoint Average: 351; sd=69.29

Endpoint Average: 416; sd=49.50

Interpretation: **No clear trend**

of RR Intervals



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see an increased number of RR intervals.

Analysis of all participants (n=10) shows an increase from baseline to endpoint, though this finding is not statistically significant.

Movement in Quantitative Data Measurements

2. Measure: SDNN

   Change: Increased from baseline to endpoint

   Explanation of Measure: SDNN is a measure of variability in heart rate and shows sympathetic activity in the nervous system. The sympathetic nervous system directs the body's rapid involuntary response to dangerous or stressful situations. A flash flood of hormones boosts the body's alertness and heart rate, sending extra blood to the muscles. An increase in SDNN shows that the time between heart beats is longer.

   Impact: A calmer, more relaxed person.

SDNN (The standard deviation of NN intervals)

Including All Participants

Baseline Average (n=10): 51.76; sd=10.41

Midpoint Average (n=6): 52.98; sd=19.30

Endpoint Average (n=2): 59.35; sd=8.41

Interpretation: **Measures increased from baseline to endpoint, but this could be due to random chance**

Participants Who Completed All Measures (n=2)

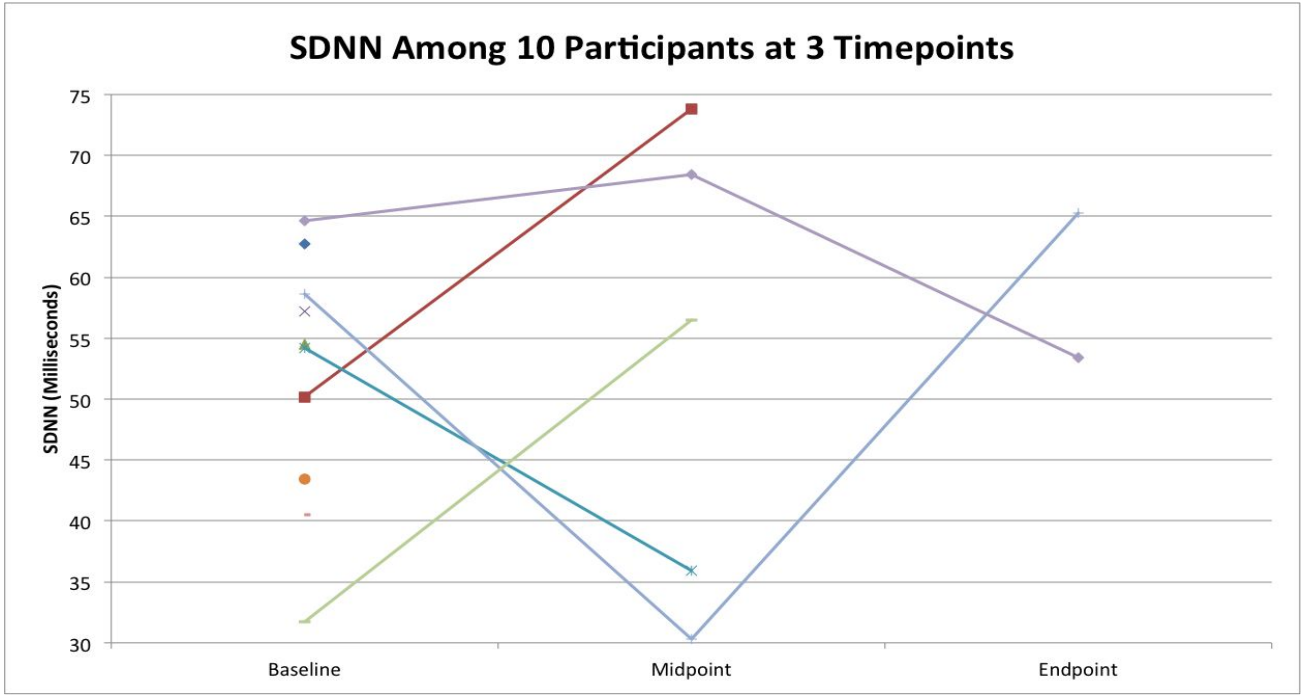
Baseline Average: 61.6; sd=4.24

Midpoint Average: 49.35; sd=26.94

Endpoint Average: 59.35; sd=8.41

Interpretation: **No clear trend**

SDNN (The standard deviation of NN intervals)



As a result of the biofeedback sessions, we would expect to see a increase in the standard deviation of NN intervals.

Analysis of all participants (n=10) shows an increase from baseline to endpoint, though this finding is not statistically significant.

**Each line, and the corresponding data point(s), represents a unique participant*

Movement in Quantitative Data Measurements

3. Measure: RMSSD

   Change: Increased from baseline to endpoint

   Explanation of Measure: RMSSD reflects beat-to-beat variance in heart rate and shows parasympathetic activity in your nervous system. Sometimes called the rest and digest system, the parasympathetic system conserves energy as it slows the heart rate, increases intestinal and gland activity, and relaxes muscles in the gastrointestinal tract. One goal of this pilot is to strengthen that system. An increase in this measures shows a strengthening of the parasympathetic system.

   Impact: A person whose nervous system has the ability to respond more quickly and more effectively to stressful situations and who can return to a place of calm and balance after being stressed.

RMSSD (Root Mean Square of the Successive Differences)

Including All Participants

Baseline Average (n=10): 42.94; sd=14.82

Midpoint Average (n=6): 49.68; sd=25.49

Endpoint Average (n=2): 63.95; sd=18.88

Interpretation: **Measures increased from baseline to endpoint, but this could be due to random chance**

Participants Who Completed All Measures (n=2)

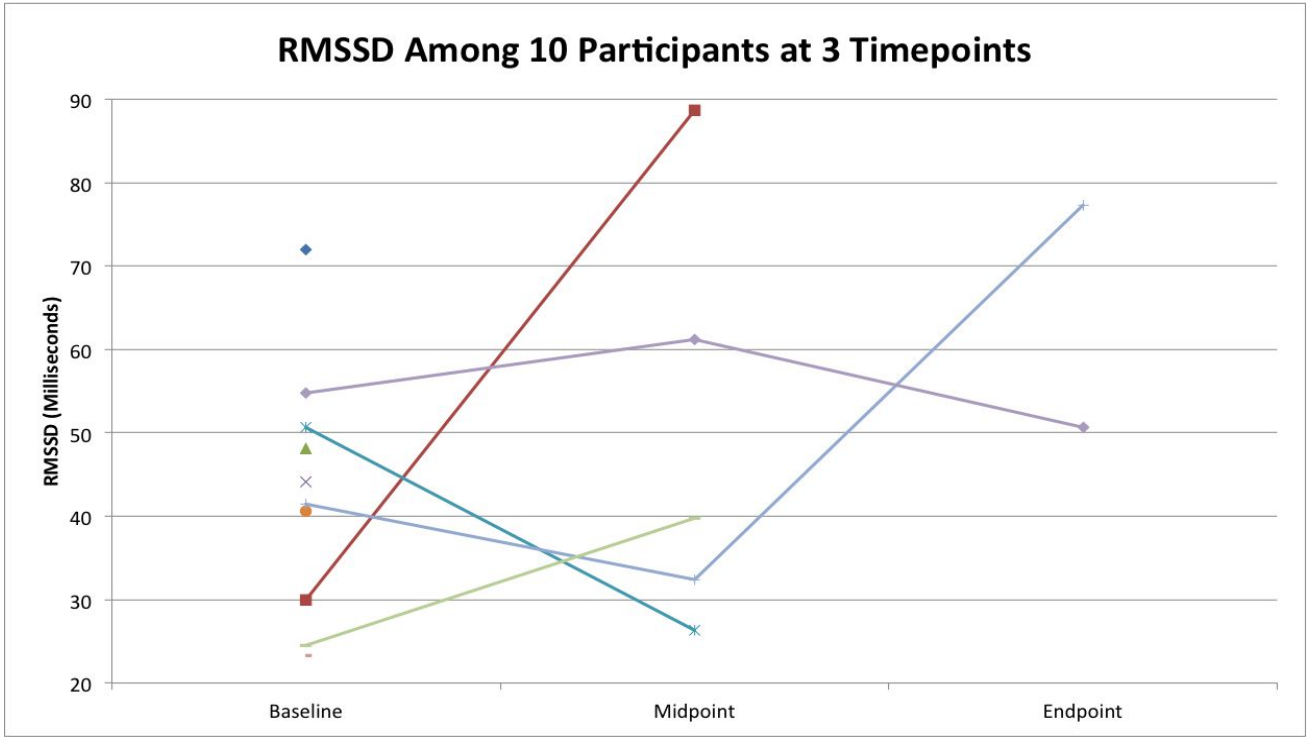
Baseline Average: 48.1; sd=9.48

Midpoint Average: 46.8; sd=20.36

Endpoint Average: 63.95; sd=18.88

Interpretation: **No clear trend**

RMSSD (Root Mean Square of the Successive Differences)



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a increase in the root mean square of the successive differences.

Analysis of all participants (n=10) shows an increase from baseline to endpoint, though this finding is not statistically significant.

Movement in Quantitative Data Measurements

4. Measure: Very Low Frequency (VLF)

   Change: Decreased from baseline to endpoint

   Explanation of Measure: This is another measure that shows sympathetic activity in the nervous system, which is the system that gets activated and involuntarily responds to dangerous or stressful situations. The more this system is activated, the more stress hormones pump through the body.

   Impact: A person whose nervous system spends less time being activated into the sympathetic response (fight, flight, freeze) and, as a result, is healthier, calmer, and more balanced.

Very Low Frequency

Including All Participants

Baseline Average (n=10): 237.21; sd=131.13

Midpoint Average (n=6): 219.8; sd= 196.80

Endpoint Average (n=2): 133.65; sd=14.21

Interpretation: **VLF measures decreased from baseline to endpoint, but this could be due to random chance**

Participants Who Completed All Measures (n=2)

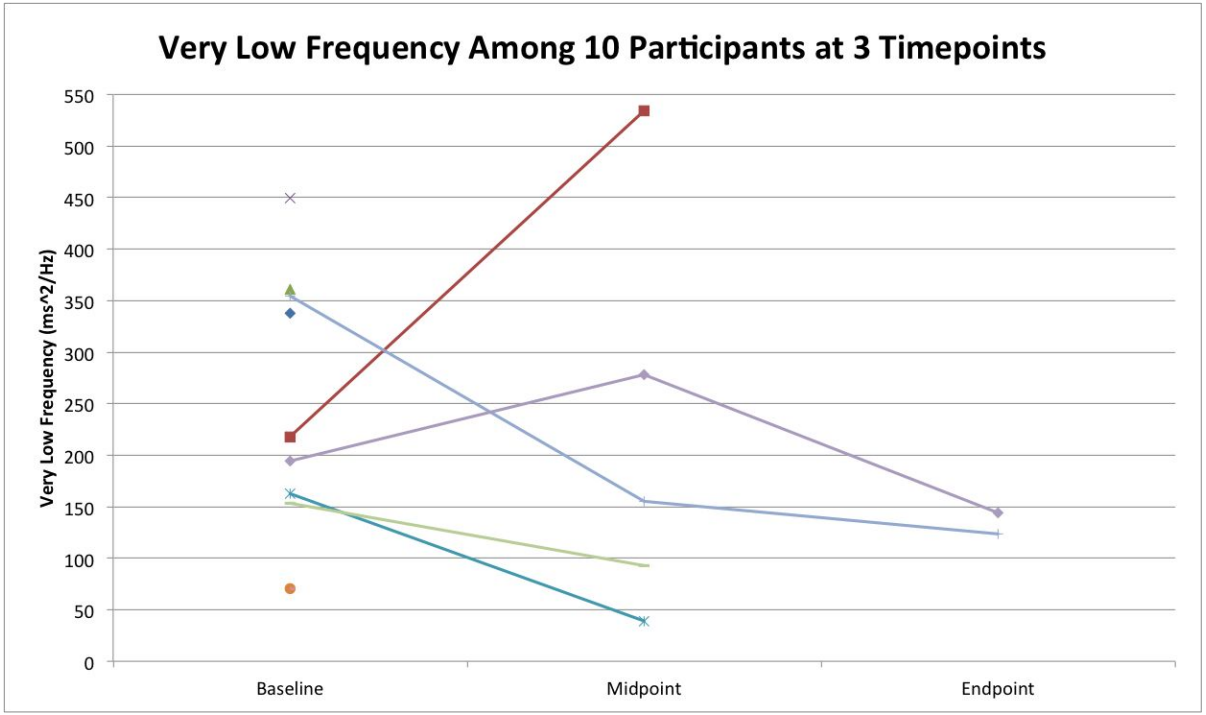
Baseline Average: 274.25; sd= 113.49

Midpoint Average: 216.65; sd=86.76

Endpoint Average: 133.65; sd=14.21

Interpretation: **VLF measures decreased from baseline to endpoint, but this could be due to random chance**

Very Low Frequency



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a decrease in very low frequency.

Analysis of all participants (n=10) shows a decrease from baseline to endpoint, though this finding is not statistically significant.

Inconclusive Quantitative Data Measurements

The following slides provide analysis and interpretation of measures that showed no clear trend. More detailed data analysis and graphical representation can be seen for the following measures:

- Normalized Coherence
- Mean Heart Rate
- Mean Inter Beat Intervals
- Low Frequency
- High Frequency
- Low Frequency/High Frequency Ratio
- Total Power

Normalized Coherence

Including All Participants

Baseline Average (n=10): 37.93%; sd=4.15

Midpoint Average (n=6): 43.36%; sd=10.42

Endpoint Average (n=2): 38.3%; sd=0.71

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

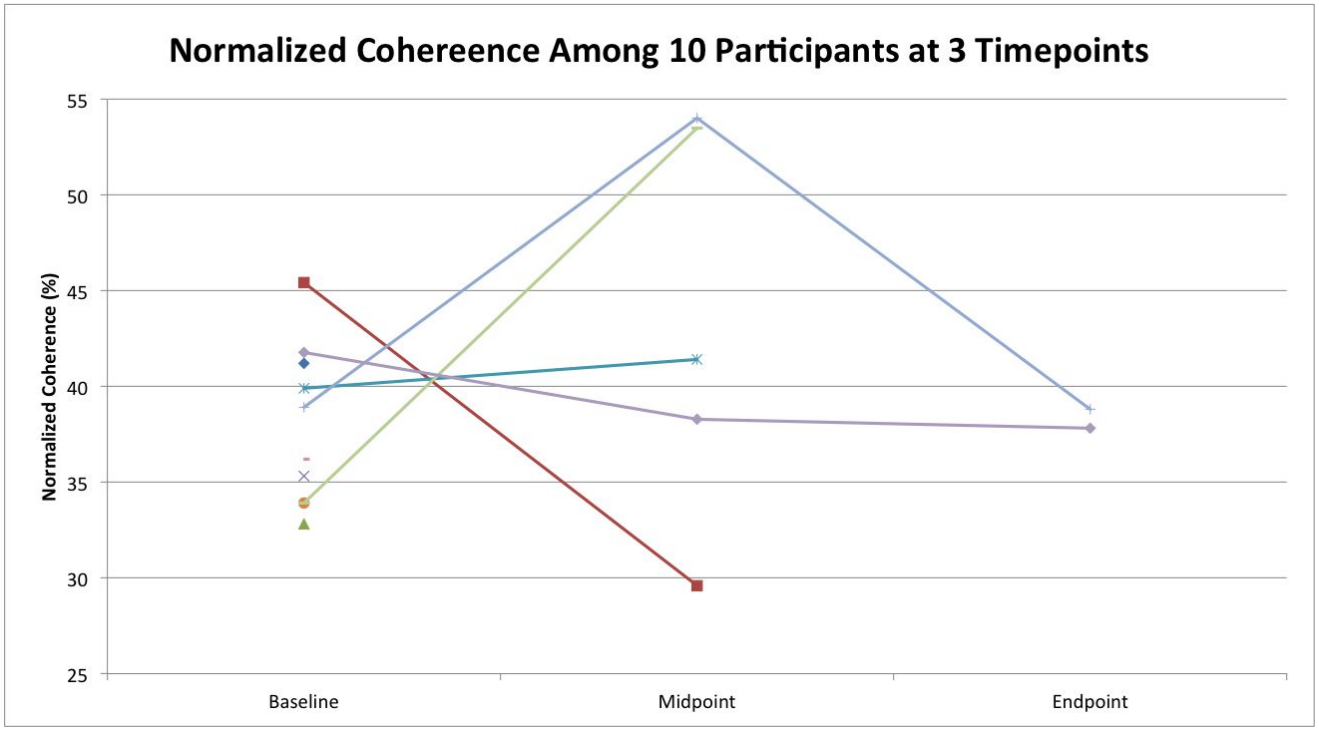
Baseline Average: 40.35%; sd=2.05

Midpoint Average: 46.15%; sd=11.10

Endpoint Average: 38.3%; sd=0.71

Interpretation: **No clear trend**

Normalized Coherence



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see an increased rate of normalized coherence.

Analysis of all participants (n=10) shows no clear trend.

Mean Heart Rate

Including All Participants

Baseline Average (n=10): 77.18; sd= 10.52

Midpoint Average (n=6): 76.7; sd=9.46

Endpoint Average (n=2): 83.85; sd=10.25

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

Baseline Average: 71.79; sd=6.43

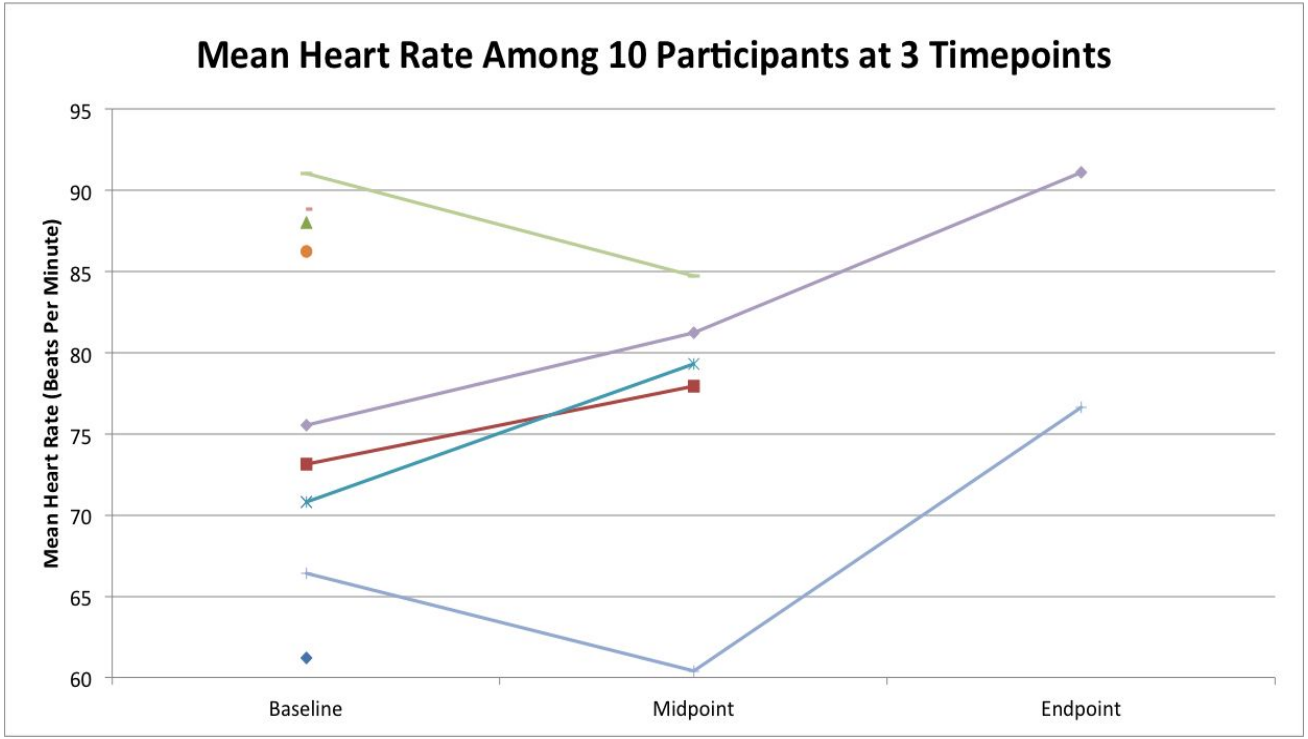
Midpoint Average: 70.8; sd=14.71

Endpoint Average: 83.85; sd=10.25

Interpretation: **No clear trend**

*sd = standard deviation

Mean Heart Rate



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a decrease in mean heart rate.

Analysis of all participants (n=10) shows no clear trend.

Mean Inter Beat Intervals

Including All Participants

Baseline Average (n=10): 794.35; sd=109.71

Midpoint Average (n=6): 797.88; sd=112.53

Endpoint Average (n=2): 725.15; sd=88.32

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

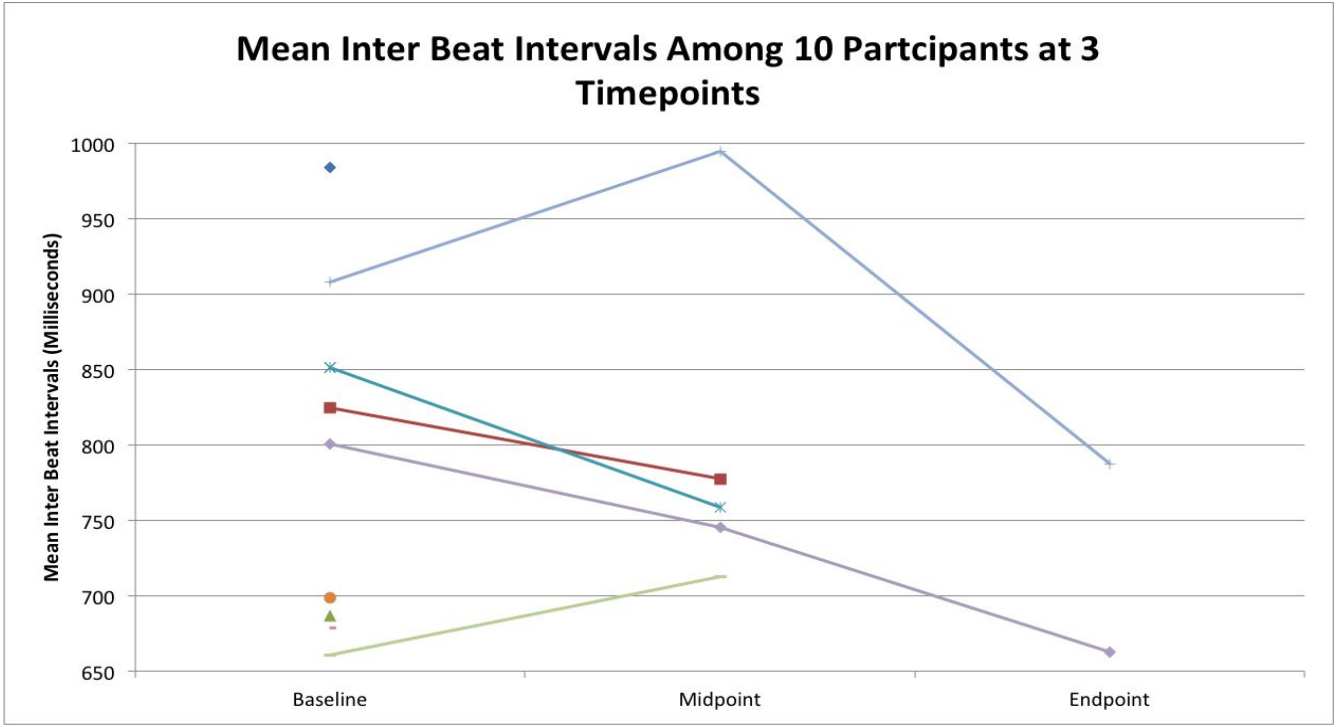
Baseline Average: 854.2; sd=76.23

Midpoint Average: 870.15; sd=176.14

Endpoint Average: 725.15; sd=88.32

Interpretation: **No clear trend**

Mean Inter Beat Intervals



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a decrease in mean inter beat intervals.

Analysis of all participants (n=10) shows no clear trend.

Low Frequency

Including All Participants

Baseline Average (n=10): 239.13; sd= 152.65

Midpoint Average (n=6): 519.42; sd= 531.86

Endpoint Average (n=2): 409.4; sd=368.12

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

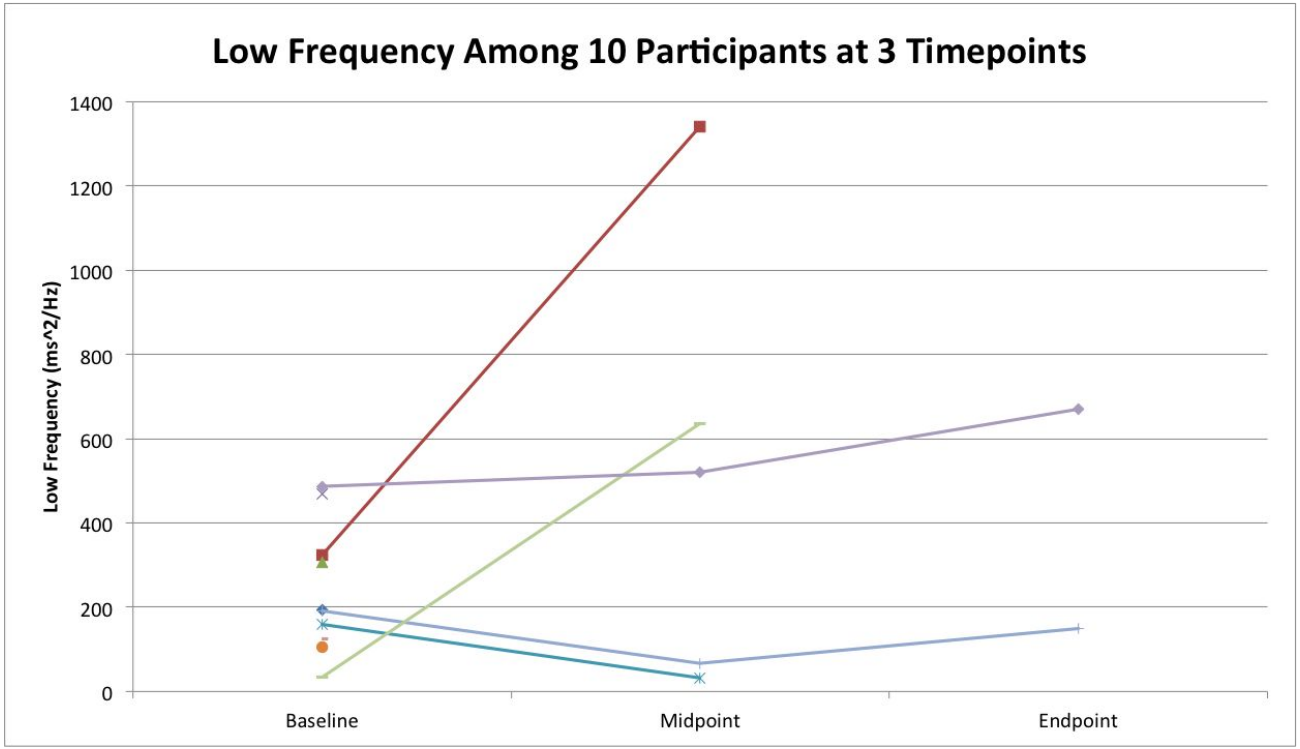
Baseline Average: 338.75; sd= 209.80

Midpoint Average: 293.6; sd=320.60

Endpoint Average: 409.4; sd=368.12

Interpretation: **No clear trend**

Low Frequency



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a decrease in low frequency.

Analysis of all participants (n=10) shows no clear trend.

High Frequency

Including All Participants

Baseline Average (n=10): 146.46; sd= 169.79

Midpoint Average (n=6): 231.88; sd= 292.89

Endpoint Average (n=2): 201; sd= 222.88

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

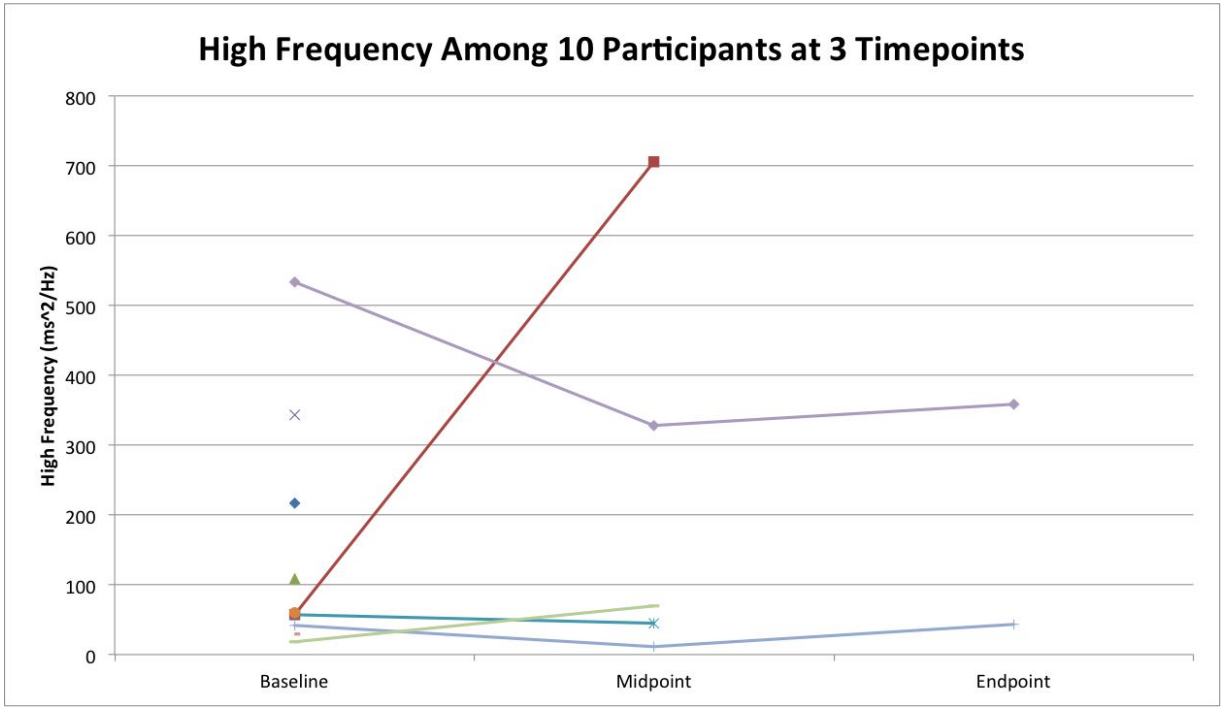
Baseline Average: 287.3; sd=347.90

Midpoint Average: 169.5; sd=224.15

Endpoint Average: 201; sd= 222.88

Interpretation: **No clear trend**

High Frequency



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see an increase in high frequency.

Analysis of all participants (n=10) shows no clear trend.

Low Frequency/High Frequency Ratio

Including All Participants

Baseline Average (n=10): 2.69; sd=1.67

Midpoint Average (n=6): 3.88; sd=3.58

Endpoint Average (n=2): 2.65; sd=1.06

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

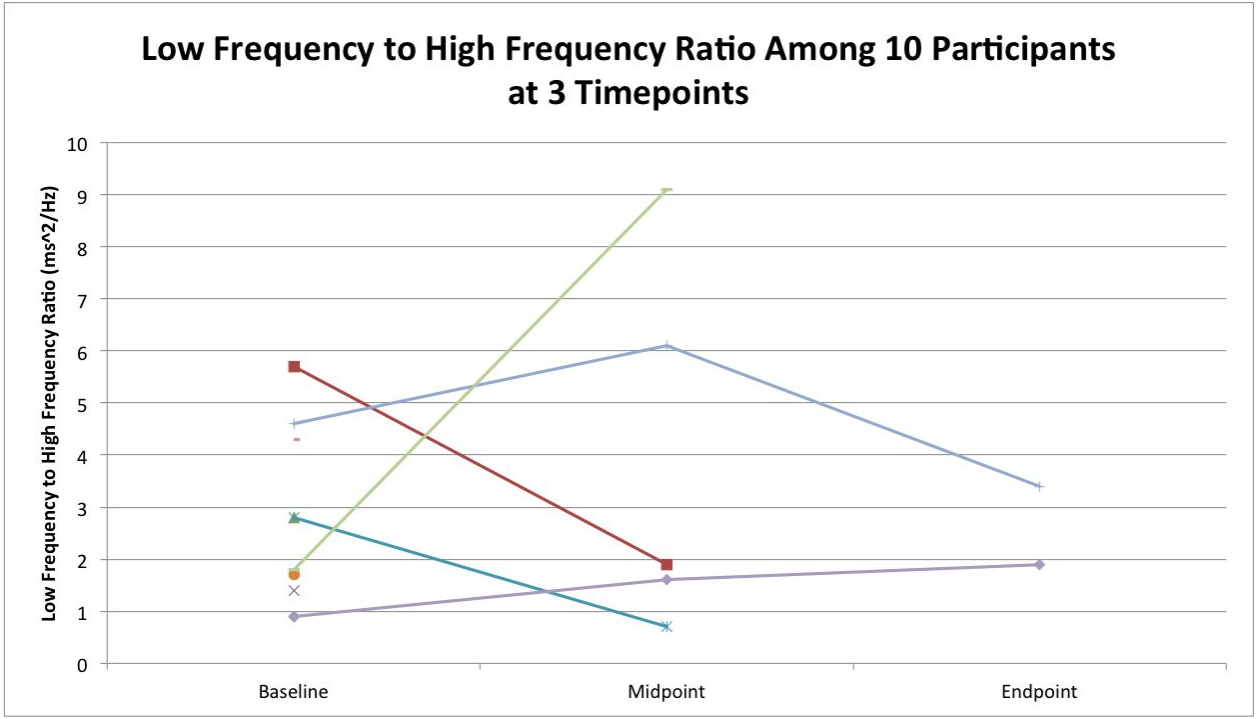
Baseline Average: 2.75; sd=2.61

Midpoint Average: 3.85; sd=3.18

Endpoint Average: 2.65; sd=1.06

Interpretation: **No clear trend**

Low Frequency/High Frequency Ratio



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see a decrease in low/high frequency ratio.

Analysis of all participants (n=10) shows no clear trend.

Total Power

Including All Participants

Baseline Avg (n=10): 660.25 ms^2/hz; sd=389.25

Midpoint Avg (n=6): 593.125 ms^2/hz; sd=490.02

Endpoint Avg (n=2): 792.5 ms^2/hz; sd=561.44

Interpretation: **No clear trend**

Participants Who Completed All Measures (n=2)

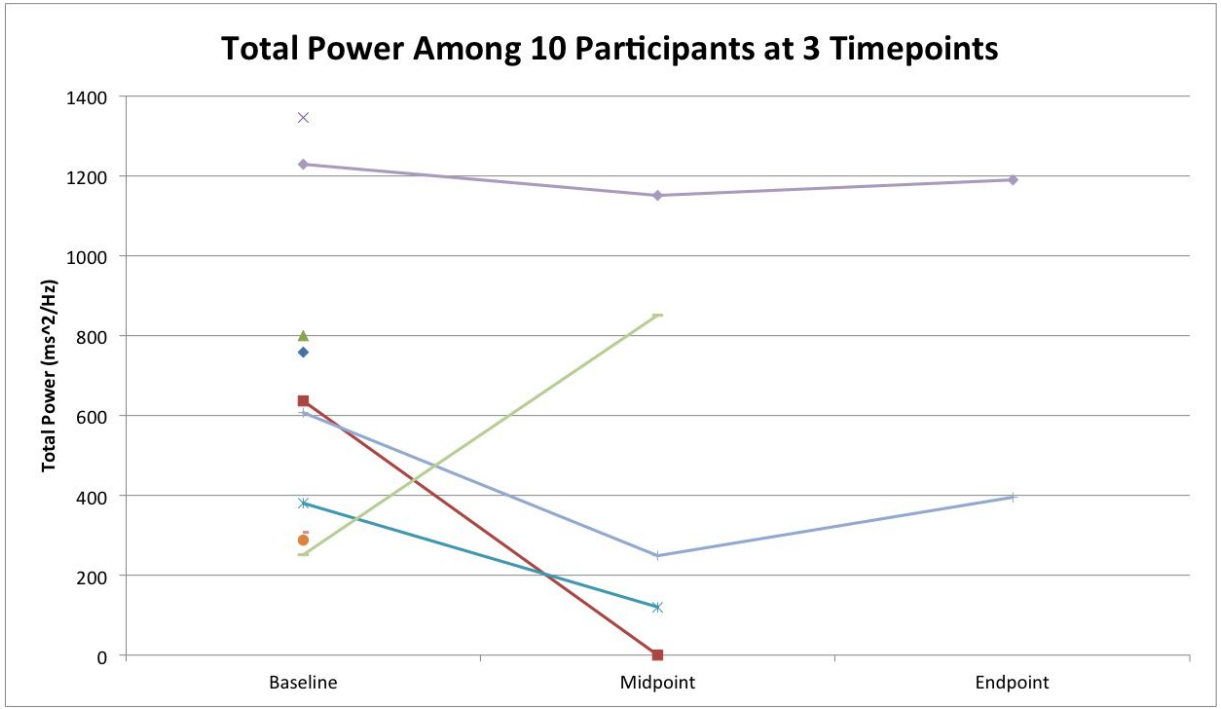
Baseline Average: 917.9 ms^2/hz; sd=438.69

Midpoint Average: 700 ms^2/hz; sd=637.95

Endpoint Average: 792.5 ms^2/hz; sd=561.44

Interpretation: **No clear trend**

Total Power



**Each line, and the corresponding data point(s), represents a unique participant*

As a result of the biofeedback sessions, we would expect to see an increase in the total power.

Analysis of all participants (n=10) shows no clear trend.

Limitations

- Small sample size reduced the statistical power of all calculations; thereby, none of the measures were statistically significant.
- Standard deviations were high for most measures indicating a large level of variability between measurements within the sample.
- Taking these limitations into consideration, the purpose of a pilot study is to look for trends in the data (not necessarily statistical significance) and to assess the feasibility of the intervention.

Participant Reports

Analysis of pre-test data (n=10) showed that:

- The majority of participants reported they *'often'* felt happy and cheerful
- At the same time, the majority of participants also reported they *'sometimes'* felt angry and sad
- Half of participants reported they *'often'* felt stressed, *'sometimes'* felt calm, and *'sometimes'* felt disappointed
- The majority of participants reported they *'almost never'* felt lonely

Participant Reports

As well, analysis of pre-test data (n=10) showed that:

- What participants reported doing while stressed greatly varied. However, the majority reported *'almost always'* or *'sometimes'* trying to manage stress the moment it happened and all respondents mentioned *'sometimes'*, *'often'* or *'almost always'* being able to effectively control their feelings when feeling overwhelmed.
- All participants reported that they *'often'*, *'sometimes'*, or *'almost always'* were able to calm themselves down when feeling distressed.
- Of note, half of participants stated they *'often'*, in these instances, breathed deeply to calm themselves down; however, two participants stated that they *'almost never'* used the tool of breathing deeply to calm themselves during stressful situations.

Participant Reports

While only five of the original ten participants completed the mid-point assessment (n=5), analysis of mid-point data found:

- All five participants either *'liked'* or *'loved'* participating in the biofeedback session
- All participants found the biofeedback sessions to be *'somewhat'* or *'very'* useful in improving their overall mood
- All participants reported they would *'definitely'* or *'probably'* recommend the biofeedback program to someone else
- Three participants reported practicing breathing techniques on their own outside the biofeedback sessions
- The two participants who, at baseline, reported *'almost never'* using breathing techniques to calm themselves down when stressed had dropped out by the midpoint assessment

Participant Reports

Since only two participants completed the post-test (n=2), general trends and patterns across all data points could not be analyzed. Regardless, analysis of end-point data found:

- Both participants found the biofeedback sessions to be either *'somewhat'* or *'very'* useful in improving their mood
- One of the participants reported, at the midpoint assessment, that s/he practiced breathing techniques outside the biofeedback sessions approximately one day per week. At post-test, this individual reported practicing breathing techniques outside the biofeedback sessions everyday.

Recommendations for Future Pilots or Program Expansion

- Aim to enroll pilot subjects who cover the range of characteristics of your target population.
- Aim to articulate and match pilot activities to the goal of the pilot.
- Explore potential for follow-up through when participants leave the jail and return to the community or to prison.
- Consider doing the pilot over a shorter period of time.
- Consider choosing participants based on how long it is anticipated that they will be in jail.
- Explore potential for a larger sample size (80% was lost, so start out planning for that). Aim for a sample size of at least 12, but probably more with the high rate of lost to followup.
- Recognize the risk of using less representative samples.
- Find other tips here and here.

Lessons Learned from ROI

- Have multiple team members at the host organization be jointly responsible for the pilot
  - We had one Lieutenant who led the project, she was an incredible project leader, and she retired after the project was over, so the institutional knowledge that was built through this pilot was not built in more staff members, we now need to re-train staff members.
- Participants in the pilot are moving locations frequently, have a better process for exiting participants from the pilot if they get transferred out of the county jail mid-pilot
- Offer the same biofeedback breathing technology to the staff of the Detention Center (County Jail)
  - There was interest from staff members about being able to participate and access the same biofeedback breathing technology as the other people.

Conclusive Statement

After reviewing and analyzing the data, we have concluded that the high levels of participant satisfaction and promising movement of indicators warrant another iteration of the biofeedback intervention.

While the findings were not statistically significant, we believe another iteration of this intervention that incorporates the recommendations and lessons learned included in this slide deck could yield statistically significant results.