NeuroRegulation

ISNR INTERNATIONAL SOCIETY FOR NEUROREGULATION & RESEARCH

Exploring Single-Case Research Design With Individualized Anxiety-Based Neurofeedback Protocols and Session Data

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Abstract

Individuals' experiences of anxiety differ in manifestation, development, and severity. Using retrospective neurofeedback session data which included quantitative electroencephalography (qEEG)-based anxiety protocols, we examined four participants' data. We employed a single-case research design (SCRD) methodology to highlight the individual variations or change across participants' neurofeedback session data. We assessed effect size using visual analysis, nonoverlap of all pairs, and simulation modeling analysis. Considering the novel concept of applying SCRD to physiological data, we compare and contrast our findings while also suggesting limitations and future areas for research.

Keywords: neurofeedback; single-case research design; anxiety

Citation: Gregory, J. C., Romero, D. E., & Jones, M. S. (2023). Exploring single-case research design with individualized anxiety-based neurofeedback protocols and session data. *NeuroRegulation, 10*(3), 159–169. https://doi.org/10.15540/nr.10.3.159

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Introduction

In 2017, the National Institute of Mental Health (NIMH), reported that approximately 31.1% of adults in the United States will experience some type of anxiety during their lifetime. Additionally, researchers conducted a systematic review and meta-analysis of studies assessing the prevalence of anxiety disorders during the COVID-19 pandemic, revealing a rate of 35.1%, or one in three adults (Delpino et al., 2022). Although the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision* designates anxiety concerns to include intrusive thoughts, tightness in the jaw, clenched fists, headaches, or other physiological and psychological dysregulation, individuals do not always experience anxiety in similar fashions (American Psychiatric Association [APA], 2022). Adding to the complexity, anxiety can also co-occur with depression or other mental health diagnoses and, depending on individual development, vary due to culture, genetics, environment, social climate, and various other ecological dynamics (NIMH, 2023). Whereas treatment methods using talk therapy (e.g., Carpenter et al., 2018) and neurofeedback demonstrate positive outcomes for reducing anxiety concerns (e.g., Cheon et al., 2015; Gregory et al., 2020; Walker, 2012), evaluating treatment efficacy utilizing methodologies that capture individual experiences of anxiety is warranted.

A methodology primarily applied in education research, yet with a growing interest among researchers in other disciplines within the last 10 years, are single-case research designs (SCRD; Ganz & Ayres, 2018; Gregory, 2022). SCRDs can also exist in literature as single-case designs, single-case experimental designs, or time series data research. Currently, scholars are developing SCRDs best practice guidelines which include recommendations for methodological approaches, data analyses, and ethical considerations (Kratochwill et al., 2023). Researchers gravitate toward SCRDs when there are numerous intervention data points and an interest in evaluating individual changes.

Method

Authors, La Vaque et al. (2002) recognize best practices for neurofeedback methodologies and studies. One of their recommendations encourages researchers to add multiple observations (La Vaque et al., 2002). Adding multiple observations to research studies includes various methodologies-including single-case research designs (SCRDs). SCRDs, also known as time series designs, utilize participants as their own baseline (Kazdin, 2021). Characteristics of SCRDs include (a) repeated measurement of the dependent variable, (b) a measurement that occurs across time, and (c) the identified "case" is either an individual, organization, business, or other group (Kazdin, 2021; Lobo et al., 2017). SCRD researchers utilize multiple baselines (i.e., participants begin the intervention at varying times), reversal designs, and multiple treatment designs based on their desired data outcomes and research goals. For example, the baseline is the "A" phase containing repeated measures but no intervention. The "B" phase involves the intervention and uses the same repeated measurement (i.e., assessment or neurofeedback intervention as the "A" phase). The overall concept is to assess if an intervention has any effect on the independent variable.

As variations of SCRDs reflect various strengths for evaluating intervention effects, the literature emphasizes the need for researchers to exercise care in analyzing their data. A similar mentality may also benefit neurofeedback researchers and clinicians considering the vast differences and intricacies in subjects' individual life experiences, physiological development, and presenting brain patterns. In addition to these factors, we measured participants' self-reported anxiety symptoms by administering pre and post Zung assessments (Zung, 1971). Since retrospective was utilized, we did not need to acquire additional IRB approval as the university has an ongoing blanket approval for the neurofeedback anxiety data. Using retrospective neurofeedback session data with anxiety-based protocols, our research questions ask:

1. Is there a change over time in participants' mean magnitude (i.e., band 1, band 2, and band 3 in BioExplorer) of their neurofeedback session-to-session data, based on their corresponding brain wave frequencies?
2. Is there a change over time in participants' anxiety as measured by pre and post Zung scores?

Clinicians

The current study utilized student clinicians, which consisted of clinical mental health masters-level students and counselor education and supervision doctoral-level students within counseling programs nationally accredited by the Council for Accreditation of Counseling and Related Education Programs. These students had previously completed the Biofeedback Certification International Alliance requirements for didactic coursework for neurofeedback and were under the supervision of a certified and licensed supervisor at the time of data collection. Volunteer clinicians (e.g., faculty, alumni) with neurofeedback training were also utilized.

Measures

Demographic Information and Treatment Record. The demographic data utilized in this study include gender, age, ethnicity, highest level of education completed, and current or previous experience with counseling. Additional data collected using session-to-session treatment records include number of sessions attended, average length of sessions, treatment protocol, average amplitude measures per frequency band trained from BioExplorer, and electrode sites (based on the international 10-20 system).

Zung Self-Rating Anxiety Scale for Adults. The Zung Self-rating Anxiety Scale (SAS) is a 20-item self-report assessment instrument, which includes measures of state and trait anxiety based on scoring in four groups of manifestations: cognitive, autonomic, motor, and central nervous system symptoms. Items are measured on a 4-point Likert type scale (1 = *None or A little of the time* to 4 = *Most or All of the time*). Example items include "I get upset easily or feel panicky," "I can breathe in and out easily," and "I feel that everything is all right and nothing bad will happen." Raw scores range from 20 to 80, which are converted to index scores by dividing the sum of the raw scores by 80 and multiplied by 100. Higher scores indicate greater severity of anxiety symptomatology (Zung, 1971). The SAS continually displays good internal consistency with a Cronbach's alpha of .82 (Tanaka-Matsumi & Kameoka, 1986); fair concurrent validity, correlating significantly (.30) with the Taylor Manifest Anxiety Scale (Zung, 1971); and to distinguish both between clinical and nonclinical groups and between patients diagnosed with anxiety disorders and those with other psychiatric diagnoses (Zung, 1971).

Instrumentation

Quantitative Electroencephalography (qEEG). Prior to beginning neurofeedback treatment, a qEEG was computed to identify an individual's standard brainwave patterns and the areas that would benefit from conditioning. At least a 24-hr window prior to the qEEG recording was suggested for clients to restrict consumption for nonessential substances, unless otherwise medically directed. All medically directed substances were factored into qEEG interpretation and protocol development.

The 19-channel qEEGs were acquired using one of two systems: (a) a BrainMaster Discovery 24 high-impedance amplifier (BrainMaster Technologies, Inc., Bedford, OH) and NeuroGuide (Applied Neuroscience, Inc., Largo, FL) software, or (b) a Mitsar BT 201 high-impedance amplifier with WinEEG software (Mitsar Co. Ltd., St. Petersburg, Russia). Recordings were captured in the eyes-closed and eyes-opened conditions using a properly sized Electro-Cap (Electro-Cap International, Inc., Eaton, OH) which was fitted as per manufacturer's guidelines with ear-clip leads. Preparation of electrodes was performed in a manner adequate to achieve impedance levels of less than 5K Ω (Jones, 2015).

Neurofeedback. For the neurofeedback sessions, clinicians utilized the BrainMaster Atlantis two-channel amplifiers (BrainMaster Technologies, Inc., Bedford, OH) and BioExplorer software (Cyberevolution, Inc., Seattle, WA). Electrode site preparation was done by cleaning the site, ground, and reference locations with rubbing alcohol and abrading using PDI sterile alcohol prep pads and Nuprep skin prep gel. Gold-plated electrodes were attached to the clients using Ten-20 conductive paste. Impedance measurements were taken to ensure that interelectrode impedance was less than 5K Ω (Jones, 2015).

Participants (Including Neurofeedback Protocols, Statistical/Data Analysis, Results)

Participant data were collected from retrospective neurofeedback data at a southern university in the United States. Participants of interest included individuals with at least 14 neurofeedback sessions during a semester and a continuation of the same protocol. For organizational purposes, we display our participants' demographic information and results from data analyses under their corresponding participant number.

Data Analysis

First, we entered data into Microsoft Excel to produce graphs which serve as our visual representation of the participants' data and resulting trend lines. Next, our analysis consisted of nonoverlap of all pairs (NAP; Parker & Vannest, 2009). NAP is not contingent on trend lines or averages, is prevalent in SCRD research, and is popular with AB Phase designs. Some researchers criticize NAP analysis and suggest its limitation of distinguishing between the two phases (Manolov & Solanas, 2018); however, with neurofeedback sessions participants continually receive the intervention instead of having a distinct treatment phase and a no-treatment phase. NAP scores are the result of comparing all data points between two phases (Fielenbach et al., 2019). For the current study, Phase A consists of the first defined group of neurofeedback sessions and Phase B the last (i.e., or successive) defined group of sessions. Resulting NAP scores produce effect sizes that range from 0.00–0.65 (i.e., 65%) a weak effect, 0.66–0.92 a medium effect, and 0.93–1.0 a large effect (Parker & Vannest, 2009).

To bolster the NAP results, we used simulation modeling analysis (SMA; Clinical Research Solutions, 2021)—a free and downloaded software program for SCRD data with <30 time points (Borckardt, 2006). The software program allows for controlling for autocorrelation, testing the slope and trend lines of the session data, and runs a 5,000-simulation test for determining the best fit trend line or most correlated model. The five models are (a) Model 1 suggests a Phase A increase in outcome measure with a decrease during Phase B; (b) Model 2 suggests a stable or level Phase A and an increase in Phase B; (c) Model 3 indicates a Phase A increase that levels out and is stable during Phase B; (d) Model 4 suggests a Phase A increase that continues into Phase B; and (e) Model 5 indicates an increase in Phase A, and immediate decrease, and an additional increase in Phase B. SMA illuminated deeper insight to participants neurofeedback session data. Specifically, this analysis can predict subtle changes within the data and how the participant might have responded to sessions if clinicians had continued the intervention.

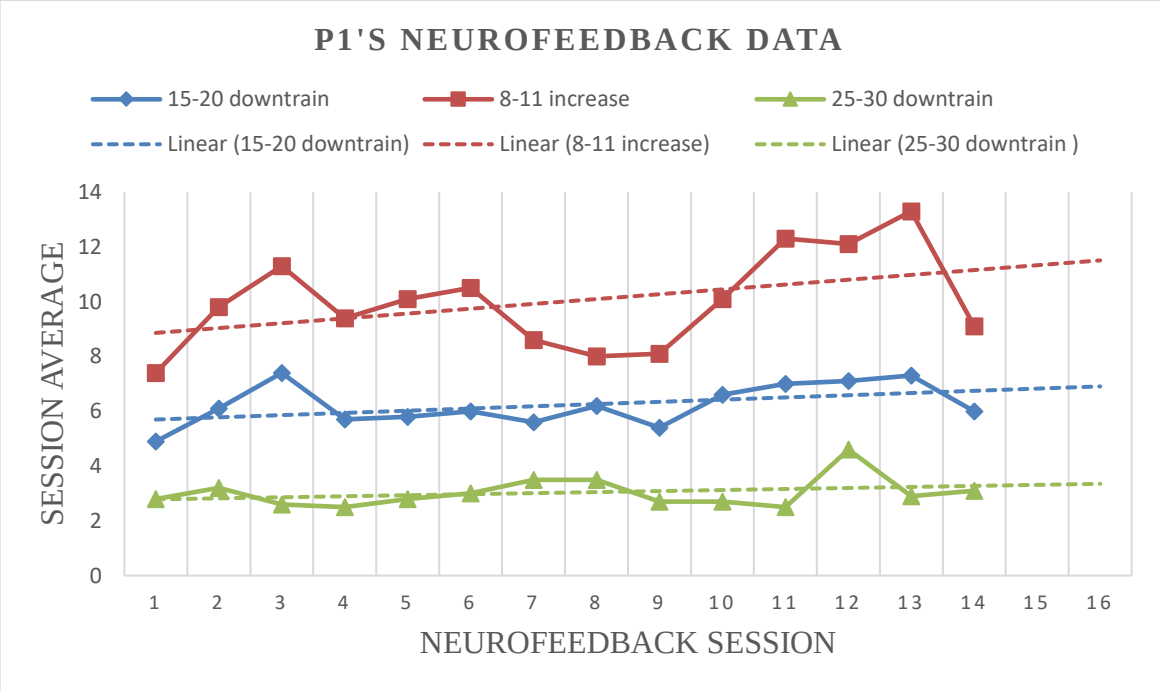
For our final analysis, we calculated change score percentage using the *Statistical Package for the Social Sciences (SPSS) software version 28* (SPSS, 2021). We compared each participant's percentage of change from their pre and post Zung raw scores. These data outcomes serve as the participants' self-report data, which Wigton and Krigbaum (2015)

strongly recommend to collect and then compare with physiological data.

Participant 1

Participant 1 (P1) identified as a 45-year-old, Caucasian, Hispanic/Latino female. During P1's first semester of neurofeedback treatment, her sessions included the protocol of downtraining 15–20, increasing 8–11, and downtraining 25–30 at PZ with eyes closed. Her sessions were an average of 23 min in length and utilized audio feedback. A visual of her session data is presented below.

Figure 1. *P1's Visual of Neurofeedback Data.*



According to P1's protocol, the visual outcomes of her downtraining bands appear to slightly increase, while the 8–11 Hz band shows an overall increasing trend. Hence, according to her protocol, the participant shows a desired trend of increasing the 8–11 Hz band. To further examine the data, we divided the 14 session averages of each band into Phase A (n = 7) and Phase B (n = 7) for determining the NAP scores and their corresponding effect sizes. These results are in Table 1.

Table 1

Nonoverlap of All Pairs Statistical Outcomes for P1

	S	*Pairs*	*NAP*	VARs	*z*	*p*	90% CI
15–20 Hz	22	49	0.725	245	1.41	.160	[−0.076, 0.974]
8–11 Hz	10	49	0.602	245	0.64	.522	[−0.321, 0.730]
25–30 Hz	5	49	0.551	245	0.32	.749	[−0.423, 0.628]

Note. S = distribution; Pairs = total pairs comparisons; NAP = nonoverlap of all pairs effect sizes; VARs = variance; z = z-score; p = p value (p = .05); CI = confidence interval.

The NAP scores support the visual trend lines of the increase in all three of the participant's bands. Also, the 8–11 Hz and 25–30 Hz bands both produced the NAP score equivalent of a weak effect, while the 15–20 Hz band is in the medium effect range.

Simulation Modeling Analysis. We ran the SMA on P1's three training bands. For P1's 15–20 Hz band, the data best fit with (Slope Vector) Model 4 (R = .33, p = .32). Model 4 is indicative of an increase in Phase A that continues during Phase B. This is an opposite desirable outcome according to P1's protocol. Her 8–11 Hz band also was most correlated with Model 4 (R = .23, p = .51), which does align with her protocol and visual graph; however, the increase was not significant. P1's 25–30 Hz band fit best to Model 3 (R = .26, p = .30). Model 3 denotes a Phase A increase and a leveling out during Phase B. Hence, if P1 had continued with sessions, this could suggest a future trend toward her protocol goal.

Zung Scores. P1 reported Zung raw scores of 44 (pre) at the start of services and 35 (post) at the conclusion of her neurofeedback treatment. Using *SPSS 28*, we calculated the percentage of change. Her change score percentage shows a 20.45% decrease in her self-reported anxiety concerns. To further interpret P1's self-reported data, we calculated P1's SAS index following Zung's procedure (Zung, 1971). P1's initial score demonstrated a SAS index of 55 (mild to moderate anxiety) at pre and a decrease in symptomology at post with a SAS index of 44 (normal range).

Participant 2

Participant 2 (P2) identified as Caucasian, Hispanic/Latino, and a 52-year-old male at the beginning of his neurofeedback treatment. His protocol included downtraining 4–7 Hz, increasing 12–15 Hz, and downtraining 25–30 Hz at CZ with EO. His feedback included audio/visual displays of episodes of a TV series and movie clips. Most of his sessions were 20 minutes in length. Figure 2 visually displays his band averages after his first university semester of neurofeedback sessions. P2's duration of neurofeedback treatment is represented in Figure 3.

Examining P2's first 14 sessions show only a positive trend that aligns with his protocol in the downtraining of 25–30 Hz. P2 continued with his neurofeedback treatment for a total of 47 sessions, which included missing band averages for session 21 and a continuation of the same protocol. These session data are in Figure 3.

Figure 2. *P2's Visual of Neurofeedback Data for His First Semester of Sessions.*

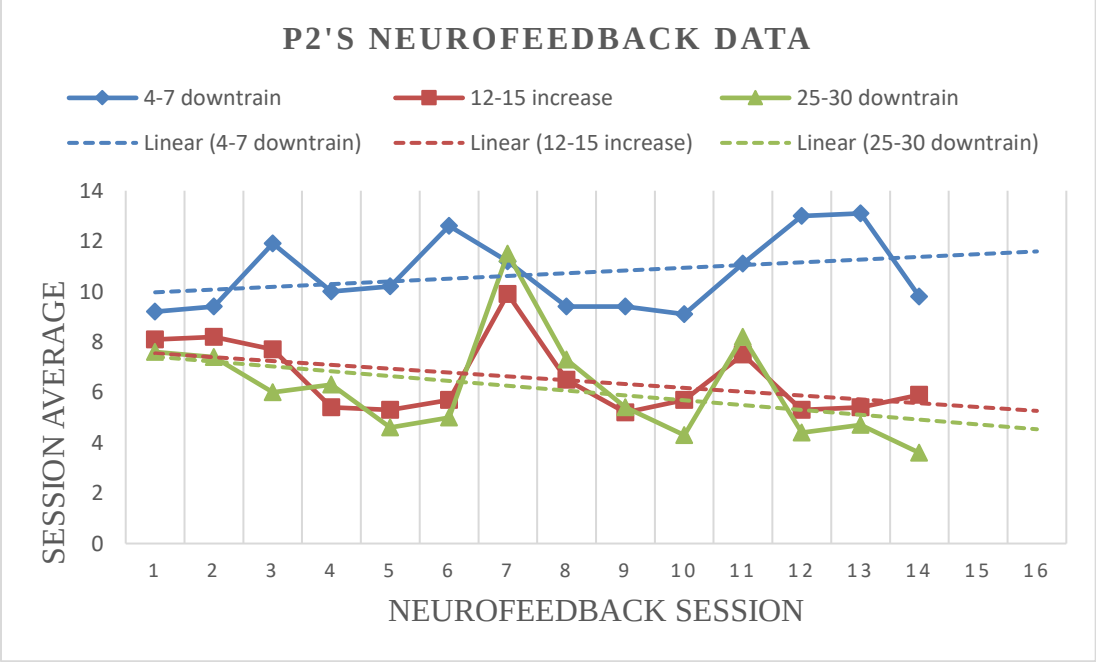
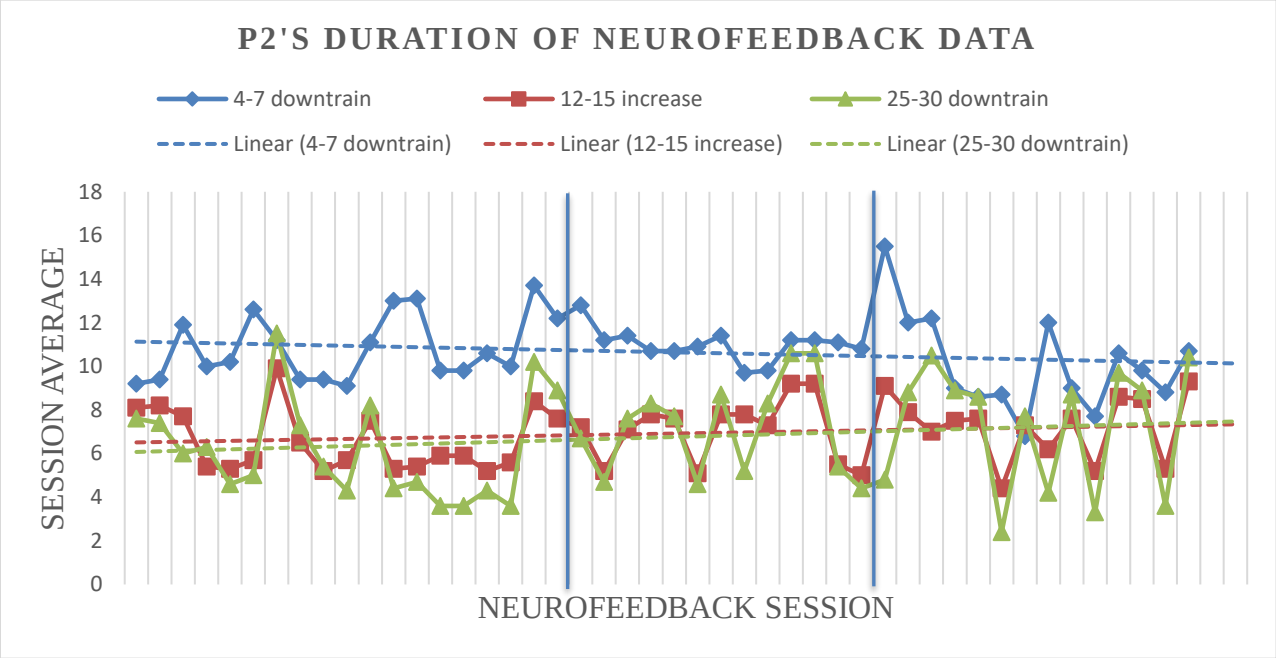


Figure 3. *P2's Visual of Neurofeedback Data for His Duration of Sessions.*



When we explored the duration of P2's data, we can see positive trend toward his protocol in downtraining 4–7 Hz and increasing 12–15 Hz. In full disclosure of data reporting, P2's data includes university semester breaks in treatment between sessions 19 to 20 and 32 to 33. These breaks in treatment were around 3–4 weeks and are marked in Figure 3. While it is vital to report the visual trends of data in SCRD, researchers also encourage further exploration of data change with statistical analyzes (Kratochwill et al., 2023).

Table 2

Nonoverlap of All Pairs Statistical Outcomes for P2

	S	*Pairs*	*NAP*	VARs	*z*	*p*	90%CI
4–7 Hz	−119	529	0.388	8287	−1.31	.191	[−0.508, 0.058]
12–15 Hz	112	529	0.606	8287	1.23	.219	[−0.071, 0.495]
25–30 Hz	134	529	0.627	8287	1.47	.141	[−0.030, 0.536]

Note. S = distribution; Pairs = total pairs comparisons; NAP = nonoverlap of all pairs effect sizes; VARs = variance; *z* = *z*-score; *p* = p value (*p* = .05); CI = confidence interval.

We performed NAP analyses for P2 using the duration of his neurofeedback treatment data. This displayed a corresponding correlation to the visual analysis and an overall decrease in his 4–7 Hz band; however, the effect was low. Additionally, P2's 12–15 Hz band also had a trend toward his protocol with an overall increase, but with a weak effect.

Simulation Modeling Analysis. Per the SMA creator, Borckardt (2006), the program was designed for data with < 30 time points. Hence, we did not utilize SMA for P2's duration of neurofeedback session data.

Zung Scores. P2's Zung scores were 29 pretreatment and 29 posttreatment. Since there was no change, we did not perform a change score computation. P2's SAS Index of 36 fell within the normal range of anxiety.

Participant 3

Participant 3 (P3) identified as a non-Hispanic, Caucasian female, age 55. Her protocol consisted of downtraining 6–10 Hz, increasing 12–15 Hz, and downtraining 25–30 Hz at FZ with EO. Her feedback included audio/visual displays of movie clips and simple balloon popping games. P3's duration of sessions took place over one university semester and totaled 18 sessions with an average length of 28 min.

P3's visual display of neurofeedback is challenging to interpret. The similar trend lines of her 12–15 Hz and 25–30 Hz bands both appear to be slightly increasing. P3's 6–10 Hz band also appears to be increasing. The difficulty in interpreting the visual analysis trends solidify the need for furthering analyzing data. Ideally data analyses will illuminate supplemental data trends.

Both of P3's bands, 6–10 Hz and 25–30 Hz, displayed medium effects in their changes. These trends were not in the desired directions. Her 12–15 Hz SMR band resulted in a large effect change and a significant result that aligned with her protocol.

Figure 4. *P3's Visual of Neurofeedback Data.*

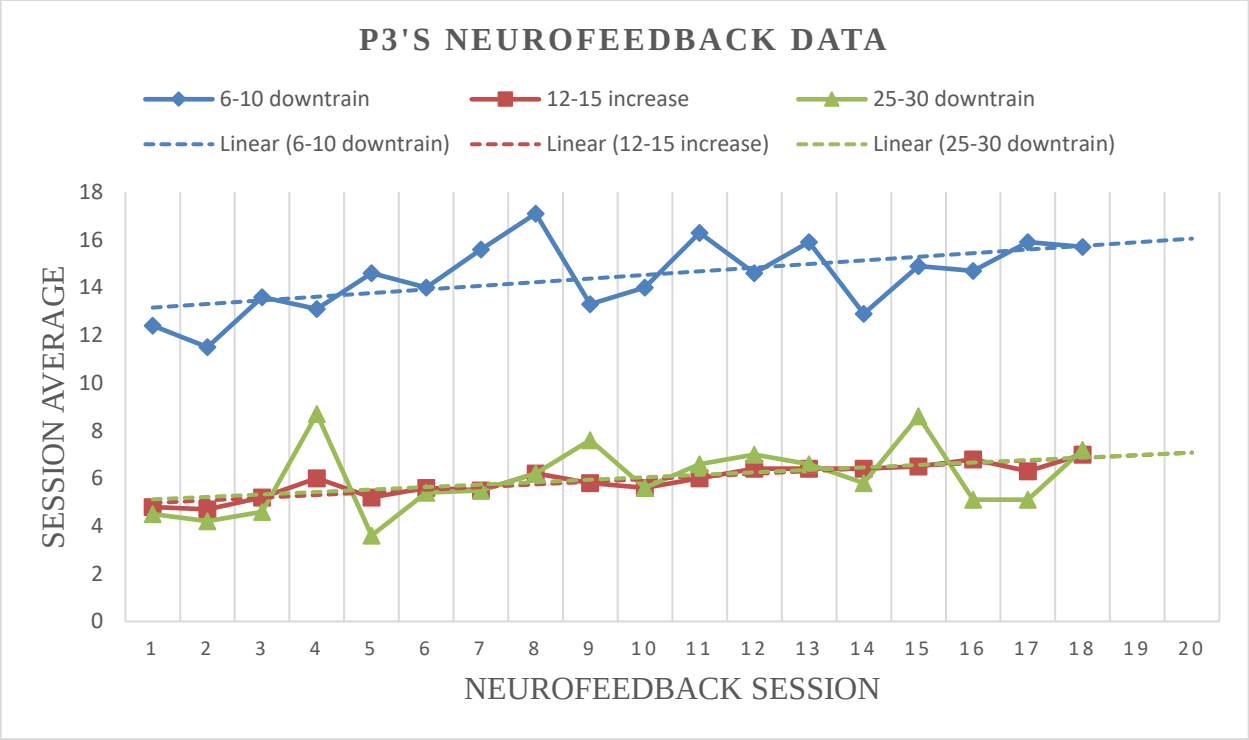


Table 3

Nonoverlap of All Pairs Statistical Outcomes for P3

	S	*Pairs*	*NAP*	VARs	*z*	*p*	90%CI
6–10 Hz	39	81	0.741	513	1.72	.085	[0.022, 0.941]
12–15 Hz	71	81	0.938	513	3.13	.002	[0.417, 1.000]
25–30 Hz	31	81	0.691	513	1.37	.170	[−0.077, 0.843]

Note. S = distribution; Pairs = total pairs comparisons; NAP = nonoverlap of all pairs effect sizes; VARs = variance; *z* = *z*-score; *p* = *p* value (*p* = .05); CI = confidence interval.

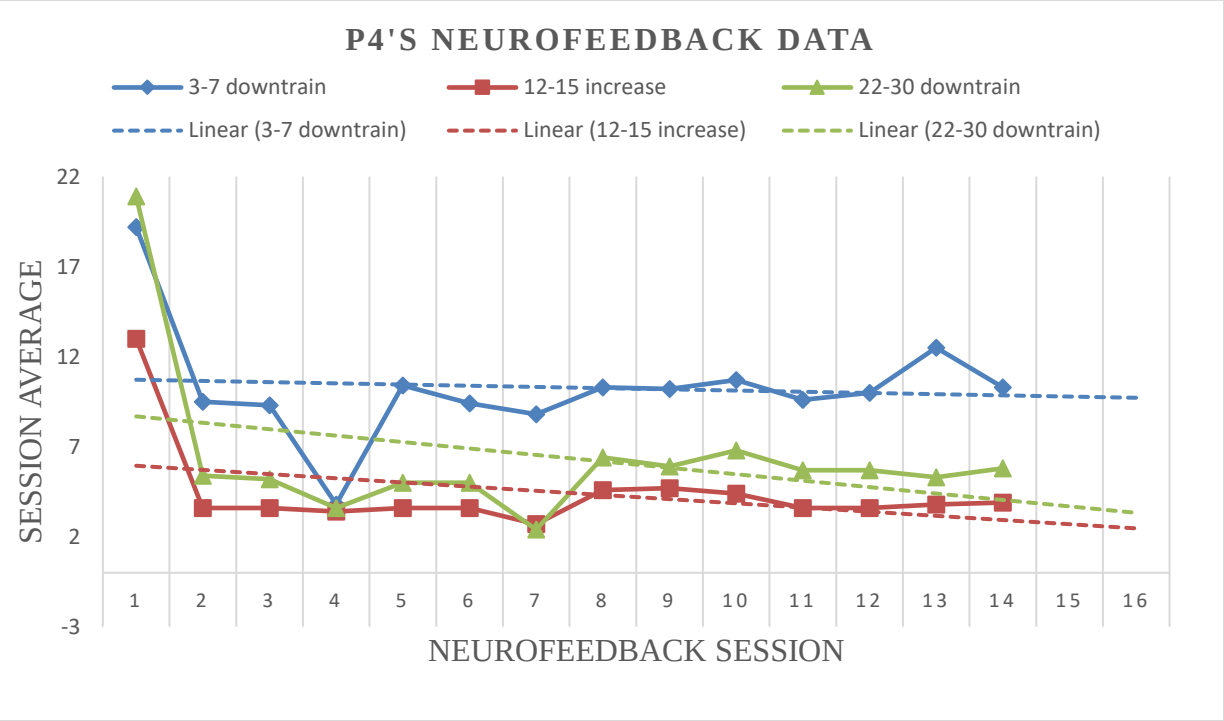
Simulation Modeling Analysis. P3' SMA results for band 6–10 Hz correlated best with Model 3 (R = .62, p = .02) and is significant, which is not ideal for her protocol considering Model 3 indicates an increase during Phase A and a leveling out effect during Phase B. However, similar to P1, if P3 had continued with neurofeedback session, a potential trend toward her protocol decreasing might have been achieved. P3's SMR band of 12–15 Hz produced the best fit with Model 4 (R = .90, p < .001). Model 4 is an ongoing increase in the data. This aligns with the participant's protocol of increasing his SMR band. For P3's 25–30 Hz band, her data best fit with Model 3 (R = .45, p = .03). Neither Model 3 nor the significant finding is the preferred trend for P3's data. Like her 6–10 Hz band, if she continued with sessions there is the potential for her to meet her protocol goal.

Zung Scores. P3 self-reported a Zung score of 43 pretreatment and 40 at the conclusion of her neurofeedback treatment. This resulted in a percentage change of −6.97%. P3's initial and post scores demonstrated a SAS index of 54 (pre) and 50 (post) both of which indicate mild to moderate anxiety.

Participant 4

P4 was a 46-year-old, who identified as female and Caucasian. She completed 14 neurofeedback sessions with a protocol of downtraining 3–7 Hz, increasing 12–15 Hz, and downtraning 22–30 Hz at Cz. Her feedback consisted of EO training with TV show clips and a waterfall visual with calming music. The majority of her sessions were 30 min in length.

Figure 5. *P4's Visual of Neurofeedback Data.*



Inspecting P4's visual graph, all her bands appear to be decreasing over time. However, the linear trend lines are potentially altered due to the first session data points being outliers. The NAP scores and SMA may prove more insightful than the visual trends. When outliers exist in SCRDs, some authors believe NAP scores as being less sensitive (Ledford et al., 2018). We opted to include all P4's session data points for the NAP analysis and removed them for her SMA.

All of P4's NAP scores produced a medium effect. Also, each of her bands showed an increase over time, which is opposite of her visual graph. This is due to her first session outliers. Her 22–30 Hz band results were significant; however, not in the direction that aligned with her protocol.

Table 4
Nonoverlap of All Pairs Statistical Outcomes for P4

	S	*Pairs*	*NAP*	VARs	*z*	*p*	90%CI
3–7 Hz	25	49	0.755	245	1.60	.11	[−0.015, 1]
12–15 Hz	27	49	0.776	245	1.73	.08	[0.026, 1]
22–30 Hz	33	49	0.837	245	2.11	.04	[0.148, 1]

Note. S = distribution; Pairs = total pairs comparisons; NAP = nonoverlap of all pairs effect sizes; VARs = variance; *z* = *z*-score; *p* = *p* value (*p* = .05); CI = confidence interval.

Simulation Modeling Analysis. For P4's SMA data analyses, we removed the first session data points for all her brain bands and included the first six sessions for Phase A and the last seven for Phase B. Her 3–7 Hz band displayed highest correlation with Model 4 (R = .51, p = .08) indicating a Phase A increase that continues into Phase B. Her 12–15 Hz band best fit with Model 5 (R = −.49, p = .15) which states an increase in Phase A with an immediate decrease and an additional increase in Phase B. P4's 22–30 Hz band best fit with Model 2 (R = .43, p = .16). Model 2 represents a stable or level Phase A with an increase in Phase B. P4's SMA analyses offered us more insight into her session data. Her 3–7 Hz and 22–30 Hz bands appear to not be responding to her protocol. Her SMR band of 12–15 Hz may or may not be responding to her uptraining protocol.

Zung Scores. P4's Zung scores were 37 at the start of services and 36 at the conclusion of neurofeedback treatment. Hence, her semester percentage change score was −2.70%. P4's initial and post scores demonstrated a SAS index of 46 (pre) and 45 (post) both of which are indicative of mild to moderate anxiety.

Discussion

Our goals for this study were to utilize a SCRD approach to examine participants' change over time through neurofeedback session data averages from their individualized neurofeedback protocols and self-report data. For the first research question, we created and reviewed a visual representation of the participants' session data and resulting trend lines, computed NAP scores, and performed SMA. Considering the NAP scores, the participants' sessions displayed mainly small to medium effect sizes or changes between Phase A and Phase B, with a few significant findings trending in the intended direction. However, in P3's SMR band, her protocol asked her to increase this area which resulted in her NAP scores showing a large effect size and her SMA displaying significant results. For all participants, we used SMA and their session data. Results were varied within each participant and their three bands. Additionally, outcomes varied across participants; yet it appears for some of their training bands, if participants had continued neurofeedback sessions, an alignment toward their protocol goals might have been achieved. Further, some participant NAP scores were significant while their SMA results using the same data did not display significance. For the final research question, all participants self-reported their Zung score decreasing or staying the same after their neurofeedback treatment.

Utilizing the SCRD approach to examine individual changes throughout the duration of the neurofeedback treatment afforded us the opportunity to see the more nuanced changes by viewing the data points from different perspectives. For instance, visually, there seems to be an increase in all three bands for P1, one of which appears to be trending in the intended direction (8–11 Hz); however, the NAP score and SMA do not suggest a significant change within the evaluated window of treatment. Conversely, when reviewing P1's self-reported SAS scores, P1 reported experiencing a 20.5% decrease in anxiety concerns moving from a mild to moderate level of anxiety to within the normal range of anxiety. This study seeks to contribute new information concerning the use of SCRD to examine neurofeedback outcomes.

Limitations and Implications for Research

The neurofeedback sessions were primarily conducted by students and in an academic setting verses a research facility. Some factors to consider may be variations in student-run sessions using different threshold settings and possessing various neurofeedback skill levels. Also, participants might

have been receiving other forms of mental health support (i.e., counseling) or biofeedback before or during their neurofeedback intervention and the effects could have altered or been responsible for the data changes. The session averages were not artifacted and due to this, data could be distorted.

SCRD for neurofeedback session data is a novel approach and future researchers may consider a similar format to this study or utilize other SCRD methods and analyses. We recommend interested researchers to view the article by Kratochwill et al. (2023) and consider their suggestions for SCRD best practices. A considerable strength of SCRD approaches may highlight subtle changes in participants' data over time (Lenz, 2015) which may provide neurofeedback professionals with insight into when a protocol shift may be necessary. Currently, neurofeedback professionals are advocating for its evidence-basis and credibility and are accordingly conducting larger sample size neurofeedback studies with double-blind procedures or control groups. This research is extremely vital for neurofeedback advocacy. However, examining individual change in physiological interventions could prove beneficial for neurofeedback professionals and their clients. Assessing individual changes may also be more meaningful to professional counselors or psychologists offering neurofeedback services.

Conclusion

This SCRD study incorporated individual-based anxiety protocols and examined neurofeedback data on an individual level. We performed a visual analysis of each participants' band averages and computed NAP scores and SMA. Results were varied within participant data and among participants. Employing SCRD and different analyses allowed us to compare and contrast significant findings while acknowledging individual protocols and individual change.

Author Disclosure

All authors disclose that this was an unfunded study and there are no conflicts of interest.

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Received: June 12, 2023
Accepted: June 26, 2023
Published: September 30, 2023