International Journal of Neurology and Neurotherapy

Aliño et al. Int J Neurol Neurother 2016, 3:041
DOI: 10.23937/2378-3001/3/1/1041
Volume 3 | Issue 1

ISSN: 2378-3001

Short Note: Open Access

A Critical View of Neurofeedback Experimental Designs: Sham and Control as Necessary Conditions

Marta Aliño*, Marien Gadea, and Raul Espert

Psychobiology Department, Psychology Faculty, University of Valencia, Spain

***Corresponding author:** *Marta Aliño, Psychobiology Department, Psychology Faculty (University of Valencia), Avda. Blasco Ibañez 21, 46010, València, Spain, E-mail: marta.alino@uv.es*

Keywords

Neurofeedback, Sham, Control, Real feedback, Placebo, Experimental design

Introduction

Neurofeedback (NF) emerged to employ neural feedback via EEG as an evolution of biofeedback in the 1960 [1,2]. Specifically, NF entails to learn to self-control the brain activity according to operant principles through a visual, auditory or even tactile representation of participant's brain activity as a feedback [3], with the aim of improving mental states, whether or not in clinical conditions [4].

To this day, specialized clinics and private institutions are offering variations on EEG-NF for the treatment of different disorders. These interventions have been largely dismissed in many studies as being placebo-driven [2], mostly due to a lack of well-controlled experimental designs. Briefly, a veritable feedback (experimental group) implies a feedback from the region or frequency of interest derived directly from the participant's brain activity. Alternatively, a sham feedback (control group) consists of a feedback not derived from the participant's brain activity but obtained from a previous trial with a different participant; another type of sham feedback is that in fact derived from the participant's brain, but not from the region or frequency of interest [2]. A critical point here is that most studies do not include a control group not exposed to NF, so the importance of the simple exposure to the technique without receiving real feedback cannot be tested.

Current Practice and Factors Associated with NF Training

Some defenders of NF argue that nonspecific factors alone cannot account for clinical improvement because changes are observable via objective measurements, including EEG [5] and resting state fMRI [6,7]. However, how can researchers or clinicians assure that the effect is due to the administration of neurofeedback if a proper experimental design is not available to evidence so? Few, if any, studies rule out the influence of other parameters. These can be intrinsic to feedback training, such as price (it costs money), length (requires many sessions), involves medical-like instrumentation and carries the appeal of brain science [8]; or are associated to individual factors that will be discussed shortly. Given the whole range of parameters and factors that might impact NF results, it is surprising that to this day, many studies do not invest in properly designing a study that could break down the weight of other factors, so that a significance of clinical improvement can only be associated with the group that receives veritable feedback. To be even stricter, not even a sham condition, but only a control condition with no feedback at all, would be valid to evidence if these factors intrinsic to the technique are partly responsible of the therapeutic effects observed.

Moreover, in an individual level, a start point is usually established by an individual estimation of baseline values for EEG as well as for cognitive activity so the expected change can be measurable for each participant. However, it is possible to find initial differences in baselines between groups and is frequently obviated by the researchers. In this situation, a first clear option is to randomize the participants. Also, derived measures like the proportion of change between baseline and the post-treatment instead of working with the raw data should be used. Therefore, these two ways of action avoid that these initial differences affect the feasibility of the experiment. But beyond this gathering of baseline values, individual factors should be added to the equation. We cannot evade the cognitive demands that NF performance requires [2]. There is an individual input that can make a whole difference in this multi-faceted instrument that is NF. Two aspects pertaining to participants are central to achieve the goal of NF, which is helping the users to gain control over specific aspects of their brain activity [3]. The first aspect implies that learning from NF is most likely dependent on a strong subjective momentary interoceptive sensory process of the participant [3]. In other words, to be aware of internal cues that give the participants valuable information about their own internal state whereas cognitive or physical, such as mind wandering [9,10], meditation [11], relaxation, etc [3]. Following this rationale, those participants who are able to associate these inner states with evidenced brain activity at that moment in their feedback are more likely to beneficiate from this type of intervention and, moreover, to obtain a long term NF training effect.

The second central aspect is the perception of control over brain activity or the NF protocol being administered, also known as "agency" by Gallagher [12]. When a participant has the feeling of causing the action or being able to control the feedback in some appropriate way, the outcome is generally better, even if the outcome results in a placebo effect [3]. Given the primary goal of NF, the agency plays an important role in self-consciousness, giving information about who is causing which action, if ourselves or other entities [12]. In this context, given that to have or not the "belief of control" might

Citation: Aliño M, Gadea M, Espert R (2016) A Critical View of Neurofeedback Experimental Designs: Sham and Control as Necessary Conditions. Int J Neurol Neurother 3:041. doi.org/10.23937/2378-3001/3/1/1041

Received: January 29, 2016: **Accepted:** February 25, 2016: **Published:** February 27, 2016

ClinMed International Library

determine the result, the rationale to include a sham and a control conditions appears.

Current Practice with Real Feedback and Placebo on a Subject Receiving NF Training

During a session where a real feedback is given (experimental condition), the perception of control is usually experienced as contingent with the feedback received and results should evidence significant outcomes in the appropriate direction of the study. However, the difficulty comes when the feedback received by the participant is not real (sham condition). As far as we know, a realistic but fake feedback has been used in many studies (around 60-70% of the literature) as the standard control group [2]. Participants are instructed to try to get control over the feedback on the screen in the same way as in a real training session with NF [3]. In this situation, is it the same when the feedback received is your real own brain activity or someone else's?

First of all, participants sometimes acknowledge their lack of control over the brain activity and the inexistence of contingency of reward. In these cases, the limitation of a sham condition appears which is risking the motivation of participants. As Gruzelier affirms [13], by using the inactive no-training control, researchers may cause a loss of interest in participants, who would desist in the task at hand (lack of motivation) or even experience feelings of frustration. An alternative has been suggested to avoid this limitation of a simple sham condition. Providing, at least, a second sham control group with feedback from a different area of their brain or different frequency of their brain activity could help equalize the belief that they are receiving veritable feedback from the region of interest [2]. However, it is not enough to train a different brain signal to build a control group. This alternative brain signal has to be functionally and neuroanatomically as independent as possible from the signals being assessed in any given study. But, certainly, participants do not always realize what they are experiencing is not a real feedback of their own brain activity and, thus, deep relaxation is inevitable in a majority of participants [13]. Indeed, in some studies, participants experienced the same level of relaxation as the experimental group despite non contingency of reward and without the significant enhancement or reduction of specific ratios trained [14]. As a result, what researchers might obtain is a placebo phenomenon where even though the participant did not receive a real feedback and, therefore, did not execute real NF training, experiments a fake feeling of control and a certain state of relaxation.

Suggestions for an Optimized Experimental Design

Therefore, an optimization of the designs applied to the modern study of NF is in demand to study and tease apart all factors impacting the results of this technique. We think that this improvement would start with the consideration of three additional groups: two sham groups (one where another area or frequency of the brain activity is trained and another where a fake feedback is administered) and a control group (non intervention). Specifically, a non intervention group with no feedback at all is a necessary condition to determine the importance of the exposure to NF consciously. There are only few studies, around 10% of the literature, where this type of group has been included in the design and it certainly marks a difference [15,16]. Also, within the ADHD and NF field, Gonzalez-Castro, Cueli, Rodriguez, Garcia and Alvarez [17] included a control group that was not trained in NF and did not receive pharmacological support either. The working hypothesis in these cases is that, although all treated groups (experimental and sham groups) will improve in the variables assessed, the control group will remain unaffected. Also, we can find in the literature studies where other treatments (mindfulness, relaxation therapy, etc.) are used as control groups, which is another valid experimental design to test the effectiveness of NF although the development of this issue is not the aim of the present short note.

Anyway, no approach is free from some limitation. To a certain degree and depending on the sample, the circumstances or the objectives of the study, a control group or a sham group where participants do not receive an intervention could have ethical connotations. Also, researchers sometimes see a saving of time in using only a sham feedback group, especially pertinent when more than one protocol or group is under study [13]. However, as we mentioned before, this decision might impact on outcome assessments negatively or not having methodologically enough power to control for practice effects, especially when cognitive testing is used in a pre-post design with NF as an intervention [13].

In summary, our claim is that the experimental designs that lack a no-feedback or sham-feedback controls cannot dissociate whether the change in measures relies on feedback or on factors such as mental strategies and the attention and motivation that comes through participation in NF experiments, or on factors intrinsic to NF itself. Thus, well-controlled designs are desperately needed in this field to tease apart the benefits of NF and its new modalities.

References

1. Kamiya, J (2011) The first communications about operant conditioning of the EEG. Journal of Neurotherapy 15: 65-73.
2. Thibault RT, Lifshitz M, Raz A (2016) The self-regulating brain and neurofeedback: Experimental science and clinical promise. Cortex 74: 247-261.
3. Ninaus M, Kober SE, Witte M, Koschutnig K, Stangl M, et al. (2013) Neural substrates of cognitive control under the belief of getting neurofeedback training. Frontiers in Human Neuroscience 7: 914.
4. van Boxtel GJ, Gruzelier JH (2014) Neurofeedback: introduction to the special issue. Biol Psychol 95: 1-3.
5. Leins U, Goth G, Hinterberger T, Klinger C, Rumpf N, et al. (2007) Neurofeedback for children with ADHD: a comparison of SCP and Theta/Beta protocols. Appl Psychophysiol Biofeedback 32: 73-88.
6. Lévesque J, Beauregard M, Mensour B (2006) Neurofeedback training on the neural substrates of selective attention in children with attention-deficit/hyperactivity disorder: a functional magnetic resonance imaging. Neuroscience Letters 301: 45-48.
7. Ros T, Théberge J, Frewen PA, Kluetsch R, Densmore M, et al. (2013) Mind over chatter: plastic upregulation of the fMRI salience network directly after EEG neurofeedback. Neuroimage 65: 324-335.
8. Ali SS, Lifshitz M, Raz A (2014) Empirical neuroenchantment: from reading minds to thinking critically. Front Hum Neurosci 8: 357.
9. Mason MF, Norton MI, Van Horn JD, Wegner DM, Grafton ST, et al. (2007) Wandering minds: the default network and stimulus-independent thought. Science 315: 393-395.
10. Vanhaudenhuyse A, Demertzi A, Schabus M, Noirhomme Q, Bredart S, et al. (2011) Two distinct neuronal networks mediate the awareness of environment and of self. J Cogn Neurosci 23: 570-578.
11. Farb NA, Segal ZV, Mayberg H, Bean J, McKeon D, et al. (2007) Attending to the present: mindfulness meditation reveals distinct neural modes of self-reference. Soc Cogn Affect Neurosci 2: 313-322.
12. Gallagher I I (2000) Philosophical conceptions of the self: implications for cognitive science. Trends Cogn Sci 4: 14-21.
13. Gruzelier JH (2014) EEG-neurofeedback for optimising performance. III: a review of methodological and theoretical considerations. Neurosci Biobehav Rev 44: 159-182.
14. Egner T, Strawson E, Gruzelier JH (2002) EEG signature and phenomenology of alpha/theta neurofeedback training versus mock feedback. Appl Psychophysiol Biofeedback 27: 261-270.
15. Gruzelier JH, Thompson T, Redding E, Brandt R, Steffert T (2014) Application of alpha/theta neurofeedback and heart rate variability training to young contemporary dancers: State anxiety and creativity. Int J Psychophysiol 93, 105-111.
16. Gruzelier JH, Holmes P, Hirst L, Bulpin K, Rahman S, et al. (2014) Replication of elite music performance enhancement following alpha/theta neurofeedback and application to novice performance and improvisation with SMR benefits. Biological Psychology 95: 96-107.
17. González-Castro P, Cueli M, Rodríguez C, García T, Álvarez L (2016) Efficacy of Neurofeedback Versus Pharmacological Support in Subjects with ADHD. Appl Psychophysiol Biofeedback 41: 17-25.