

NCT05503017: Computerized Intervention Targeting the Error-Related Negativity and Balance N1 in Anxious Children

Updated June 5, 2026.

Included documents:

- Statistical Analysis Plan
- IRB Approved Protocol
- Informed Consent Document (for parents/guardians)
- Assent Document (for children)
- Child Journals (blank copies)
 - Intervention: Making Mistakes
 - Control: Healthy Foods

Statistical Analysis Plan

Power analysis. This study was powered based on a large effect ($r=0.75$, Cohen's $d=2.27$) of the intervention on the ERN in preliminary data from $N=10$ children (age 5-7), requiring $N=28$ children in the intervention condition.

Participants. 54 eligible anxious children completed the lab visit ($N=28$ randomized to the active intervention, $N=26$ randomized to the control condition). Parents and children were fully informed before providing written consent/assent. This study was conducted at Florida State University and approved by the Florida State University Institutional Review Board.

Child eligibility was determined by interviewing a parent or guardian over the phone prior to the date of the lab visit (Payne et al. 2025). Specifically, 9-12 year-old children were eligible to participate if they met DSM-5 criteria for generalized anxiety disorder, social anxiety disorder, and/or obsessive-compulsive disorder without comorbid depression or attention-deficit hyperactivity disorder, based on a clinical interview with a parent or legal guardian, using the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS) interview (Kaufman et al. 1997). Children who were eligible to participate frequently met criteria for more than one of the targeted disorders. The use of these disorders to guide inclusion/exclusion is on the basis of their established relationships to the ERN (Meyer 2017; Moser 2017). Children were ineligible to participate if they could not speak English, were unable to stand unassisted for a minimum of 15 minutes (e.g., due to developmental or neurological problems), had a head injury resulting in a loss of consciousness in the past three months, or reported a history of severe psychopathology other than anxiety (e.g., psychosis).

The majority of participants were recruited from the community surrounding Florida State University through flyers posted throughout the community and through digital flyers emailed by the local school district to parents of children in the local elementary and middle schools. Several participants were recruited by directly emailing families that had previously enrolled a child in unrelated studies at Florida State University and consented to being recontacted for future studies.

Overview of lab visit. As detailed below, children performed a balance task to elicit the balance N1 and a Go/NoGo task to elicit the ERN (Figure 1, detailed below, counterbalanced in order across children). Children were then randomized to either the intervention or control condition (both ~45 minutes, including videos and an activity packet of exercises) before repeating the experimental tasks to reassess the primary outcomes. Anxiety symptoms were also assessed using the Screen for Child Anxiety and Related Emotional Disorders (SCARED) (Birmaher et al. 1999; Muris et al. 1999; Muris and Steerneman 2001) child- and parent-report forms. Parents/guardians additionally reported marital status, level of education, income, and the child's race and ethnicity.

Balance Task. To evoke the balance N1, balance disturbances were delivered using a lean-and-release balance perturbation system (Payne et al. 2025). During each trial, children leaned forward into a full-body harness connected to the wall behind them by a flexible cable supporting ~5% of their body weight. In each of 30-35 trials, once the child attained a steady leaning posture and a stable load force in the support cable, the support cable was suddenly released (at unpredictable times), causing the child to begin to fall forward. In most cases, children stepped forward to recover balance. Brain activity, load forces, and head accelerations were monitored live to ensure a steady baseline before each release of the supporting cable. Rest breaks were allowed *ad libitum*.

As decided *a priori* and previously described (Payne et al. 2025), the first 20 trials in each session (pre and post) were excluded as practice trials, and the remaining 10 trials were included in analyses. The decision to exclude 20 practice trials was necessary because balance recovery behavior adapts rapidly, and failing to allow that adaptation to complete before the baseline measurement would confound comparisons across time points. Up to 5 additional trials were added to the end of the series when unusual behavior or forces were observed prior to release. Offline trial selection was determined by force data before processing brain activity, as described below.

Go/NoGo Task. A Go/NoGo task was used to elicit the ERN (Payne et al. 2025). Children were instructed to "blast" cartoon aliens (visual stimulus targets, 75% of trials) by pressing the mouse button and to "save" cartoon astronauts (visual stimulus distractors, 25% of trials) by not pressing the button. Each stimulus was displayed for 500ms, with 1000-2000ms intertrial intervals. After verifying that children understood the task

instructions during a practice block of 5 trials, the experimenter left the room while children completed two blocks of 100 trials, with accuracy-based feedback provided as text on the screen between blocks to encourage faster or more accurate responding when error rates were above or below 85-95%.

Randomization. A research assistant used Wei's urn randomization model for allocation (Matthews et al. 2010; Stout et al. 1994; Wei and Lachin 1988). To ensure balanced assignments across age and sex, four separate pre-randomized lists were designated for 9-10 and 10-11 year-olds by sex, using the randomizeR package (Uschner et al. 2018) in open-source R software. Task order was also determined by this randomization to ensure an equal balance of task orders across condition, age, and sex. Tasks were performed in the same order at pre and post.

Single-blind design. A research assistant administered the intervention or control condition according to the next assignment on the randomized list for the corresponding age/sex stratum. The experimenter responsible for the experimental tasks and data collection was blinded to the assignment until data collection was complete.

Before participation, children were told they would be randomly assigned to watch one of two videos that might be helpful for some anxious children, and were not given any other information about the conditions. However, children could form opinions about whether the videos related to anxiety, and are not considered blinded in this sense. All families received links to access both conditions after participation.

Intervention. The 45-minute computerized intervention was designed to reduce sensitivity to mistakes through cognitive-behavioral techniques (Meyer et al. 2020), including interactive quizzes, information reframing mistakes as opportunities to learn, and ways to deal with mistakes. The intervention was initially designed for adults (Meyer et al. 2020), modified for young children (Meyer et al. 2023), and expanded to include exposures to making mistakes on purpose. The intervention uses developmentally appropriate language and stories that young children can understand and relate to (Mirzadegan et al. 2025). Trained research assistants were available to answer questions from the child during the intervention.

The intervention is based on constructs that relate to the ERN, including the Child Error Sensitivity Index (Chong and Meyer 2019), perfectionism, fear of evaluation by others, and over-valuation of negative consequences of mistakes. The intervention focuses on basic concepts such as: "making mistakes is how we learn," "everybody makes mistakes," and "good things can come from mistakes." There are also several behavioral tasks that demonstrate the potential utility of mistakes. The intervention is interactive, with games and recorded vignettes, and questions to gauge comprehension of the concepts. Intervention videos can be accessed at <https://makingmistakes1.weebly.com/child-making-mistakes-video.html> (enter "999" for journal number).

The intervention was intended to shift the tendency to negatively overreact to mistakes and other situations where things do not go your way, and was not specifically designed to target either experimental task. Although the emphasis on mistakes has a more obvious parallel to the Go/NoGo task than the balance task, if the two evoked brain responses truly reflect the same neural phenomenon, it should be impossible to influence one without influencing the other.

Control condition. The control condition was similar to the active intervention in length and format, but focused on self-care topics and healthy lifestyle choices (e.g., healthy foods, good sleep), unrelated to error sensitivity. The control condition was originally designed for adults (Meyer et al. 2020) and was modified to be appropriate for young children. Control condition videos can be accessed at <https://makingmistakes1.weebly.com/child-healthy-living-video.html> (enter "999" for journal number).

The control condition was intended to control for expectations (i.e., placebo effect) and to assess the impact of repeated measures on the primary outcomes, making it possible to test for a specific effect of the intervention.

Data recording and pre-processing. Data during the experimental tasks were collected with an ActiCHamp plus amplifier (Brain Products) using active EEG electrodes (actiCAP snap electrodes; Brain Products) placed at Fz, FCz, Cz (international 10-20 system) with two additional electrodes placed directly on the skin 1-2cm above the mastoid bones (behind the ears) for offline rereferencing. Impedances <25kOhm were obtained for active electrodes before starting the tasks. Eye activity (electrooculography, EOG) was measured with passive electrodes (E220X electrodes, Brain Products) for artifact correction. EEG and EOG data were filtered between

0.1-25Hz using Butterworth filters (3rd order, forward and backward passes for zero-lag), and epoched around trials before correcting eye-related artifacts using the Gratton and Coles algorithm (Gratton et al. 1983). Head accelerations (3D acceleration sensor, Brain Products) and force (tension) in the cable during leaning (LSB302 300lb tension and compression load cell, Futek) were monitored live to ensure a steady pre-release baseline and recorded by the EEG amplifier.

Balance task data processing. As previously described (Payne et al. 2025), balance task data were time-locked to release of the cable supporting the forward leaning posture. The first 20 trials in each session were excluded as practice trials. 10 of the remaining trials were then selected for analyses based on force data (minimizing variability of pre-release load force and deviations from the goal of 5% body weight). FCz data were then averaged across the selected trials within sessions and individuals, and baseline subtracted (50-150ms before release).

The balance N1 (primary outcome) was measured as the mean voltage at FCz 50-150ms after releases (**Figure 2**). A subsequent positivity (N1p, 150-250ms) was additionally measured (exploratory outcome) based on the prior finding that (anxious vs. nonanxious) group differences persisted into this window (Payne et al. 2025).

Go/NoGo task data processing. As previously described (Payne et al. 2025), Go/NoGo task data were time-locked to responses of clicking the mouse button, and an automated procedure rejected extreme or unusual trials (<1% of all trials), and then data sets with fewer than 6 artifact-free error trials (~4% of all sessions) were excluded from further analyses as a measure of quality control (Meyer et al. 2013; Payne et al. 2025). FCz data were then averaged across trials within response type (error, correct) and session (pre, post) for each participant, and baseline-subtracted (300-500ms before response).

The ERN (primary outcome) and correct-related negativity (CRN) were measured as the mean of a 100ms window centered on responses (Figure 1) for error and correct trials. The error positivity (Pe) was also measured as the mean of 200-400ms after errors. CRN and Pe are not associated with *a priori* hypotheses but are included in analyses for a more complete description of evoked brain activity.

Statistics for primary outcome measures. All of the evoked brain response amplitudes were found to be normally distributed based on Shapiro-Wilk tests ($p>0.05$). One individual was found to have an extreme value (more than three standard deviations from the mean) for their ERN at the pre-control time point and is therefore excluded from relevant analyses. No outcomes change with the inclusion/exclusion of this individual.

ANCOVA analyses assessed the effect of condition (intervention vs. control) on the ERN (or balance N1) response amplitudes at the post session while controlling for the response amplitudes at the pre session.

Birmaher B, Brent DA, Chiappetta L, Bridge J, Monga S, and Baugher M. Psychometric properties of the Screen for Child Anxiety Related Emotional Disorders (SCARED): a replication study. *J Am Acad Child Adolesc Psychiatry* 38: 1230–1236, 1999.

Chong LJ, and Meyer A. Understanding the Link between Anxiety and a Neural Marker of Anxiety (The Error-Related Negativity) in 5 to 7 Year-Old Children. *Dev Neuropsychol* 44: 71–87, 2019.

Gratton G, Coles MG, and Donchin E. A new method for off-line removal of ocular artifact. *Electroencephalogr Clin Neurophysiol* 55: 468–484, 1983.

Kaufman J, Birmaher B, Brent D, Rao U, Flynn C, Moreci P, Williamson D, and Ryan N. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): initial reliability and validity data. *J Am Acad Child Adolesc Psychiatry* 36: 980–988, 1997.

Matthews EE, Cook PF, Terada M, and Aloia MS. Randomizing research participants: promoting balance and concealment in small samples. *Res Nurs Health* 33: 243–253, 2010.

Meyer A. A biomarker of anxiety in children and adolescents: A review focusing on the error-related negativity (ERN) and anxiety across development. *Dev Cogn Neurosci* 27: 58–68, 2017.

Meyer A, Chong L, Wissemann K, Mehra L, and Mirzadegan I. An Experimental Therapeutics Approach to the Development of a Novel Computerized Treatment Targeting Error-Related Brain Activity in Young Children. *Behav Ther* 54: 652–665, 2023.

Meyer A, Gibby B, Wissemann K, Klawohn J, Hajcak G, and Schmidt NB. A brief, computerized intervention targeting error sensitivity reduces the error-related negativity. *Cogn Affect Behav Neurosci* 20: 172–180, 2020.

Meyer A, Riesel A, and Proudfit GH. Reliability of the ERN across multiple tasks as a function of increasing errors. *Psychophysiology* 50: 1220–1225, 2013.

Mirzadegan IA, Lewis EM, Cole SL, and Meyer A. Perceived acceptability and appropriateness of a web-based program targeting risk for anxiety in young children and their parents. *J Pediatr Psychol* 50: 6–17, 2025.

Moser JS. The Nature of the Relationship between Anxiety and the Error-Related Negativity across Development. *Curr Behav Neurosci Rep* 4: 309–321, 2017.

Muris P, Merckelbach H, Schmidt H, and Mayer B. The revised version of the screen for child anxiety related emotional disorders (SCARED-R): factor structure in normal children. *Personality and Individual Differences* 26: 99–112, 1999.

Muris P, and Steerneman P. The revised version of the screen for child anxiety related emotional disorders (SCARED-R): first evidence for its reliability and validity in a clinical sample. *British Journal of Clinical Psychology* 40: 35–44, 2001.

Payne AM, Schmidt NB, Meyer A, and Hajcak G. The Balance N1 Is Larger in Children With Anxiety and Associated With the Error-Related Negativity. *Biol Psychiatry Glob Open Sci* 5: 100393, 2025.

Stout RL, Wirtz PW, Carbonari JP, and Del Boca FK. Ensuring balanced distribution of prognostic factors in treatment outcome research. *J Stud Alcohol Suppl* 12: 70–75, 1994.

Uschner D, Schindler D, Hilgers R-D, and Heussen N. randomizeR: An R Package for the Assessment and Implementation of Randomization in Clinical Trials. *Journal of Statistical Software* 85: 1–22, 2018.

Wei LJ, and Lachin JM. Properties of the urn randomization in clinical trials. *Control Clin Trials* 9: 345–364, 1988.

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	08/19/22	To avoid inviting ineligible participants to the lab visit, the diagnostic interview has been moved into a preceding parent-only remote session with verbal consent. A few surveys have been added or updated.	Yes.
2	05/29/23	We added another questionnaire and another building at FSU for the lab visits.	No
3	09/05/23	Replacing PI Greg Hajcak with N. Brad Schmidt	Yes
4	11/29/23	Adding Leon County Schools as a recruitment route	No

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1.0 Study Summary

Study Title	Investigating the error-related negativity (ERN) and the balance N1 in children with anxiety disorders
Study Design	Within- and between-subjects and -groups comparisons of EEG measures and anxiety, before and after a brief computerized intervention
Primary Objective	Compare the balance N1 to the ERN
Secondary Objective(s)	Test whether the computerized intervention similarly reduces both the balance N1 and ERN in children with anxiety
Research Intervention(s)	A computerized intervention for children that aims to reduce over-reactivity to making mistakes
IND/IDE #	NA
Study Population	Two groups: (1) Children with anxiety disorders (generalized anxiety disorder, social anxiety disorder, and/or obsessive-compulsive disorder) and (2) a control population of children without anxiety disorders. All children will be age 9-12, attended by their legal guardian. Parents of potential participants will be interviewed in a preceding session to determine child's eligibility and group membership.
Sample Size	N=160 children
Study Duration for participants	Up to 90 minutes for parent interview session, then 2-4 hours for child lab visit
Study Specific Abbreviations/ Definitions	ADHD – attention-deficit hyperactivity disorder Balance N1 –the first negative peak evoked in the EEG signal after a balance disturbance Anx – the study population with anxiety disorders CALIS – Child Anxiety Life Interference Scale CASI – Childhood Anxiety Sensitivity Index CBCL – Child Behavior Checklist CESI – Child Error Sensitivity Index CFR – Code of Federal Regulations EEG – electroencephalography ERN – error-related negativity ERP – event related potential FDA – Food and Drug Administration GAD – generalized anxiety disorder KSADS-PL – Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime noAnx – the control population OCD – obsessive compulsive disorder PANAS-C-SF – Positive and Negative Affect Scale – Child – Short Form SAD – social anxiety disorder SCARED – Screen for Child Anxiety Related Disorders

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2.0 Objectives*

- 2.1 The **objective** of this proposal is to measure both the balance N1 and error-related negativity (ERN) in children with generalized anxiety disorder, social anxiety disorder, or obsessive-compulsive disorder (GAD, SAD, OCD; diagnoses associated with increased ERN; ages 9-12, called Anx throughout the proposal) and a control group of children without these diagnoses (noAnx; ages 9-12), and to test whether Anx children present with an enhanced balance N1 (**Aim 1**). We will test the association between the balance N1 and ERN, examining whether they explain unique or overlapping variance in anxiety (**Aim 2**). Finally, we will test the effect of a single-session intervention targeting error sensitivity on both the balance N1 and ERN in the Anx children (**Aim 3**).
- 2.2 **Aim 1:** We predict that the balance N1 will be enhanced in the Anx group (Hyp 1a). We will also replicate the increased ERN in the Anx group (Hyp 1b).
Aim 2: We predict the balance N1 and ERN will be moderately associated across the entire sample (Hyp 2a). We will also test the novel hypothesis that the balance N1 will relate to anxiety severity within the anxious group (Hyp 2b).
Aim 3: We predict that the intervention developed by co-mentors Hajcak and Meyer, which reduces the ERN amplitude in adults and children will similarly reduce the ERN amplitude in anxious children compared to the control intervention (Hyp 3a). Further, we will test the novel hypothesis that this effect will generalize to a similar reduction in the balance N1 after intervention (Hyp 3b).

3.0 Background*

- 3.1 Dr. Payne has 3 first-author primary research articles investigating the balance N1 in young adults (Payne et al. 2019a; Payne and Ting 2020c; Payne and Ting 2020a), with additional investigations in older adults (Payne 2019c; Payne et al. 2022; Payne et al. 2021). In our review paper (Payne et al. 2019b), Drs. Payne and Hajcak suggested that the ERN and balance N1 may reflect outputs of a common neural system based on multiple moderating factors shared between the two potentials. Although the balance N1 is enhanced by state anxiety (Adkin et al. 2008), it has never been investigated in populations with anxiety disorders, or with respect to individual differences in anxiety. Further, the balance N1 and the ERN have never been compared in amplitude within the same subjects, with the exception of Dr. Payne's preliminary data in healthy younger and older adult populations.
- 3.2 In some of Dr. Payne's investigations of the balance N1, he also collected the ERN as preliminary data for the current project, demonstrating that the balance N1 and ERN are associated in both

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young and older adults. Preliminary data provided by co-mentor Meyer demonstrates a significant reduction in the ERN amplitude in 10 children who have undergone the proposed intervention.

- 3.3 This project is designed to extend Dr. Payne's previous work on the **balance N1** to test the extent to which it could serve as an additional or alternative biomarker for anxiety alongside the **ERN**.

The **ERN** is a neural correlate of error processing that is enhanced in people with anxiety disorders (Meyer 2017; Olvet and Hajcak 2008). Increased ERN predicts future onset (Meyer et al. 2015a) and worse outcomes (Meyer et al. 2021) of anxiety disorders in children, and is therefore a potential intervention and prevention target for the development of anxiety disorders. However, the ERN is confounded by lack of experimental control over error frequency, timing, and sequencing, as subjects must commit errors spontaneously (Holroyd and Coles 2002b; Jentzsch and Dudschig 2009; Santesso et al. 2005; Wessel 2018). Further, the ERN is sensitive to task instructions, such as the relative emphasis of speed vs. accuracy (Gehring et al. 1993). Therapeutic interventions can reduce the ERN in a single session (Meyer et al. 2020), but these methodological limitations make it unclear whether this reduction is due to reinterpretation of the specific task, or a change in error processing that would generalize to behaviors of daily life. A paradigm offering experimental control over more natural errors could overcome these methodological limitations to present a more powerful biomarker of anxiety disorders and risk.

In Dr. Payne's thesis, he characterized the **balance N1** (Payne 2019c; Payne et al. 2019a; Payne and Ting 2020c; Payne and Ting 2020a; Payne et al. 2019b), which is evoked by experimentally imposed errors to standing balance and shares many features of the ERN. Drs. Payne and Hajcak previously suggested the balance N1 and ERN reflect the output of a common error detection system based on their similar scalp topography and sensitivities to changes in motivation, perceived consequences, perceptual salience, expectation, development, and aging (Payne et al. 2019b). Dr. Payne's preliminary data show that balance N1 and ERN amplitudes are associated in younger and older adults, further supporting the possibility of overlapping neural mechanisms. Importantly, balance perturbations provide experimental control over the imposed balance errors and evoke an involuntary behavioral reaction that requires no prior instruction, eliminating many of the confounds of the ERN. Further, the balance N1 can be robustly measured in individual trials (Ditz et al. 2020; Payne et al. 2019a), in contrast to the ERN, which requires hundreds of trials, and does not require the exclusion of individuals based on making too many or too few errors. While

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anxiety-inducing conditions enhance the balance N1 within individuals (Adkin et al. 2008), no studies have examined individual differences in the balance N1 in relation to anxiety disorders, or compared the balance N1 and ERN in children.

This project will provide a better understanding of the extent to which pathological error monitoring generalizes beyond computer-based cognitive tasks and may validate a more robust and easily measured biomarker of error processing. Further, the relationship between these evoked responses and their changes through intervention may provide insight into the overlap between balance and anxiety disorders and treatment, including work demonstrating that balance training can alleviate anxiety in young children (Bart et al. 2009), and well-documented benefits of psychotherapy to balance disorders (Schmid et al. 2011; Yardley and Redfern 2001), which may facilitate the development of multidisciplinary interventions for the prevention and treatment of anxiety disorders.

4.0 Study Endpoints*

- 4.1 After a remote interview of the parent to determine eligibility, eligible child participants will come into the lab for a single experimental session consisting of baseline assessment of the EEG outcomes (balance N1 and ERN), intervention or control condition, and reassessment of the EEG outcomes. The study will end once N=64 sufficiently complete data sets are obtained per group, which we expect will require recruitment of ~80 per group.

5.0 Study Intervention/Investigational Agent

- 1.1 Description: A computerized intervention or control condition will be administered to the children with anxiety disorders. Children in the control group will not undergo the intervention. The intervention will use developmentally appropriate language, and stories that young children can relate to. The intervention is based on the constructs of the Child Error Sensitivity Index (CESI), as well as other constructs that relate to the ERN – for example, perfectionism, fear of evaluation from others, and over-valuation of the negative consequences of errors. The intervention will focus on basic concepts such as: “making mistakes is how we learn new things”, “everybody makes mistakes”, and “good things come from mistakes.” The intervention will be interactive, including games and recorded vignettes, as well as questions to gauge children’s comprehension of the concepts being presented. The brief computerized intervention is designed to last approximately 45 minutes.

For the control condition, we will use an active control previously

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used by Dr. Schmidt. This will be a computerized presentation, in the same format as the active intervention, but will focus on self-care topics – unrelated to error sensitivity.

The intervention and control condition videos can be viewed at the following links:

Intervention: <https://makingmistakes1.weebly.com/child-making-mistakes-video.html>

Control: <https://makingmistakes1.weebly.com/child-healthy-living-video.html>

When asked to enter a journal number, enter **999**.

Journals to be filled out by the child during these videos are uploaded with the submission.

- 5.1 Although the EEG system is specified by the manufacturer as scientific equipment for research use, and not an FDA regulated medical device (<https://brainvision.com/terms-and-conditions/>), the EEG system can be considered an investigational device as used to measure the effect of the intervention on the outcome measures in the present study.

The EEG system is a nonsignificant risk device. This designation is appropriate because EEG system is noninvasive, and the risks associated with its use (described in section 15) relate only to possible discomfort or mild, temporary irritation from the hypoallergenic gel placed between the scalp and the recording electrodes.

As a nonsignificant risk device, IRB approval will confer an abbreviated Investigational Device Exemption (IDE), requiring compliance with FDA Regulations under 21 CFR 812, to be ensured by Dr. Payne and Dr. Schmidt.

The following actions will be taken to comply with these regulations. We attest that the device is not a banned device under 21 CFR 895. The device will be labeled in accordance with 21 CFR 812.5 (label detailed below). All procedures, including informed consent, will be performed as described in the IRB-approved protocol. Use of the device in the context of this study will be monitored in accordance with 21 CFR 812.46. Records required under 21 CFR 812.140(b) (4) and (5) and 21 CFR 812.140(a)(3)(i) will be maintained in a single location on the Schmidt lab server. Any relevant reports under 21 CFR 812.150(b) (1) through (3) and (5) through (10) and 21 CFR

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812.150(a) (1), (2), (5), and (7) will be submitted to FDA upon occurrence of relevant events as required. This includes any unanticipated adverse device effects involving the EEG system in the context of this study, any withdrawal of IRB approval, any relevant device recalls, use of the device in the context of this study without obtaining informed consent, changes in the determination of the nonsignificant risk designation of the device as used in the context of the study, and any other report requested by the reviewing IRB or FDA. As a nonsignificant risk device, yearly progress reports and final reports upon completion of the investigation under 21 CFR 812.150(b) (4) will be sent to FSU's IRB as requested and do not need to be sent to the FDA. Further, we attest that we are not promoting or misrepresenting the EEG system or doing any other activities prohibited under 21 CFR 812.7.

The label on the EEG system states the following:

“Manufacturer: Brain Products GmbH, Zeppelinstraße 7,
 82205 Gilching, Germany” and
 “CAUTION—Investigational device. Limited by Federal (or
 United States) law to investigational use.”

6.0 Procedures Involved*

- 6.1 The study design includes (1) cross-sectional comparisons of the balance N1 and the ERN between Anx and noAnx groups, (2) within and between group correlations between the balance N1, the ERN, and anxiety severity at baseline, and (3) within the Anx group, longitudinal comparisons of the balance N1 and ERN between pre- and post-intervention time points in the intervention relative to the control condition, as well as tests of association between longitudinal changes of the balance N1 and ERN.

Eligibility of the child will be determined by a diagnostic interview of the parent about the child using the Kiddie Schedule for Affective Disorders and Schizophrenia – Present and Lifetime Versions (KSADS-PL), which is a semi-structured clinical interview for the assessment of psychopathology in children and adolescents (Kaufman et al. 1997) that we routinely use in our research studies. This interview will occur over the phone following verbal consent using the provided script. As in previous studies, the interviews will be audio recorded for the purposes of coding reliability. Participants will be asked if it is okay to record the interview before each interview begins.

Eligible participants will be informed about the study procedures, including COVID-19 related procedures, and invited to the lab. Lab

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personnel and participants who exhibit a recent onset of COVID-19 symptoms, who have had recent contact with someone with COVID-19, or who fail this CDC-sponsored screening tool on the day of their recording session (<https://covid19.apple.com/screening>) will not be allowed to enter the building and/or laboratory.

Upon arrival at the lab, participants will be further informed about the study procedures. Then, the consent and assent forms will be given to the parent or legal guardian and child, respectively, and both will be given the opportunity to ask questions before signing them. Signed informed consent and assent documents will be stored separately from all other study materials (which will be associated with an alphanumeric code, e.g., participant01) to limit risks of a breach of confidentiality.

Anxiety will be assessed by the Screen for Child Anxiety Related Emotional Disorders (SCARED), which is a 41-item questionnaire that will be filled out by the child.

To capture a broad spectrum of symptoms, we will also administer a shortened version of the Child Behavior Checklist (CBCL), a 113-item parent-report checklist that assesses emotional and behavioral problems (internalizing and externalizing) over the past 6 months (Achenbach and Ruffle 2000). Specifically, we will use the revised depression and ADHD subscales from this measure (Lengua et al. 2001).

Additionally, to assess error sensitivity in children, we will use the Child Error Sensitivity Index (CESI) (Chong and Meyer 2019). This measure includes 9 items indexing error sensitivity, for example: “I feel upset when other people don’t like something I have done”, “If I make a mistake, I always want to fix it”, and “When I make a mistake, I feel anxious”, and has good psychometric properties.

Children may also fill out the Childhood Anxiety Sensitivity Index (CASI), which includes 18 items related to worries about bodily sensations related to anxiety (Silverman et al. 1991).

Children will also fill out the Situational Vertigo Questionnaire to assess for symptoms associated with vestibular dysfunction (Dannenbaum et al. 2019). An Attentional Focus Questionnaire will also be given immediately after the balance perturbations (given twice to the Anx group, once for each perturbation series, before and after intervention) to assess attentional focus and feelings of worry during the balance perturbations (Johnson et al. 2019).

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Children will also fill out the shortened child version of the Positive and Negative Affect Scale (PANAS-C-SF) (Ebesutani et al. 2012; Hughes and Kendall 2009). Children and parents will fill out the Child Anxiety Life Interference Scale, child and parent forms, respectively (Lyneham et al. 2013; Pereira et al. 2015).

There is a chance that participants or their caregivers may experience mild, transient distress related to answering questions in the questionnaires or interviews. All self-report and interview questions are consistent with the type normally asked as part of a routine psychological or medical evaluation. Interviews will be administered by trained personnel who can assist the participant or caregiver in processing any potential distress, if necessary. In addition, the interviews can be terminated at any time, and items on the self-report measure can be skipped. Participants and their caregivers will be informed that they are free to end participation at any point in the study.

We anticipate that these surveys will take less than 15 minutes to complete.

Additional subject characteristics such as child age, height, weight, and relevant demographic information will also be reported or measured as applicable. Current psychoactive medications will also be recorded, including whether they are taken regularly, and whether they were taken on the day of the experimental session.

Children may also be asked to complete simple balance tasks, such as balancing on one leg for up to a minute as a measure of general balance stability. This may be completed on a Wii balance board recording the center of pressure beneath the feet. A spotter will stand within reach of the child to prevent falls.

As detailed below, all eligible participants (both in the Anx and noAnx groups) will then participate in the baseline measurement of the EEG outcomes (ERN and balance N1, ~30-45 minutes). Those in the Anx group will additionally undergo the intervention or control condition (~45 minutes) and subsequent reassessment of the EEG outcomes (~30-45 minutes). Procedures for the Anx and noAnx groups are identical through the completion of the baseline measurement of the EEG outcomes, at which point those in the noAnx group will have completed their participation, but those in the Anx group will continue through the intervention or control condition video and reassessment of the EEG outcomes. Within the Anx group, the only difference between those randomized to the intervention or control condition is which version of the 45-minute

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video is viewed between baseline and reassessment of the EEG outcomes.

EEG electrodes will be applied to the participant's head and worn for up to 3 hours. In order to obtain acceptable signal quality, electrode gel must be applied to each electrode with a blunt tipped syringe that will also be used to gently part the hair and abrade the skin to remove dead skin cells if the signal quality is poor. It is possible that a participant could have an allergic reaction to the electrode gel, but this is very unlikely as the gel is hypoallergenic and designed for this specific purpose. It is also possible that the participant will experience some mild discomfort from the tip of the syringe rubbing against the scalp, and they will be informed of this beforehand and asked to tell us if they experience discomfort so that the experimenters can adjust the pressure or, if necessary, accept lower electrode quality. While there will be 32 electrodes, approximately 5 of those electrodes are critical to the outcomes, and preparation will focus on those. In rare cases, participants may have temporary redness of skin where 5 additional electrodes (attached with small stickers) are placed on the face around the eyes to record blinks, or where 4 and 2 additional electrodes pairs are placed below the knee and on the neck, respectively.

A computer-based Go/No-Go task will be performed to elicit the ERN (primary outcome measure). This task will take 5-10 minutes and will be performed by both groups at baseline, and a second time in the Anx group after the intervention or control condition. This task involves two visual stimuli, one depicting a cartoon alien, and one depicting a cartoon astronaut. Children will be asked to quickly click a mouse button to "blast the aliens" when they appear on the screen and to withhold a response (i.e., not click the mouse button) when an astronaut appears on the screen. It is possible that some of the children, particularly those with anxiety disorders, will experience mild distress when making rare, but expected errors. These errors are necessary to the experimental procedures and cannot be avoided because these errors are the events that evoke the ERN (primary outcome measure), which we will quantify as a measure of how they process their own mistakes. Participants will be informed that they can stop the task at any point.

Physical balance perturbations will be applied to the participants to elicit the balance N1 (primary outcome measure). This task will take 10-15 minutes and will be performed by both groups at baseline, and a second time in the Anx group after the intervention or control condition. Participants will wear a chest harness that will be used to connect them to a wall behind them via a cable (approximately 3-4 feet). While connected to the wall behind them, they will be instructed to lean forward by a small amount, such that the cable is

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supporting a small fraction of their body weight (~5%). Participants will be forewarned that the cable will be suddenly released, but the timing of that release will be unpredictable. When the cable is detached, their body will begin to accelerate forward (due to the loss of support) and the participant will (involuntarily) activate muscles in their legs to recover their balance, with or without taking a step. The participants may experience mild distress upon release of the cable, comparable to that experienced when tripping, or when missing a step on the stairs. This mild distress is necessary to the experimental procedures and cannot be avoided because the release of the support cable is the event that evokes the balance N1 (primary outcome measure). The load in the cable prior to release will be set such that the balance disturbance is very small (e.g., participants may ultimately move a few centimeters and will not need to take a step to recover balance, although some will choose to do so). The behavioral reaction to the cable release is involuntary, and anyone capable of standing without assistance (i.e., does not use a cane or walker) should have no difficulty recovering balance. However, in extremely rare events, participants may overreact to the small disturbance (e.g., startling into a jump), putting them at risk of falling, particularly in the first few trials. To protect against this risk, a dedicated spotter will be present within 3 feet of the participant in a position where they can take a single step forward to prevent a fall.

Participants in the Anx group will then be randomly assigned to watch one of two 45-minute videos, corresponding to either the active intervention (“Making mistakes”) or the control condition (“Healthy Living”) as described in the previous section, before repeating the measurement of the EEG outcomes. The computer-based intervention is designed to directly reduce the sensitivity to errors through cognitive behavioral techniques, and includes interactive quizzes and information about making mistakes, implications of making errors, and ways to deal with making mistakes, among other topics relevant to error sensitivity. Participants randomized into the control condition will undergo a similarly formatted computer-based presentation focused on self-care topics and healthy lifestyle choices, unrelated to error sensitivity. Participating in either the intervention or the control condition is low risk, as it contains helpful ways to think about one’s behaviors to improve well-being. Participants randomized into the control condition will be given the option to additionally complete the active intervention at home.

There are no other anticipated risks for participating in this study, including social, cultural, financial, or legal risks.

- 6.2 Risks of loss of confidentiality will be minimized by separating experimental data, which will be associated with an alphanumeric

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code, from any identifying information. All identifying information, including signed consent forms, collected during the proposed project will be kept in a locked storage cabinet to which only Dr. Schmidt, Dr. Payne, and trained project coordinators will have access. All data will be stored on a secure, password-protected server, on password-protected computers, separate from any identifying information. All data collected will be marked with the participant's alphanumeric code and will not be marked with the participant's name or any other identifying information. The document linking this alphanumeric code will also be stored on the computer using the secure, password-protected server. Dr. Schmidt will be responsible for monitoring maintenance of confidentiality, while all laboratory personnel will also have training on proper confidentiality practices and regulations. In the event of any breaches of confidentiality, the participant and their primary caregiver will be notified by Dr. Payne—and the breach would be reported to Florida State University's Institutional Review Board.

The risk of allergic reaction to the electrode gel will be minimized through the use of hypoallergenic gel that is designed for this specific purpose and widely used in human subjects' research. In the very rare event of an allergic reaction, the risk is limited to mild skin irritation (i.e., mild itching and redness at the site of application) and is expected to resolve within 24 hours. The experiment may be ended early in such an event to allow immediate removal of the electrode gel.

The risk of physical injury during balance perturbations is minimized through both preventive and reactive strategies. The risk of falling is minimized through a preventive strategy by using very small balance perturbations, just large enough to evoke a minimal reaction, without putting the participant at risk of falling or sustaining injury. However, in the very unlikely event that a participant overreacts to the balance disturbance (e.g., startles into a jump), a dedicated spotter will employ a reactive strategy by taking a single step forward and intervening to prevent a fall or bodily injury.

Although rare, participants or their parent/guardian may endorse suicidality, increased suicide risk, or increased risk of harm to others. If participants endorse any of these items as a part of the clinical interview, the interviewer will inform the participant that this information will need to be disclosed to the participant's parent/guardian; this will be done with the participant present. A suicide risk assessment will then be performed by an interviewer trained in suicide risk management to determine suicidality severity and an appropriate course of action. The method, described below, is standard for studies conducted in Dr. Hajcak's laboratory and is aligned with an evidence-based approach developed by Dr. Thomas

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Joiner, a licensed clinical psychologist who directs the FSU Psychology Clinic and is considered a world-leading expert in the study of the nature, causes, and management of suicidal behavior. The following approach will be used to determine risk severity:

1. Low Risk for Suicide: Individuals are considered at low risk for suicide if they are multiple attempters with no other risk factors or are non-multiple attempters who experience suicidal ideation of limited intensity and duration; further, individuals must have no or mild resolved plans and preparation, as well as no or few other risk factors.
2. Moderate Risk for Suicide: Individuals are considered at moderate risk for suicide if they have attempted multiple times with the presence of any other risk factor. Non-multiple attempters with moderate-to-severe resolved plans and preparations or moderate-to-severe suicidal ideation that coincides with at least two other risk factors is also considered to be at moderate risk for suicide.
3. Severe/Extreme Risk for Suicide: Individuals are considered at severe or extreme risk for suicide if they are multiple attempters with two or more risk factors—or if they are non-multiple attempters with severe resolved plans and preparations with two or more other risk factors.

Based on risk stratification, the following actions are taken: For all participants with suicidal ideation, phone numbers for mental health resources will be provided to the primary caregiver (i.e., parent/legal guardian). At their request, participants will be provided a referral to clinicians at the FSU Psychology Clinic, which is located on the first floor of the Psychology Department Building—the same building that houses Dr. Schmidt's main laboratory.

1. Low Risk for Suicide: The individual and their caregiver will be provided coping strategies and recommendation to seek out social support if he or she becomes suicidal. If these strategies are unsuccessful, the caregiver will be instructed to contact an emergency mental health resource (e.g., National Suicide Prevention Lifeline; 1-800-273-TALK) or contact 9-1-1.
2. Moderate Risk for Suicide: The individual and their caregiver will be guided through making a safety plan with a list of activities to complete while feeling distressed or experiencing suicidal ideation. This safety plan will be individually-tailored to meet the participant's needs. The plan will also contain phone numbers to contact an emergency mental health resource (e.g., National Suicide Prevention Lifeline; 1-800-273-TALK) or contact 9-1-1. The individual and their caregiver will also be encouraged to seek treatment options (e.g., therapy, medication) and will be provided with referral information to mental health and/or substance-use treatment services. The individual and their caregiver will also be

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given the opportunity to go to the FSU Psychology Clinic for further care. A follow-up call will be scheduled within 3-4 days to monitor suicide risk—and further encourage treatment and use of the developed safety plan. In the event of moderate risk, Dr. Schmidt will be immediately contacted and consulted to determine the best course of action in terms of ensuring the safety of the individual.

3. Severe/Extreme Risk for Suicide: All steps for both Low and Moderate Risk for Suicide will be followed; however, the option of hospitalization will be discussed with the primary caregiver (i.e., parent/legal guardian). If hospitalization—or further care at the FSU Psychology Clinic—is refused, then the experimenter will call 9-1-1 so that emergency services can escort the participant to an emergency medical facility. The interviewer will follow up with the individual after evaluation/hospitalization to evaluate risk to ensure coordination of further care. Moreover, Dr. Schmidt will be immediately contacted and consulted to determine the best course of action and decide on any additional steps needed to ensure the safety of the individual.

Information related to child abuse may also be assessed during the study. Research staff will follow both federal and state mandates related to child abuse reporting requirements. Participants will be informed of the need to report child abuse prior to eliciting this information by interviewers, which also serves to minimize the associated risk of loss of confidentiality. In cases of reported abuse by the child or parent/legal guardian, the parent/legal guardian will be informed about the federal and state mandated reporting laws, both verbally and in writing; in cases where it is necessary to make a child abuse report, the family will be informed prior to contacting any state agency and will be given the option of making a self-referral to protective services. All other study procedures and aspects of the proposed research pose no more than minimal risk.

- 6.3 As detailed in the proceeding section, data will include parent-report and child self-report questionnaires, diagnoses, obtained via remote clinical interview (K-SADS-PL), and other questionnaires filled out during the study visit, including SCARED, CBCL, PANAS-C-SF, CALIS, CASI, and the CESI. Other data will include the EEG outcome measures, the balance N1 and the ERN, assessed in the behavioral tasks described in the preceding sections.

7.0 Data and Specimen Banking*

- 7.1 Data will be kept in electronic form on a password protected lab server. Data will be kept in a de-identified manner (using ID numbers) for ongoing analyses. The ID number will only be matched to names in a separate and password protected excel sheet that only the PI and research coordinators have access to.

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- 7.2 De-identified data, including questionnaires and EEG recordings, will be stored in electronic form on a password protected lab server. Data will be kept in a de-identified manner (using ID numbers) for ongoing analyses. The ID number will only be matched to names in a separate and password protected excel sheet that only Dr. Schmidt, Dr. Payne, and research coordinators have access to.
- 7.3 If a participant requests their data (EEG, self-report, or observational data), we will provide a summary of relevant data, along with a brief description of the measure. Identifiable data will not be released to anyone other than a participant.

8.0 Sharing of Results with Subjects*

- 8.1 We do not plan to share results with participants (unless they request us to do so).
- 8.2 Data may be shared with other investigators without asking for consent and assent again, but it will not contain information that could directly identify participants.

9.0 Study Timelines*

- 9.1 Parents of potential participants will participate in a remote interview of up to 90 minutes. Eligible children who are enrolled in the study will then participate in a single experimental session lasting 2-4 hours.

We will pilot 5-10 participants to finalize details of the protocol such as the pre-perturbation load force and number of perturbation trials prior to Spring 2023. We aim to complete testing of N=20 participants in each of the two groups by the end of Summer 2023, and to complete the full sample of N=80 participants in each group by the end of Spring 2024.

Primary data analyses will begin alongside data collection and will continue for 3-6 months following completion of subject testing. We anticipate completion of primary analyses by the end of Fall 2024.

10.0 Inclusion and Exclusion Criteria*

- 10.1 The parent or guardian of potential child participants will participate in a diagnostic interview in which the KSADS-PL will be used to determine whether the child meets diagnostic criteria for specific conditions relevant to the inclusion/exclusion criteria. This interview will be conducted remotely, without the child present, following verbal consent. During the interview, the parent will also be questioned about other eligibility criteria (see 10.2). If the child is determined to be eligible, the parent and child will be invited for an in-person laboratory visit. Individuals who do not pass the COVID

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screeners described above will be excluded or rescheduled as appropriate.

- 10.2* Inclusion criteria consists of ages 9-12 years, ability to stand 15 minutes without assistance or supportive devices, sufficient English fluency to understand the intervention content, and vision that can be corrected to 20/40 or better with corrective lenses. Inclusion in the Anx group requires the child to meet diagnostic criteria for generalized anxiety disorder (GAD), social anxiety disorder (SAD), and/or obsessive-compulsive disorder (OCD), which are also exclusion criteria for the noAnx group.

Exclusion criteria for both groups includes meeting diagnostic criteria for attention-deficit hyperactivity disorder (ADHD) or depression, the presence of a significant medical condition, disability, developmental disorder, severe psychopathology (i.e., bipolar disorder, psychosis, thought disorder, neurological disease, severe or extreme suicide risk), or any head injuries that have resulted in a loss of consciousness over the prior three months. Participants are also excluded if they do not speak or understand English.

- 10.3* This study will not include adults unable to consent, pregnant women, prisoners. The study will include children.

11.0 Vulnerable Populations*

- 11.1* This research study involves children between the ages of 9 – 12 years old. We will collect parental consent for all study procedures, as well as child assent. Additionally, children will be reminded throughout the lab visit that they can take a break or stop the study at any time.
- Protocol for screening participants for COVID-19 is stated in the protocol addendum, “COVID-19 Human Subjects Research Standard Operating Procedure (SOP) and Risk Mitigation Plan for EEG Research.”

12.0 Local Number of Subjects

- 12.1* All 128 anticipated subjects in the final sample will be accrued locally, which may require initial recruitment of up to 160 participants.

13.0 Recruitment Methods

- 13.1* Participants in the study will be children recruited using the Family Registry at FSU or a targeted mailing list. The FSU Center for Developmental Science implements on-going recruitment throughout the Tallahassee community, focusing on children and families. They

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maintain a database, which includes the names, ages, and contact information of children and families interested in participating in research studies. The Family Registry is comprised of over 1,500 families to date, and continues to grow each week due to regular recruitment events in the community. We plan to recruit families with children between the ages of 9 and 12 years of age. In addition to utilizing the Registry at FSU, we plan to post fliers in the community and recruit families at additional community events. Fliers will also be distributed electronically from the Leon County School District to parents.

We will also recruit using ResearchMatch.org. ResearchMatch.org has a database of people interested in participating in research, and those with 9–12-year-old children will receive a standardized recruitment email (as detailed in the attached document) that includes the following text specific to this study: “We are recruiting 9–12-year-old kids who (1) worry excessively, (2) get anxious in social situations, and/or (3) have obsessions and/or compulsions. We will first interview a parent or primary caregiver over the phone (up to 90 minutes, paid \$5 per 15-minute interval, in amazon gift cards via email) to determine eligibility for the study. If eligible, we will invite you and your child for a single in-person lab visit lasting 2-4 hours. During this visit, you and your child will answer questions on the computer, and your child will play a computer game and do a balance recovery task while we record muscle and brain activity using sensors placed on the skin and scalp. Some children will also be asked to watch a 45-minute video before repeating the two tasks. At the end of the visit, your child will pick out a small toy prize and we will pay you (the parent/caregiver) \$20/hour in cash (pro-rated to 15-minute intervals) for your time in the lab.”

- 13.2 Source of recruitment: FSU Center for Developmental Science Family Registry and fliers that will be posted through-out the community. We also plan to utilize a targeted mailing list for children and families in the Tallahassee community
- 13.3 Parents of children between 9-12 years of age who indicate interest in participating will be remotely interviewed using the KSADS interview to determine eligibility of their child for either of the experimental groups.
- 13.4 The flier that we plan to use for recruitment is attached to this submission. It includes a picture of a minions stuffed animal with an EEG cap on. We state that families with children between the ages of 9 and 12 are eligible to participate in our study and provide our lab contact information.

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13.5 Parents will be compensated \$20 an hour (prorated to 15-minute intervals) for a total of \$5-40 for the remote diagnostic interview in digital gift cards sent via email within one week of the interview. While this interview will end early if the child is determined to be ineligible, the parent will still be compensated for their participation in the interview. Participants in the in-person session will be compensated \$20/hour in cash for participation, for a total of \$40-80 for a completed session including the intervention for the Anx group or a total of \$20-60 for completed session without intervention for the noAnx group. Children will also receive a small toy prize after the intervention (Anx) or at the end of the experimental session (NoAnx). Participants who decide to leave early will be compensated at the same hourly rate.

14.0 Withdrawal of Subjects*

14.1 We do not anticipate subjects being withdrawn from the study without their consent.

15.0 Risks to Subjects*

15.1 Anticipated risks are minimal. There is a chance that some parents or children may experience mild, transient distress during parts of the assessments. All questions (self-report and parent-report) are the type typically asked during routine psychological or medical evaluations. If necessary, the assessment can be interrupted or terminated. The family (parent and patient) will be clearly informed that they are free to terminate participation at any point in the protocol.

The EEG recording is non-invasive but may cause slight discomfort when rubbing the scalp to improve signal quality. EEG gel is hypoallergenic but in rare cases some participants may experience mild, temporary itching or tingling sensation in response to the electrode cap or electrode gel.

There is also a small chance of minor injury (e.g., a small bruise) during the balance perturbations. The balance perturbations will be calibrated to a minimal perturbation, which should ultimately cause a few centimeters of body motion without requiring the participant to take a step to recover balance. However, in very rare cases, participants may startle to the point of jumping or swinging their arms out, which may cause them to bump into the wall. An experimenter will be within reach of the participant to stop them in these very rare cases, which are typically limited to the first 1-3 trials.

Informed consent and assent will be obtained prior to participation in the in person experimental session, and risks will be explained carefully to the participant and their guardian. Risk of loss of

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confidentiality are minimized by keeping all identifying information in a locked storage cabinet to which only Dr. Schmidt and the study coordinators will have access. All data will be stored separately from identifying information and will be password protected.

Upcoming procedures are repeatedly explained to the children and their guardian, giving them a sense of control over what is happening in their environment. Rather than closed yes/no questions, open-ended questions with regard to comfort and well-being will be used throughout the procedures to give subjects the opportunity to voice any concerns or discomfort. Subjects will also be given the opportunity to ask questions regarding the research procedures at any time during the protocol.

Although we don't expect it frequently, some participants may endorse increase risk for suicidality. In this event, safety assessments will be conducted as described in the procedures section above to ensure the participant receives resources and treatment as appropriate.

We will be following the procedures outlined in the attached COVID-19 Human Subjects Research Standard Operating Procedure (SOP) and Risk Mitigation Plan for EEG Research document. Participants may feel uncomfortable following some of the COVID-19 safety procedures, such as having to wear a mask. If participants feel uncomfortable at any time, due to these reasons, we will discontinue the session.

16.0 Potential Benefits to Subjects*

16.1 Although the benefits of participation are minimal, de-briefings from Dr. Hajcak's previously funded studies in adolescents indicated that most children enjoy participating in the assessments—many of which are presented as games—and many of the children derive satisfaction from contributing to science and knowledge about their own development. Although not a study purpose, parents who have concerns about their child's psychological functioning will have the opportunity to talk with Dr. Schmidt, a licensed clinical psychologist in the state of Florida, and referrals will be made, if necessary.

16.2 There are no direct benefits of participation.

17.0 Data Management* and Confidentiality

17.1 Aim 1 is powered based on the medium effect sizes of increased ERN amplitudes in children with GAD (Cohen's $d=0.60$) (Hanna et al. 2020) or OCD (Cohen's $d=0.56$) (Carrasco et al. 2013) compared to non-anxious children, requiring a sample size of $N=64$ in each group to achieve Power= 0.80 for $\alpha=0.05$ (Cohen 1992). Aim 2 is powered based on the large effect size of correlations between the

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balance N1 and ERN in Dr. Payne preliminary data ($R^2 > 0.25$, $r > 0.5$), requiring $N=28$. Aim 3 is powered based on the large effect of the proposed intervention on the ERN in co-mentor Meyer's preliminary data ($r=0.75$, Cohen's $d=2.27$), requiring $N=28$. Thus, recruiting $N=80$ children in both Anx and noAnx groups, and then randomizing the $N=80$ in the Anx group into an active intervention ($N=40$) or control condition ($N=40$) will ensure sufficient power to address the primary hypotheses of each aim.

Aim 1. We predict both the balance N1 and ERN will be larger in Anx vs. noAnx groups. The independent variable is group and the dependent variables are the amplitudes of the balance N1 and ERN. The balance N1 and the ERN will be analyzed using two separate one-tailed t-tests to test whether the balance N1 (Hyp 1a) and ERN (Hyp 1b) are larger in the Anx group vs. the noAnx group.

Aim 2 (primary). Pearson product-moment correlations will measure and test the predicted association between the balance N1 and ERN amplitudes across individuals (Hyp 2a), both in the overall sample, and separately within the Anx and noAnx groups.

Aim 2 (secondary). Further, we predict that the balance N1 and the ERN will be associated with anxiety severity in the Anx group (Hyp 2b), tested using Pearson product-moment correlations between the balance N1 or ERN amplitudes and SCARED total score. We will also use logistic regressions to compare effect sizes of N1 and ERN in differentiating groups, and test whether the balance N1 and ERN account for unique or overlapping variance in Anx disorder status when combined as simultaneous predictors in a logistic regression.

Aim 3 (primary). Baseline and reassessment ERN and balance N1 amplitudes will be quantified for each individual and entered into mixed-model ANOVAs with assignment to the intervention or control condition as a between-subjects factor and time (baseline vs. reassessment) as a within-subjects factor to test (Hyp 3a/b) whether the ERN and balance N1 amplitudes are reduced following an intervention designed to reduce sensitivity to errors. Specifically, We predict an interaction effect wherein the ERN and balance N1 will be reduced after the intervention to a greater extent than after the control condition.

Aim 3 (secondary). We will use Pearson product-moment correlations to test whether changes in the magnitude of the ERN after the intervention are associated with changes in the magnitude of the balance N1 as evidence for overlapping mechanisms.

- 17.2 All identifying information collected during the project will be kept in a locked storage cabinet to which only Dr. Schmidt and the study coordinator will have access. All data will be stored separately from identifying information and will be password protected. No names

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will be maintained in data records; rather, information will be coded by ID numbers only. Dr. Payne will be responsible for monitoring the maintenance of confidentiality. In the event of a breach of confidentiality, he will inform the subject and their parents that the breach occurred; any breaches of confidentiality will be reported to the Institutional Review Board. Codifying participants by unique identifiers is an extensive practice that is highly efficient at protecting anonymous participation. No individual child or family will be identified in any publications or presentations of the research findings.

17.3 We will apply standardized quality control methods that have been routinely used in Dr. Hajcak's lab.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 A Data Safety and Monitoring Plan is uploaded as a separate attachment, but relevant points will be described here briefly.

Based on the low risks, single-site, single-session, and simple study design, data and safety monitoring will be performed by the study team without an external data and safety monitoring committee.

Although very unlikely, it is possible that a participant could sustain a minor injury during the balance perturbations (e.g., small bruise). Any contact with an object or surface in the room (e.g., a wall or floor) during the balance perturbations, even in the absence of any associated injury or discomfort, will be documented in the data collection forms and reviewed by the study team at the end of every session to determine whether any proactive actions can be taken to prevent or minimize the risks associated with such contact in the future (e.g., moving an object, padding the wall). These notes will be transferred to a combined electronic log, stored on the Schmidt lab server and will be reviewed monthly by the study team throughout data collection to determine whether the study environment or study protocol need to be modified to ensure safety, or whether the protocol or consent form need to be modified to more accurately reflect the risks of the study.

The anticipated risks associated with the intervention and EEG system relate to potential discomfort, but not harm or injury.

Any serious adverse events will be documented and reported to the IRB, NIMH, and FDA, as appropriate. As no serious adverse events are anticipated, the occurrence of any serious adverse event during the study procedure will temporarily suspend the research activities until the study team and the IRB (and if appropriate, the NIMH and FDA), determine that it is safe to resume research activities. Given

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the single-session design, there are no time-sensitive follow-up activities that would be disrupted by such a suspension.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Data will be kept in electronic form on password protected lab computers. Data will be kept in a de-identified manner (using ID numbers) for up to 10 years. Any paper material (e.g., consent forms, self-report forms) will be kept in de-identified folders in locked file cabinets in the lab for up to 10 years. The preceding 10-year periods may be longer, if required by applicable law.

19.2 Upcoming procedures are repeatedly explained to the participant, giving them a sense of control over what is happening in their environment. Rather than closed yes/no questions, open-ended questions regarding comfort and well-being will be used throughout the procedures to give subjects the opportunity to voice any concerns or discomfort. Subjects will also be given the opportunity to ask questions regarding the research procedures at any time during the protocol.

19.3 Only Dr. Schmidt, Dr. Payne, and the study coordinators will have access to identifiable information.

20.0 Compensation for Research-Related Injury

20.1 NA; this study does not involve more than minimal risk to subjects.

21.0 Economic Burden to Subjects

21.1 NA.

22.0 Consent Process

22.1 Interested families will first be sent an electronic (or physical) copy of the consent form for the in-person experimental session, which also describes the diagnostic interview for the remote parent-only session, and given as much time as desired to review this information. Parents who are interested in enrolling their child in the study will then be scheduled for the diagnostic interview session, which will determine whether their child is eligible to participate in the in-person experimental session.

The consent process for the parent-only remote diagnostic interview will occur over the phone, using the provided verbal consent script.

The consent and assent process for the in-person experimental session will take place at the beginning of the lab visit in a room in the lab, after a conversation about the details of the study, and before any research procedures begin. Subjects will also be given enough time to review the consent form on their own and will be given the

PROTOCOL TITLE: Investigating the error-related negativity and the balance N1 in children with anxiety disorders

opportunity to ask questions regarding the research procedures before signing and throughout the protocol. Additionally, throughout the lab visit, upcoming procedures are repeatedly explained to the children and their parent, giving them a sense of control over what is happening in their environment. Rather than closed yes/no questions, open-ended questions with regard to comfort and well-being will be used throughout the procedures to give subjects the opportunity to voice any concerns or discomfort. Participants will also be provided information about COVID-19 and the safety precautions that the lab is taking.

We will be following “SOP: Informed Consent Process for Research (HRP-090)” for the in-person experimental session.

The consent form includes a statement that information about this study will be available on clinicaltrials.gov. An unsigned copy of the IRB-approved consent form will be posted to the clinicaltrials.gov site as required by the NIH.

Subjects who are not yet adults (infants, children, teenagers)

- Participants in the study will be between the ages of 9 – 12 years old, so they will be individuals under the age of 18 years and therefore not yet adults.
- Parental permission will be obtained from one parent or legal guardian (who accompanies the child to the lab visits).
- Assent will be obtained from the child participant. This will be documented with the child assent form (included in the main consent document).

23.0 Process to Document Consent in Writing

23.1 To obtain consent for the in-person experimental session involving the child, we will be following “SOP: Written Documentation of Consent (HRP-091).”

23.2 To obtain consent for the remote parent-only diagnostic interview, we will obtain a verbal consent using the provided verbal consent script. This interview presents no more than minimal risk, and all questions are the type normally asked as part of a routine psychological evaluation.

23.3 A consent/assent form for the in-person experimental session and a verbal consent script for the parent-only remote diagnostic interview session are to be submitted with this protocol.

24.0 Setting

24.1 The research team will identify and recruit potential subjects from the FSU Family Registry and from fliers that will be distributed throughout the community. The initial interview will occur over the phone, and in-person procedures will be performed in the Risk for

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Anxiety and Depression laboratory space at Innovation Park campus or in Dr. N. Brad Schmidt's lab space in the Psychology Building at Florida State University.

25.0 Resources Available

25.1 Participants will be N=160 children (9-12 years old) recruited using the Family Registry at Florida State University (FSU) and the surrounding community. The FSU Center for Developmental Science implements ongoing recruitment throughout the Tallahassee community, focusing on children and families, and maintains a growing database containing over 1500 families that can be contacted to participate in research studies. In addition to utilizing the Registry at FSU, we plan to post fliers in the community, including in clinics that treat children with anxiety disorders, and online (e.g., Facebook), and to recruit families at additional community events. Dr. Hajcak has recruited N=300 children (ages 11-14) in ongoing studies, whose younger siblings may also be invited to participate in the proposed study. Dr. Hajcak has also recently completed a study in a similarly narrow age range (5-7 years-old), recruiting 100 children in less than 8 months, at a rate of approximately 12 per month. Therefore, the projected recruitment and timeline for the current proposal are very feasible.

Dr. Payne will work on this project full-time throughout the duration of his F32 award up to 3 years.

The proposed data collection was initially conducted in Dr. Hajcak's Risk for Anxiety and Depression (RAD) laboratory space, which has approximately 1,000 square feet of space and is located at Tallahassee's Innovation Park—a state-of-the-art innovation hub that is dedicated to conducting world-class research across disciplines. This lab space includes BrainVision actiCHamp Active Electrode systems for EEG/ERP data collection and has four computers equipped with the software necessary for running the EEG task of the proposed research (Presentation), recording and processing data (ActiView, BrainVision Analyzer2, MATLAB, EEGLab, ERPLab), and conducting statistical analyses (SPSS, R). All of the relevant equipment was moved into Dr. Schmidt's lab space at in June 2023, and all of the remaining data collection will be conducted in Dr. Schmidt's lab space.

All study personnel will be trained in human subjects research, and will have sufficient training for any aspect of the protocol they are assisting, including clinical interviewing. Dr. N. Brad Schmidt will be available for psychological evaluation and referral of the participant to care if such a need is identified during the protocol as described in sections above.

26.0 Multi-Site Research*

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NA

- Achenbach TM, and Ruffle TM.** The Child Behavior Checklist and related forms for assessing behavioral/emotional problems and competencies. *Pediatr Rev* 21: 265-271, 2000 10.1542/pir.21-8-265.
- Adkin AL, Campbell AD, Chua R, and Carpenter MG.** The influence of postural threat on the cortical response to unpredictable and predictable postural perturbations. *Neurosci Lett* 435: 120-125, 2008 10.1016/j.neulet.2008.02.018.
- Bart O, Bar-Haim Y, Weizman E, Levin M, Sadeh A, and Mintz M.** Balance treatment ameliorates anxiety and increases self-esteem in children with comorbid anxiety and balance disorder. *Res Dev Disabil* 30: 486-495, 2009 10.1016/j.ridd.2008.07.008.
- Carrasco M, Harbin SM, Nienhuis JK, Fitzgerald KD, Gehring WJ, and Hanna GL.** Increased error-related brain activity in youth with obsessive-compulsive disorder and unaffected siblings. *Depress Anxiety* 30: 39-46, 2013 10.1002/da.22035.
- Chong LJ, and Meyer A.** Understanding the Link between Anxiety and a Neural Marker of Anxiety (The Error-Related Negativity) in 5 to 7 Year-Old Children. *Dev Neuropsychol* 44: 71-87, 2019 10.1080/87565641.2018.1528264.
- Cohen J.** A power primer. *Psychol Bull* 112: 155-159, 1992.
- Dannenbaum E, Chilingarian G, and Fung J.** Validity and Responsiveness of the Visual Vertigo Analogue Scale. *J Neurol Phys Ther* 43: 117-121, 2019 10.1097/NPT.0000000000000261.
- Ditz JC, Schwarz A, and Muller-Putz GR.** Perturbation-evoked potentials can be classified from single-trial EEG. *J Neural Eng* 17: 036008, 2020 10.1088/1741-2552/ab89fb.
- Ebesutani C, Regan J, Smith A, Reise S, Higa-McMillan C, and Chorpita BF.** The 10-Item Positive and Negative Affect Schedule for Children, Child and Parent Shortened Versions: Application of Item Response Theory for More Efficient Assessment. *Journal of Psychopathology and Behavioral Assessment* 34: 191-203, 2012 10.1007/s10862-011-9273-2.
- Gehring WJ, Goss B, Coles MGH, Meyer DE, and Donchin E.** A Neural System for Error-Detection and Compensation. *Psychological Science* 4: 385-390, 1993 10.1111/j.1467-9280.1993.tb00586.x.
- Hanna GL, Liu Y, Rough HE, Surapaneni M, Hanna BS, Arnold PD, and Gehring WJ.** A Diagnostic Biomarker for Pediatric Generalized Anxiety Disorder Using the Error-Related Negativity. *Child Psychiatry Hum Dev* 51: 827-838, 2020 10.1007/s10578-020-01021-5.
- Holroyd CB, and Coles MG.** The neural basis of human error processing: reinforcement learning, dopamine, and the error-related negativity. *Psychol Rev* 109: 679-709, 2002b 10.1037/0033-295x.109.4.679.
- Hughes AA, and Kendall PC.** Psychometric properties of the Positive and Negative Affect Scale for Children (PANAS-C) in children with anxiety disorders. *Child Psychiatry Hum Dev* 40: 343-352, 2009 10.1007/s10578-009-0130-4.

PROTOCOL TITLE: Investigating the error-related negativity and the balance N1 in children with anxiety disorders

Jentsch I, and Dudschig C. Why do we slow down after an error? Mechanisms underlying the effects of posterror slowing. *Q J Exp Psychol (Hove)* 62: 209-218, 2009 10.1080/17470210802240655.

Johnson KJ, Zaback M, Tokuno CD, Carpenter MG, and Adkin AL. Exploring the relationship between threat-related changes in anxiety, attention focus, and postural control. *Psychol Res* 83: 445-458, 2019 10.1007/s00426-017-0940-0.

Kaufman J, Birmaher B, Brent D, Rao U, Flynn C, Moreci P, Williamson D, and Ryan N. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): initial reliability and validity data. *J Am Acad Child Adolesc Psychiatry* 36: 980-988, 1997 10.1097/00004583-199707000-00021.

Lengua LJ, Sadowski CA, Friedrich WN, and Fisher J. Rationally and empirically derived dimensions of children's symptomatology: expert ratings and confirmatory factor analyses of the CBCL. *J Consult Clin Psychol* 69: 683-698, 2001 10.1037/0022-006X.69.4.683.

Lynneham HJ, Sburlati ES, Abbott MJ, Rapee RM, Hudson JL, Tolin DF, and Carlson SE. Psychometric properties of the Child Anxiety Life Interference Scale (CALIS). *J Anxiety Disord* 27: 711-719, 2013 10.1016/j.janxdis.2013.09.008.

Meyer A. A biomarker of anxiety in children and adolescents: A review focusing on the error-related negativity (ERN) and anxiety across development. *Dev Cogn Neurosci* 27: 58-68, 2017 10.1016/j.dcn.2017.08.001.

Meyer A, Gibby B, Wissemann K, Klawohn J, Hajcak G, and Schmidt NB. A brief, computerized intervention targeting error sensitivity reduces the error-related negativity. *Cogn Affect Behav Neurosci* 20: 172-180, 2020 10.3758/s13415-019-00760-w.

Meyer A, Hajcak G, Torpey-Newman DC, Kujawa A, and Klein DN. Enhanced error-related brain activity in children predicts the onset of anxiety disorders between the ages of 6 and 9. *J Abnorm Psychol* 124: 266-274, 2015a 10.1037/abn0000044.

Meyer A, Mehra L, and Hajcak G. Error-related negativity predicts increases in anxiety in a sample of clinically anxious female children and adolescents over 2 years. *J Psychiatry Neurosci* 46: E472-E479, 2021 10.1503/jpn.200128.

Olvet DM, and Hajcak G. The error-related negativity (ERN) and psychopathology: toward an endophenotype. *Clin Psychol Rev* 28: 1343-1354, 2008 10.1016/j.cpr.2008.07.003.

Payne AM. Perturbation-evoked cortical responses are associated with balance ability in healthy young adults and in older adults with Parkinson's disease. In: *Wallace H Coulter Department of Biomedical Engineering*. Atlanta, GA: Georgia Institute of Technology & Emory University, 2019c.

Payne AM, Hajcak G, and Ting LH. Dissociation of muscle and cortical response scaling to balance perturbation acceleration. *J Neurophysiol* 121: 867-880, 2019a 10.1152/jn.00237.2018.

Payne AM, McKay JL, and Ting LH. The cortical N1 response to balance perturbation is associated with balance and cognitive function in different ways between older adults with and without Parkinson's disease. *Cerebral Cortex Communications* 2022 10.1093/texcom/tgac030.

Payne AM, Palmer JA, McKay JL, and Ting LH. Lower Cognitive Set Shifting Ability Is Associated With Stiffer Balance Recovery Behavior and Larger Perturbation-

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Evoked Cortical Responses in Older Adults. *Frontiers in Aging Neuroscience* 13: 2021 10.3389/fnagi.2021.742243.

Payne AM, and Ting LH. Balance perturbation-evoked cortical N1 responses are larger when stepping and not influenced by motor planning. *J Neurophysiol* 124: 1875-1884, 2020c 10.1152/jn.00341.2020.

Payne AM, and Ting LH. Worse balance is associated with larger perturbation-evoked cortical responses in healthy young adults. *Gait & Posture* 80: 324-330, 2020a 10.1016/j.gaitpost.2020.06.018.

Payne AM, Ting LH, and Hajcak G. Do sensorimotor perturbations to standing balance elicit an error-related negativity? *Psychophysiology* 2019b 10.1111/psyp.13359.

Pereira AI, Muris P, Barros L, Goes R, Marques T, and Russo V. Agreement and discrepancy between mother and child in the evaluation of children's anxiety symptoms and anxiety life interference. *Eur Child Adolesc Psychiatry* 24: 327-337, 2015 10.1007/s00787-014-0583-2.

Santesso DL, Segalowitz SJ, and Schmidt LA. ERP correlates of error monitoring in 10-year olds are related to socialization. *Biol Psychol* 70: 79-87, 2005 10.1016/j.biopsycho.2004.12.004.

Schmid G, Henningsen P, Dieterich M, Sattel H, and Lahmann C. Psychotherapy in dizziness: a systematic review. *J Neurol Neurosurg Psychiatry* 82: 601-606, 2011 10.1136/jnnp.2010.237388.

Silverman WK, Fleisig W, Rabian B, and Peterson RA. Childhood Anxiety Sensitivity Index. *Journal of Clinical Child Psychology* 20: 162-168, 1991 10.1207/s15374424jccp2002_7.

Wessel JR. An adaptive orienting theory of error processing. *Psychophysiology* 55: 2018 10.1111/psyp.13041.

Yardley L, and Redfern MS. Psychological factors influencing recovery from balance disorders. *J Anxiety Disord* 15: 107-119, 2001 10.1016/S0887-6185(00)00045-1.

Permission to Take Part in a Human Research Study

Title of research study: Investigating the error-related negativity and the balance N1 in children with anxiety disorders

Investigator: N. Brad Schmidt, Ph.D.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of the study. More detailed information is listed later in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because your child is between 9-12 years of age.

What should I know about a research study?

- Someone will explain this research study to you.
- Participation in this study is a choice, and you may change your mind at any time.
- You may ask questions before deciding, as well as throughout participation, and your decision will not be held against you.

Why is this research being done?

Anxiety affects balance in adults, but this relationship is less clear in kids. We want to know whether anxiety affects balance in kids.

How long will the research last and what will I need to do?

The lab visit should last 2-4 hours. You will be asked to first participate in a phone interview (up to 90 minutes) in which we will ask questions about your child to determine their eligibility for the lab visit. We need both children with anxiety and children without anxiety, but we may decide your child is ineligible after the interview. If this happens we will still compensate you for your time in the interview.

If your child is eligible, and you enroll them in the lab visit, they will complete two tasks (described below). Depending on which group we assign to your child, we may also ask them to watch a 45-minute video before repeating the two tasks. The video will focus either on making mistakes or healthy lifestyle choices.

Before the tasks, we will place recording electrodes on your child's head, neck, hand, and leg (below the knee) to record electrical activity during the tasks. In one task, your child will play a brief (5-10 minutes) computer game, where they will press a button to blast aliens that appear on the screen. In another task (10-15 minutes), your child will lean forward while a small fraction of their weight is supported by a chest harness attached to the wall behind them. This support will be suddenly released, causing them to sway forward and involuntarily recover their balance. We will stand by your child to make sure they do not fall. We may also ask your child to rate how they felt about the tasks, or to do other balance tasks, such as balancing on one leg or standing as still as possible. We will also have you and your child fill out a few surveys about their thoughts, feelings, and behavior.

More detailed information about the study can be found under ***“What happens if I say yes, I want to be in this research?”***

Permission to Take Part in a Human Research Study

Is there any way being in this study could be bad for me?

Potential risks include getting tired or uncomfortable from the questions and tasks. Your child could also bump into the wall during the balance tasks, but this is unlikely. It is also possible that there are other risks of participation that we are not aware of.

We are mandated reporters and have to report if your or your child tell us they have thoughts or plans to harm themselves or others, or that someone else is harming them.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

Will being in this study help me in any way?

We cannot promise any benefit to your child from taking part in this research, but the video presentation may be helpful to some anxious children. Participation will contribute to our understanding of the nature of anxiety in childhood.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide not to participate, and if you decide to participate, you may change your mind at any time.

Permission to Take Part in a Human Research Study

Detailed Information: The following is more detailed information about this study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Brad Schmidt at schmidt@psy.fsu.edu. Dr. Schmidt's office is located in the Psychology B building, room B344; (850) 644-1707.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 160 children to participate in this study.

What happens if I say "yes" to being in this research?

During the lab visit, your child may participate in some or all of the following activities:

1. Interviews and surveys: You and your child will be interviewed and given surveys about their feelings, thoughts, and behaviors.
2. Physiology Recording: We will record your child's brain activity and muscle activity as they perform tasks (described below). We record brain activity using electroencephalography (EEG). To do this, we use a specialized cap that contains 32 recording electrodes that your child will wear on their head. We will add gel to the electrodes to improve the signal. This gel will wash out easily with warm water unless allowed to dry overnight. Other electrodes will be placed on their face, neck, hand, and leg below the knee. These recordings are completely painless, non-intrusive, and safe. They are similar to heart rate recordings (i.e., electrocardiogram or EKG) that are typical during routine physical exams. The EEG system is an investigational device used for research purposes and is not intended to diagnose or treat any disease or condition.
3. Vigilance task: Your child will perform a task that requires them to rapidly respond to stimuli. The computer will display cartoon aliens and astronauts, and your child will be asked to quickly press a button only when the aliens appear on the screen. This task can assess attention and response monitoring.
4. Balance task: Your child will be asked to lean forward while a chest harness supports a small fraction of their weight through a cable attached to the wall behind them. Across multiple trials, the support behind them will be suddenly released, causing your child to sway forward and involuntarily recover balance. We will stand near your child to ensure they do not fall. Your child may also be asked to do other simple balance tasks like standing as still as possible or balancing on one leg.
5. Video Presentation: Your child may complete a task in which they watch a video on the computer. This video may be about reacting to mistakes or about healthy choices (e.g., eating fruits and vegetables, exercising, etc.). Your child may be asked to answer questions about this video. If your child watches the video, they will also be asked to repeat tasks 3 and 4 above.

Permission to Take Part in a Human Research Study

The version of the presentation your child gets will be chosen by chance, like flipping a coin. A study coordinator, but not Dr. Payne (i.e., the one recording your child's brain activity), will know which version your child gets. At the end of your participation, or if you withdraw from this study, we will provide more information about these two presentations, and links to access both presentations from home.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time it will not be held against you. You will be compensated for the time spent in the study, even if you decide to leave early.

Is there any way being in this study could be bad for me? (Detailed Risks)

Potential risks (to you and/or your child) include getting tired or uncomfortable from the interview, surveys, and tasks. The interview will ask some personal questions about your child's thoughts, feelings, and behavior. If you or your child would prefer not to answer certain questions, you are both free not to do so.

We are mandated reporters and have to report if your or your child tell us they have thoughts or plans to harm themselves or others, or that someone else is harming them.

During the EEG recording, there is a small possibility of mild skin irritation (redness) where the electrode contacts the skin. However, this is rare and temporary.

The computer task may be frustrating, and the balance task can be a bit scary or surprising at first. There is also a small chance that your child may bump into the wall during balance tasks.

It is also possible that there are other risks of participation that we are not aware of.

What happens to the information collected for the research?

We make efforts to limit the use and disclosure of your personal information to people who need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, which oversee research at FSU, and the Food and Drug Administration, as this study is FDA-regulated.

We are mandated reporters and are required to report if your or your child tell us they have thoughts or plans to harm themselves or others, or that someone else is harming them.

Deidentified data (i.e., data from which any information that could identify you or your child has been removed) may be used for future research studies or shared with other investigators without your additional informed consent.

We may publish the results of this research, but we will keep your name and other identifying information confidential to the extent allowed by law.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What else do I need to know?

This research is being funded by the National Institute of Mental Health.

If you agree to take part in this research study, we will pay you \$20/hour for the visit (prorated to 15-minute intervals, up to \$80 for a maximum of four hours). If attending the lab visit causes any financial burden to your family, you can request up to \$40 for travel reimbursement costs.

Permission to Take Part in a Human Research Study

Most tests in research studies have no clear meaning for health care. If you have any concerns about your child, we will provide information after the study on how to contact the FSU's sliding scale fee psychology clinic, but we will not provide compensation for any medical care referrals, or in the case of any research-related injury. Neither you, nor your insurance, will be billed for expenses for the measurements and activities performed as part of this study. Participation in this study will not require changes (including costs) to any ongoing clinical care.

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

 Printed name of child

 Signature of parent or individual legally authorized to consent to the child's general medical care

 Date

 Printed name of parent or individual legally authorized to consent to the child's general medical care

- ☐ Parent
☐ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

 Signature of parent

 Date

 Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- ☐ Second parent is deceased
☐ Second parent is unknown
☐ Second parent is incompetent
☐ Second parent is not reasonably available
☐ Only one parent has legal responsibility for the care and custody of the child

Assen
 + ☐ Obtained
☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

 Signature of person obtaining consent and assent

 Date

 Printed name of person obtaining consent

Assent to Take Part in Research



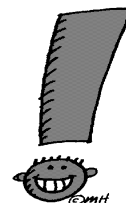
What is a research study?

Research studies help us learn new things. First, we ask a question. Then we try to find the answer.

This paper talks about our research and the choice that you have to take part in it. Please ask us any questions that you have at any time.

Important things to know...

- You get to decide if you want to take part.
- You can say 'No' or you can say 'Yes'.
- We will not be upset if you say 'No'.
- If you say 'Yes', you can always say 'No' later at any time.



Why are we doing this research study?

We are doing this research study to find out more about anxiety.



What would happen if I join this research?

If you decide to be in this research study, we would ask you to answer questions, and to wear sensors that measure your brain while playing on the computer and while we test your balance. You may also be asked to watch a 45-minute video.

- Questions: One of us will ask you and your adult questions about your behavior, thoughts, and feelings (about 30 minutes). If you don't mind, we may record this.
- Sensors: You may be asked to wear a cap that measures your brain. This may feel a little weird and will include some hair gel under the sensors. We may also place a few sensors on your face, neck, hand, and your leg below the knee. These may be taped, and may feel weird at first.
- Computer game: You may be asked to play a computer game (5-10 minutes) where you will press a button to blast aliens when they appear on the screen, and you will try not to blast astronauts.
- Balance test: You may be asked to lean forward while wearing a chest harness tied to the wall behind you. The harness will suddenly let go, causing you to sway forward so we can observe how you correct your balance (10-15 minutes). This can feel a bit surprising or scary at first, but we will keep you safe. We may also ask you to try other things, like balancing on one leg, or trying to stand very still (1-5 minutes).
- Video: You may be asked to watch a 45-minute video, focused on either healthy living or on making mistakes. The video will stop and ask you to write things down a few times. If you are

Assent to Take Part in Research

asked to watch the video, we will ask you to repeat the computer game and balance test again after the video.



Could bad things happen if I join this research study?

Some of the things that we will ask you to do might make you uncomfortable or be hard to do. If you would prefer not to answer certain questions, you may ask to skip them. The sensors may be uncomfortable and can sometimes cause redness of the skin. You may get tired or frustrated while doing the tasks. Please let us know if you want to take a break between tasks. You could bump into the wall during the balance tasks, but this is unlikely, and we will stand near you just in case. We will try to make sure that no bad things happen. Remember, you can skip questions that you don't want to answer, and you can let us know if you would like to leave.



Could the research study help me?

We can't promise this study will help you in any way, but the videos may be helpful to some kids with anxiety. We hope to learn things from this study that will someday help kids with anxiety.



What else do I need to know about this research study?

If you don't want to be in the research study, you don't have to be. You can stop being in the research study at any time. If you want to stop, please tell someone on the research team.

If you complete the study today, you will get to pick a small toy prize.

You can ask us questions at any time, so please feel free to ask us anything. Take the time you need to make your choice.



Is there anything else?

If you want to be in the research study after we talk, please write your name on the next page. We will write down our name too. This shows we talked about the study and that you want to take part.

Assent to Take Part in Research

Name of Participant (to be written by child or adolescent)

I agree to be audiotaped

YES (initial) _____ NO (initial) _____

Researcher's Signature

I have fully explained the research study described by this form. I have answered the participant and/or parent/guardians' questions and will answer any future questions to the best of my ability. I will tell the family and/or the person taking part in this research of any changes in the procedures or in the possible harms/possible benefits of the study that may affect their health or their willingness to stay in the study.

Printed Name of Research Team Member Obtaining Assent

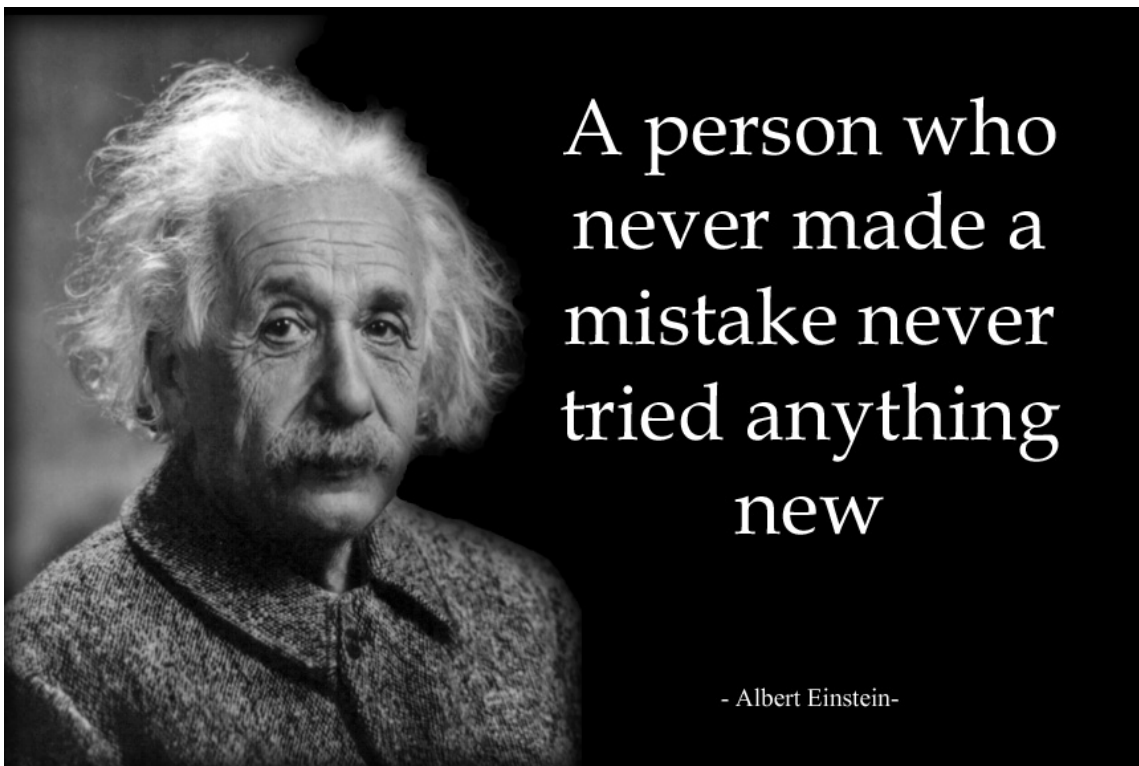
Signature of Research Team Member

Date

Time

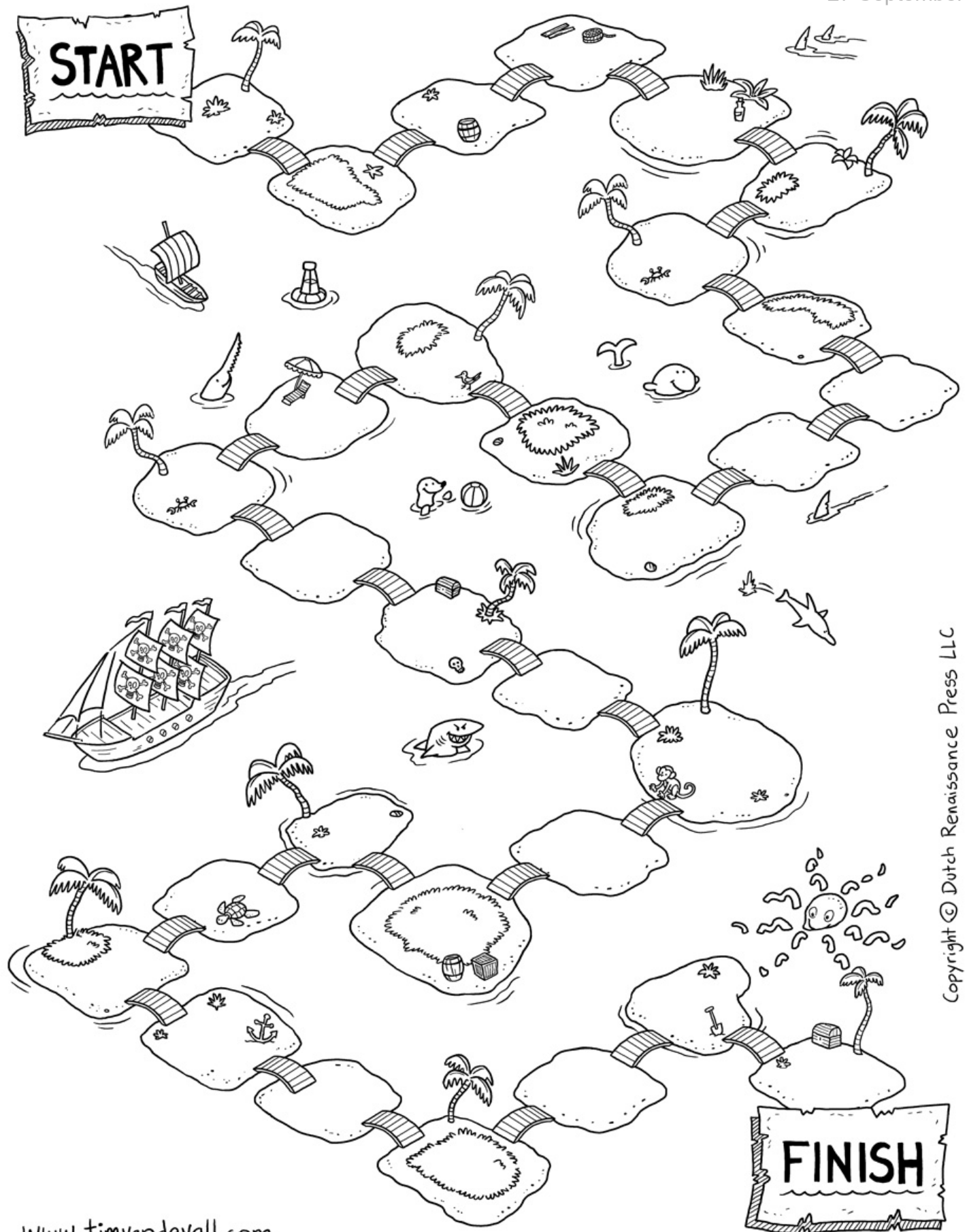
MY JOURNAL: MAKING MISTAKES

CHILD JOURNAL ID NUMBER:



A person who
never made a
mistake never
tried anything
new

- Albert Einstein-



Some people think they are the only ones who make mistakes. But, **EVERYONE** makes mistakes!!!!

We make mistakes all the time: at school, at home, on the playground even when we are walking.

In your journal, write down one time you can remember making a

mistake. ■ _____



Making Mistakes on Purpose: spell it wrong!



Do you think you have trouble making mistakes?



Why do you think this?
(circle or write your answers)

I don't like making mistakes.

I only play a game if I know I will win.

I blame other people for my mistakes.

I like to do things perfectly.

I wait to do things until the last minute.

I pay a LOT of attention to my mistakes.

I give up without really trying.



Think about the mistake you made. What did you tell yourself (or think) about this mistake? What types of things do you usually tell yourself (or think) about making mistakes? (circle or write your answer)

Mistakes are BAD!

I am bad for making mistakes

I ALWAYS make mistakes.

I should be PERFECT.

I HATE making mistakes!

Mistakes are a chance to learn!

It's ok to make mistakes!

Everybody makes mistakes.

It's ok not to be perfect.

Mistakes can be funny!

Making Mistakes on Purpose: drawing!

The Mistake Bully versus the Mistake Buddy:
Which one do you think is more helpful???

Mistake Bully



Mistake Buddy



TM & © Universal Studios

What are
some things
that your

Mistake Buddy can say? (circle things Mistake Buddy might say)

Mistakes are BAD!

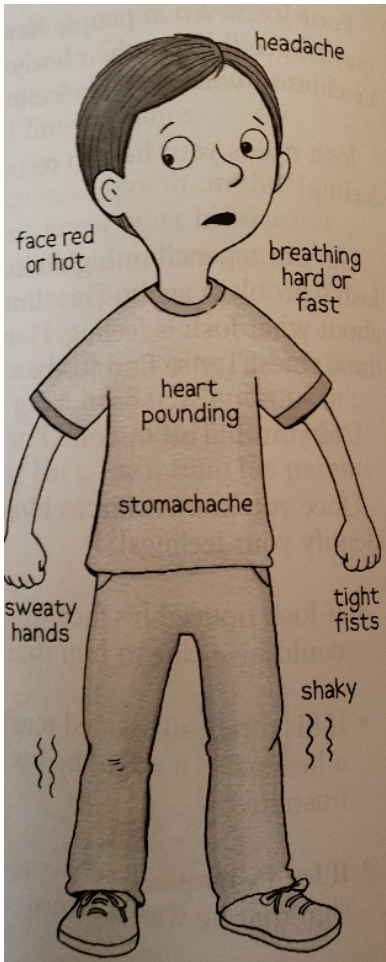
It's ok to make mistakes!

Everybody makes mistakes.

I should be PERFECT.

Mistakes can be funny!

Mistakes are a chance to learn!



Where do you feel mistakes in your body?

(circle or write your answers)

What are some things you can do when your body is upset?

(circle or write your answer)

Think happy and calm thoughts

Tell yourself: It is OK to make mistakes

Breath slowly in and out

Making Mistakes on Purpose: naming animals!

1.) _____

2.) _____

3.) _____

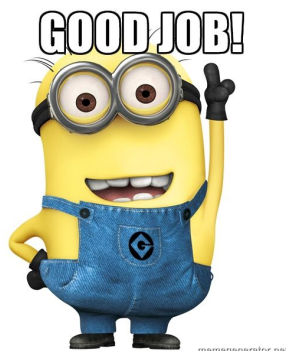
4.) _____

5.) _____

6.) _____

7.) _____

8.) _____



What are some things you do when you are afraid of making mistakes? (circle or write your answer)



I hide from mistakes.

I don't try things if I think I will make a mistake.

I try to do things perfectly.

I wait until the last minute.

I give up without trying.

I only do things that I am good at.

What are some things you can do to FACE YOUR FEARS of making mistakes? (circle or write your answer)

I can make small mistakes on purpose.

I can do things, even if I am not good at them.

Making Mistakes on Purpose: numbers!

- 1.)
- 2.)
- 3.)
- 4.)
- 5.)
- 6.)
- 7.)
- 8.)
- 9.)
- 10.)

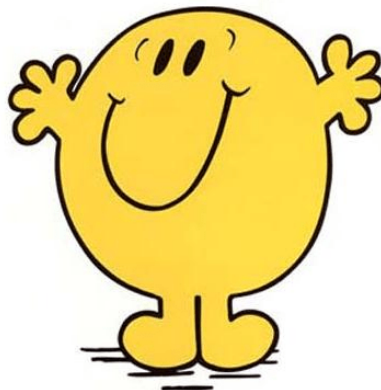


Check Your Understanding (circle your answer):

- 1.) What is a helpful thought the Mistake Buddy might suggest?
 - a. It is ok to make mistakes!
 - b. It is bad to make mistakes.

- 2.) Who makes mistakes?
 - a. Everybody makes mistakes!
 - b. Only some people make mistakes.

- 3.) Why should we practice making small mistakes on purpose?
 - a. So that we can get used to making mistakes!
 - b. So that we never make mistakes.



Talking back to your mistake bully (thinking helpful thoughts):

- Mistakes are a chance to learn!
- It's ok to make mistakes.
- Everybody makes mistakes.
- Making mistakes means that I am challenging myself.
- It's ok not to be perfect.
- Mistakes can be funny!
- I can laugh at my mistakes.



If you notice that your body is upset by mistakes, you can:

Breathe in and out,
slowly and calmly!

Think happy
thoughts – like, your
favorite food or
your favorite place.



You can remind yourself: “It’s OK to make mistakes!”

You can remind yourself: “Mistakes are a chance to learn!”

What can you do if you notice that you do unhelpful behaviors: like, not doing things that are new, or not doing things you are not good at, or giving up before you begin, or not doing something unless it is perfect:

You can FACE YOUR FEARS!!!

You can make small mistakes on purpose or try new things.

You can teach yourself that it is OK to make mistakes.

You can teach yourself that it is OK to not be good at some things.

You can teach yourself that it is OK to not be perfect.

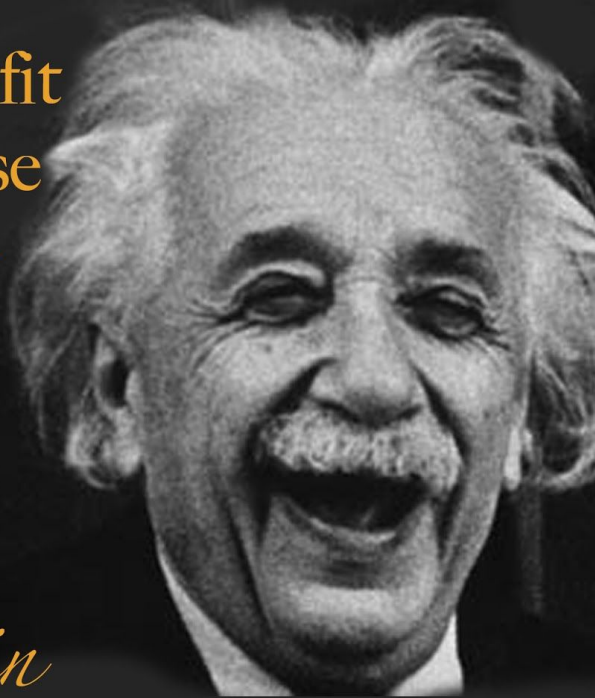


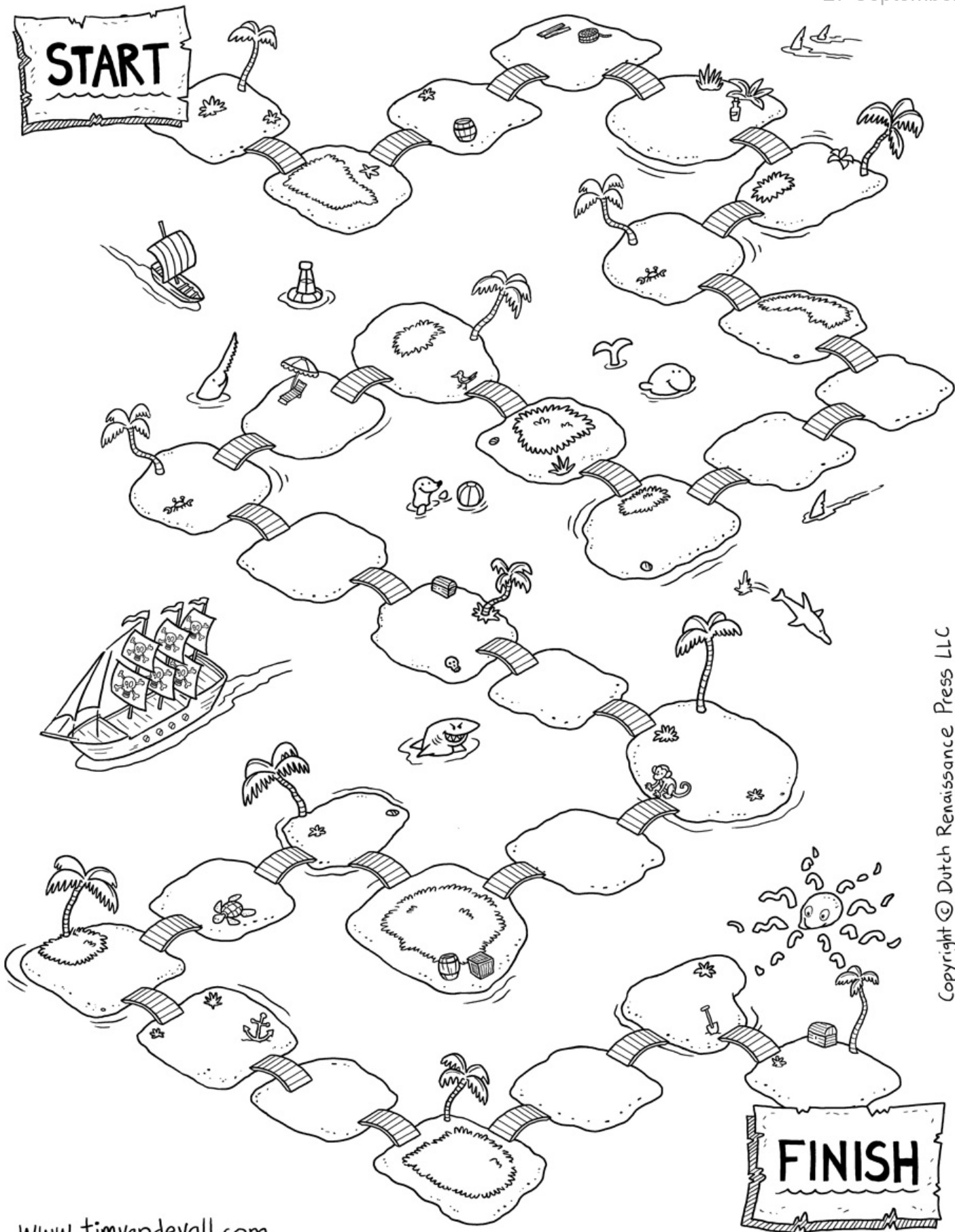
MY JOURNAL: HEALTHY FOODS

MY JOURNAL NUMBER:

“Nothing will benefit health and increase the chance for survival on Earth as the evolution to a vegetarian diet.”

Albert Einstein





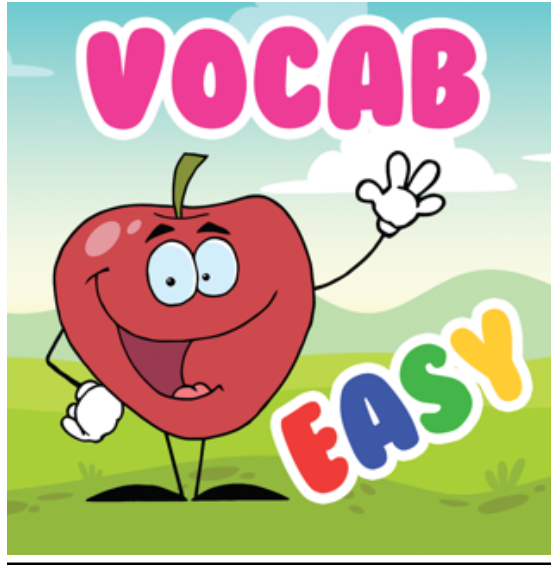
There are all kinds of fruits to learn about! Lots of people know about apples, oranges, and bananas, but did you know there are 2,000 (two-thousand) types of fruits??

Fruits are healthy for our bodies, and they give us vitamins and minerals . . . *also*, they can be sweet and delicious, too!

In your journal, write down one thing you learned about apples, bananas, or cherries. _____



Learning More about our Food: spell the fruit!



Do you think fruits and veggies are healthy?



Which facts about produce are true?
(circle or write your answers)

The peel of the apple is the healthiest part.

Bananas give you energy.

Cherries are a stone fruit.

Grapes grow from a tree like an apple.

The mango is the “king of the fruits.”

Oranges, cherries, and bananas have vitamin C.

What other facts can you remember?



Think about the veggies we've learned about. What are some things you remember about these veggies? Mark the answer options below (circle or write your answer)

Broccoli is blue.

Carrots are the queen of the veggies!

Carrots can help your VISION.

You CAN'T eat a cauliflower.

Cucumbers are mostly water!

Mushrooms have a different set of nutrients

Onions are bulbs of tightly packed leaves.

Potatoes make you feel really full!

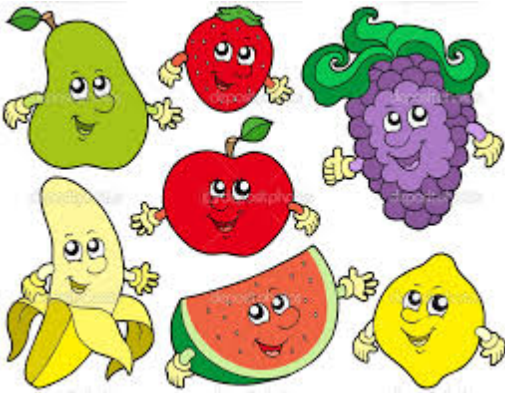
Spinach has no nutrition.

Tomatoes are a vegetable, not a fruit.

Having Fun with Produce: drawing!

Fruits versus Vegetables:
Which one do you think is more healthy???

Friendly Fruits



Awesome Veggies



What are some things that you can do to make yourself healthier? (circle things you can do)

Eat lots of fruits!

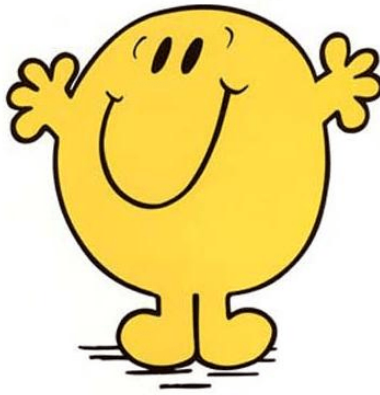
Eat lots of veggies!

Spend time with friends and family.

Get outside and play!

Try new foods you haven't had yet!

Get lots of sleep every night.



Things we learned about fruits and veggies:

- Fruits AND veggies can be delicious!
- There are many kinds of fruits and vegetables.
- They contain vitamins and minerals.
- Eating them can help make your body healthy.
- They can be refreshing on a hot day!
- Some peels you CAN eat, and some you can't.
- They come in many different colors!