Study Information

Title

Provide the working title of your study. It is helpful if this is the same title that you submit for publication of your final manuscript, but it is not a requirement.

Central executive training (CET) for ADHD: Initial development and comparison to behavioral parent training (BPT)

Authors

The author who submits the preregistration is the recipient of the award money and must also be an author of the published manuscript. Additional authors may be added or removed at any time.

Michael Kofler

Research Questions

Please list each research question included in this study.

1. Is CET a feasible and acceptable intervention for caregivers and their children with ADHD? Is its feasibility and acceptability comparable to the current gold-standard psychosocial treatment for ADHD (BPT)?
2. Does CET improve working memory in children with ADHD, and are these improvements superior to those found for BPT (which is not expected to improve working memory)?
3. Does CET improve ADHD symptoms in children with ADHD, and are these improvements non-inferior to improvements associated with gold-standard BPT?
4. (Fidelity Check) Does BPT improve oppositional-defiant symptoms in children with ADHD, and how does CET compare to BPT for these expected improvements?

Hypotheses

For each of the research questions listed in the previous section, provide one or multiple specific and testable hypotheses. Please state if the hypotheses are directional or non-directional. If directional, state the direction. A predicted effect is also appropriate here.

Primary Outcome
1. Near-transfer: Central executive training (CET) will produce greater improvements than behavioral parent training (BPT) on the Rapport phonological (PH) and visuospatial (VS) working memory tests (2 group x 2 task x 2 time points (pre, post)). Critical test is the group x time interaction. The 2 tasks are included in the omnibus ANOVA to (1) address recommendations to probe cognitive abilities using multiple tests, and (2) maximize power for the critical group x time interaction. The 2 working memory tests are considered to tap the same 'central executive' working memory; they differ in whether that central executive is processing phonological or visuospatial information. If the group x time interaction is significant at p = .05 or less, it will be followed by Bonferroni-corrected within-group post-hocs for each task and ANCOVA of post-treatment covaried for pre-treatment separately for each task (i.e., residualized gain scores). These post-hocs will also be performed if the main effect of time is significant (but not the group x time interaction) to allow us to better characterize change within each group (i.e., did each treatment produce significant change?). Stimuli correct per trial will be used.

Statistical models

Transformations

Follow-up analyses

Inference criteria

Data exclusion

Missing data

Exploratory analysis

Scripts

Script

Other

Other

Secondary Outcomes
2. Far-transfer subjective ADHD symptoms: BPT and CET will both show significant reductions in ADHD symptoms measured by unblinded parent ratings. Two scales are used: the norm-referenced BASC-2 (T-scores based on age and gender norms) and CSI-IV (raw symptom severity scores). Both have separate Attention Problems and Hyperactivity/Impulsivity subscales. Both will be tested via 2 group x 2 subscale x 2 time point mixed-model ANOVA. Critical test is the group x time interaction for both. Post-hoc plan follows #1 above.
3. Far-transfer objective (proximal) ADHD symptoms: CET will show greater reductions in actigraph-measured hyperactivity than BPT during the Rapport PH and VS working memory tests. Same 2 group x 2 task (PH-actigraphy, VS-actigraphy) x 2 time points approach as above; same post-hoc plan. Critical test is the group x time interaction. Actigraph data will be PIM intensity scores, summed across 3 actigraphs (non-dominant wrist, left ankle, right ankle).
4. Far-transfer objective (distal) ADHD symptoms: CET will show greater reductions in actigraph-measured hyperactivity than BPT during the low cognitive load Painting tasks at the beginning and end of each testing session. Same 2 group x 2 task (PaintBeginning-actigraphy, PaintEnd-actigraphy) x 2 time points approach as above; same post-hoc plan. Critical test is the group x time interaction. Actigraph data will be PIM intensity scores, summed across 3 actigraphs (non-dominant wrist, left ankle, right ankle).
5. Far-transfer subjective oppositional-defiant symptoms: BPT will show greater improvements in unblinded parent reports of oppositional defiant symptoms on the CSI-IV. Only the ADHD and ODD sections of the CSI-IV were administered. Analysis will be 2 group x 2 timepoints mixed-model ANOVA. Critical test is the group x time interaction. CSI-IV raw symptom scores for the ODD dimension will be used as dependent variable. Bonferroni-corrected paired-sample t-tests for each group separately (pre vs. post), and between-group at post covaried for pre-treatment ODD symptoms are tested because of compelling evidence that BPT improves these symptoms (manipulation check; if no significant reductions in BPT group, may indicate limited BPT efficacy).
Feasibility/Acceptability Outcomes
6. Client Satisfaction Questionnaire-8 (CSQ-8) parent report at post-treatment (total scores) will be compared across groups (BPT vs. CET). No significant differences expected.
7. Barriers to Treatment Participation Scale (BTPS) parent report at post-treatment (total scores and all subscales). No significant differences are expected. The Relevance of Treatment subscale will be interpreted as evidence of intervention expectancies.
8. CET only: System Usability Scale (SUS). Child reported feasibility of CET system. Expected to be high (mean of at least 3.5 on 5-point Likert scale, where higher scores indicate better usability).
9. CET training duration. Total minutes trained and total training games completed will be reported. Descriptive; no hypotheses are offered.

Recommended elements
1. All hypothesized interactions are expected to look like Figure 1 in Redick (2015). In other words, no pre-treatment group differences, and differential improvements favoring the group hypothesized to improve. Should pre-treatment group differences be observed, differential improvements favoring the group hypothesized to improve would be observed when using post-treatment covaried for pre-treatment analysis (residualized gain scores). No differences in this test indicate equivalence between interventions.
2. P-values and Bayes Factors will be reported. P-values will be considered primary in cases of discrepant results (to follow current conventions in the field). P-values of .05 or less will be considered significant (after Bonferroni corrections for post-hoc tests). Bayes Factors of 3 or greater will be considered significant.

Sampling Plan

Existing Data

Preregistration is designed to make clear the distinction between confirmatory tests, specified prior to seeing the data, and exploratory analyses conducted after observing the data. Therefore, creating a research plan in which existing data will be used presents unique challenges. Please select the description that best describes your situation. Please do not hesitate to contact us if you have questions about how to answer this question (prereg@cos.io).

Registration prior to accessing the data

Explanation of existing data

If you indicate that you will be using some data that already exist in this study, please describe the steps you have taken to assure that you are unaware of any patterns or summary statistics in the data. This may include an explanation of how access to the data has been limited, who has observed the data, or how you have avoided observing any analysis of the specific data you will use in your study. The purpose of this question is to assure that the line between confirmatory and exploratory analysis is clear.

The data exists in pieces on the PI's lab server, and we have begun to collate them into a united dataset that will be used

for analyses. All data handling decisions were made by Co-PIs without access to the data, most of whom are at different universities. The primary and secondary outcomes to be reported in this study were determined by Co-PIs without access to the data.

Data collection procedures

Please describe the process by which you will collect your data. If you are using human subjects, this should include the population from which you obtain subjects, recruitment efforts, payment for participation, how subjects will be selected for eligibility from the initial pool (e.g. inclusion and exclusion rules), and your study timeline. For studies that don't include human subjects, include information about how you will collect samples, duration of data gathering efforts, source or location of samples, or batch numbers you will use.

Description of essential elements

Preregistration is for data analysis; data collection is almost complete. All outcome measures and analyses were selected without access to the data.

Study Timeline
Children were not randomized to treatment condition. Families recruited between June 2013 and December 2014 were offered behavioral parent training (BPT). The final BPT post-treatment session was completed in June 2015. Families recruited between June 2015 and December 2016 were offered central executive training (CET). The final CET post-treatment session was completed in [TBD, likely May/June] 2017. Recruitment to CET was closed when the software for the active comparator was completed. We are currently conducting a pilot randomized trial of CET versus this active comparator (inhibition training).

Identical procedures were used for both samples. Both treatments were delivered in small group format (2-4 families) or individually as needed to accommodate families' schedules. Schedule changes were accommodated to the extent possible (e.g., make-up sessions the same week).

Inclusion/Exclusion Criteria
All children and caregivers completed an identical evaluation, regardless of group assignment, that included detailed, semi-structured clinical interviewing (K-SADS; Kaufman et al., 1997). The K-SADS (2013 Update) assesses developmental history as well as onset, course, and impairment of DSM-5 (APA, 2013) disorders in children and adolescents. Parent and teacher ADHD ratings were obtained from the Behavior Assessment System for Children (BASC-2; Reynolds & Kamphaus, 2004) and Child Symptom Inventory (CSI-IV; Gadow & Sprafkin, 2002).

Study eligibility required all of the following (1) DSM-5 diagnosis of ADHD (any presentation) by the directing clinical psychologist based on K-SADS; (2) Borderline/clinical elevations on at least one parent and one teacher ADHD rating scale. A previous diagnosis of ADHD was also sufficient for inclusion. All children had current impairment (K-SADS). Comorbidities reflect clinical consensus best estimates. Positive screens for learning disabilities will be based on score(s) 1 SD or more below age-norms on one or more Kaufman (KTEA-2/3; 2004, 2014) academic skills battery subtests.

Medication rates will be reported. Psychostimulants were withheld for at least 24-hours prior to all research testing sessions (i.e., all working memory performance and actigraph hyperactivity data was collected off-medication). Following convention in our assessment clinic, children prescribed psychostimulants received their usual dose during the baseline psychoeducational assessment (IQ, achievement testing) to provide the best estimates of their child's skills/abilities in the psychoeducational report provided to parents. Changes in medication status during treatment will be reported.

Children were excluded for gross neurological, sensory, or motor impairment; seizure disorder, psychosis, or intellectual disability; or non-stimulant medications that could not be withheld for testing. No inclusion/exclusion based on working memory/executive functioning performance was set.

Procedures
Pre-treatment testing occurred during a larger battery of two, 3-hour sessions. Post-testing occurred during a single, 3-hour session. A 90-minute mid-treatment testing session was conducted for children in the BPT group. As specified in the NIH R34 proposal, no mid-treatment sessions were completed for the first CET groups. This design difference was considered acceptable because it favored the null (i.e., test-retest effects, if present, would favor the BPT group). Statistical tests will therefore assess pre-post changes.

All tests were counterbalanced within/across sessions to minimize order/fatigue effects. Children received brief breaks after each task, and preset longer breaks every 2-3 tasks to minimize fatigue.

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Sample size

Describe the sample size of your study. How many units will be analyzed in the study? This could be the number of people, birds, classrooms, plots, interactions, or countries included. If the units are not individuals, then describe the size requirements for each unit. If you are using a clustered or multilevel design, how many units are you collecting at each level of the analysis?

The final analyzed sample size is expected to be BPT = 27, CET = 27. BPT collection is complete; the last CET group is anticipated to be complete in May/June 2017.

Sample size rationale

This could include a power analysis or an arbitrary constraint such as time, money, or personnel.

Families recruited between June 2013 and December 2014 were offered behavioral parent training (BPT). The final BPT post-treatment session was completed in June 2015. Families recruited between June 2015 and December 2016 were offered central executive training (CET). The final CET post-treatment session was completed in [TBD, likely May/June] 2017. Recruitment to CET was closed when the software for the active comparator was completed. We are currently conducting a pilot randomized trial of CET versus this active comparator (inhibition training).

Stopping rule

If your data collection procedures do not give you full control over your exact sample size, specify how you will decide when to terminate your data collection.

Recruitment to BPT was stopped when CET was ready for testing. Recruitment to CET was stopped when the active comparator was ready for testing. Families are now being recruited to a pilot RCT of CET vs. this active comparator. That trial is registered at clinicaltrials.gov (NCT03042338).

Variables

Manipulated variables

Describe all variables you plan to manipulate and the levels or treatment arms of each variable. For observational studies and meta-analyses, simply state that this is not applicable.

Treatments

Behavioral Parent Training (BPT)
Evidence-based behavioral parent training (BPT; Evans et al., 2014) was provided using the Barkley (2013) Defiant Child protocol. BPT was delivered with fidelity in small group format by behaviorally trained, PhD-level clinicians (MJK, DES, HSS).

Central Executive Training (CET)
CET is a translational, evidence-informed, hybrid (in-office and at-home), software-based treatment protocol that includes gaming elements and an automated token economy to reinforce training goals and improve player engagement. The final 10-week protocol includes weekly, in-office sessions with the child (1 hour) and a concurrent parent psychoeducational group, combined with parent-supervised, in-home training (goal: 15-min/day, 2-3 days/week).

CET beta testing. The CET sample was recruited in 3 waves to facilitate software refinements and testing of key design features. As specified in the NIH grant proposal (R34 MH102499), the first subgroup trained on one game per week, the second subgroup had immediate access to all 9 training games, and the third subgroup (approximate n=9 per subgroup) received the final protocol that implemented all CET features. To reduce child expectancies, children were told that they were “beta testers” for our video game design team. Breadth of training across the 9 games was facilitated by a software algorithm that limited initial access each day to three games the child had not completed recently (third

subgroup only). Children earned additional rewards and access to all nine games for completing this daily "Mission Mode." Leveling was set to ensure incremental increases in difficulty based on child performance. This process occurred during the current study and involved iterative changes and extensive testing with graduate/undergraduate Research Assistants (alpha testing) and children with ADHD (beta testing).

CET focus groups. Caregivers in the first two CET subgroups participated in focus groups. Key CET design changes based on these focus groups included overhauling the on-screen instructions, modifying the home screen to show child progress (daily games completed), and automation of the token economy via children earning on-screen 'tickets' that are exchanged for tangible, in-office rewards. Key logistical changes from these focus groups included improved communication with caregivers (e.g., access/login instructions, progress monitoring of days/games completed at home), modified expectations for at-home training duration (original goal of 30-minutes/day decreased to 15-minutes/day) and frequency (original daily training goal decreased to 2-3 days/week), and modified treatment duration (original 12-weeks decreased to 10-weeks). Finally, caregiver feedback resulted in the addition of a caregiver psychoeducational group that began mid-way through testing with subgroup 2. Most caregivers described homework as the biggest obstacle to at-home CET training; opinions were split approximately evenly regarding priority of CET vs. homework, with differences focused primarily on weighing immediate vs. delayed consequences.

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Measured variables

Describe each variable that you will measure. This will include outcome measures, as well as any predictors or covariates that you will measure. You do not need to include any variables that you plan on collecting if they are not going to be included in the confirmatory analyses of this study.

Measures

Intellectual Functioning (IQ)
IQ was estimated using the Verbal Comprehension Index from the WASI-II (BPT) or WISC-V (CET) (Wechsler, 2011, 2014). The changeover was made to provide caregivers the most up-to-date evaluation possible. Standard scores are used.

Socioeconomic Status (SES)
Hollingshead (1975) SES was estimated based on caregiver(s)' education and occupation.

Primary Outcomes (Working Memory)
The Rapport et al. (2009) computerized working memory tests correctly classify children with vs. without ADHD at similar rates as parent and teacher ADHD rating scales (Tarle et al., 2017), and predict hyperactivity (Rapport et al., 2009), inattention (Kofler et al., 2010), and impulsivity (Raiker et al., 2012). Reliability and validity evidence includes internal consistency (α=.82-.97), 1-3-week test-retest reliability (.76-.90; Sarver et al., 2015), and expected relations with criterion working memory complex span (r=.69) and updating tasks (r=.61)(Wells et al., under review). Six trials per set size were administered in randomized/unpredictable order (3-6 stimuli/trial; 1 stimuli/second) as recommended (Kofler et al., 2016). Five practice trials were administered before each task (80% correct required). Task duration was approximately 5 (visuospatial) to 7 (phonological) minutes.

Phonological working memory. Children were presented a series of jumbled numbers and a letter (1 stimuli/second). The letter was never presented first or last to minimize primacy/recency effects, and was counterbalanced to appear equally in the other serial positions. Children reordered and recalled the numbers from least to greatest, and said the letter last (e.g., 4H62 is correctly recalled as 246H). Two trained research assistants, shielded from child view, independently recorded oral responses. Interrater reliability will be computed (% agreement = % of trials for which both RAs transcribed the identical sequence).

Visuospatial working memory. Children were shown nine squares arranged in three offset vertical columns. A series of 2.5 cm dots were presented sequentially (1 stimuli/second); no two dots appeared in the same square on a given trial. All dots were black except one red dot that never appeared first or last to minimize primacy/recency effects. Children reordered the dot locations (black dots in serial order, red dot last) and responded on a modified keyboard.

Dependent variables. Stimuli correct per trial were computed at each set size as recommended (Conway et al., 2005), and averaged to provide a single indicator for each task. Higher scores reflect better working memory.

Secondary Outcomes (ADHD Symptoms)
Subjective report. Parent-reported Attention Problems and Hyperactivity/Impulsivity T-scores on the BASC-2 (age and gender norms) served as the primary subjective assessment of treatment effects on ADHD symptoms.

Objective measurement. Basic Motionlogger® (Ambulatory Monitoring, 201x) are acceleration-sensitive devices that sample movement intensity 16 times per second (16 Hz), collapsed into 1-second epochs. The estimated reliability for

actigraphs placed at the same site on the same person ranges from .90 to .99 (Tryon et al., 1991). Children were told that the actigraphs were “special watches” that let them play the computer learning games. Observer XT (Noldus, 201X) software was used to code start and stop times for each task, which were matched to the time stamps from the actigraphs.

Actigraphs were placed on the child’s non-dominant wrist and both ankles using Velcro watch bands. Following Rapport et al. (2009), a total hyperactivity score was computed by summing activity level across the three actigraphs. Hyperactivity scores were computed separately for movement during each of the working memory tests described above, as well as for movement during the control conditions that occurred as the first and last activities of each testing session. Movement scores reflect movement intensity (Proportional Integrating Measure; PIM).

During these control conditions, children used Microsoft Paint for five consecutive minutes at the beginning and end of all pre- and post-treatment sessions. Children sat in the same chair and interacted with the same computer used for the working memory tasks while interacting with a program that placed relatively modest demands on working memory (i.e., the Paint program allows children to draw/paint anything they like on the monitor using a variety of interactive tools).

Feasibility/Acceptability Outcomes
Client Satisfaction Questionnaire (CSQ-8; Nguyen et al., 1983). The CSQ-8 is an extensively studied, 8-item generic measure of clients’ perceptions of the value of services received. Parents completed the CSQ-8 at post-treatment. Total scores will be used.

Barriers to Treatment Participation Scale (BTPS; Kazdin et al., 1997). The BTPS is a 44-item measure of perceived treatment barriers; item scores are summed to provide a Total Barriers score and 4 subscores: (1) Stressors/obstacles; (2) Treatment demands/issues; (3) Perceived relevance; and (4) Relationship with the Therapist. Parents completed the BTPS at post-treatment. Total scores will be used for each subscale.

System Usability Scale (SUS; Canon-Bowers & Bowers, 2010). The SUS is a 10-item, IRT-developed scale assessing ease of use on a 5-point Likert scale. Children in the CET group completed the SUS each week for a different training game, and at post-treatment for the CET system overall. Total scores will be used.

CET Training Duration. The CET software records training duration for each completed training task; total minutes trained and total completed games are reported.

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Indices

If any measurements are going to be combined into an index (or even a mean), what measures will you use and how will they be combined? Include either a formula or a precise description of your method. If your are using a more complicated statistical method to combine measures (e.g. a factor analysis), you can note that here but describe the exact method in the analysis plan section.

Described for each measure above.

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Design Plan

Study type

Please check one of the following statements

Experiment - A researcher randomly assigns treatments to study subjects, this includes field or lab experiments. This is also known as an intervention experiment and includes randomized controlled trials.

Blinding

Blinding describes who is aware of the experimental manipulations within a study. Mark all that apply.

No blinding is involved in this study.

Study design

Describe your study design. Examples include two-group, factorial, randomized block, and repeated measures. Is it a between (unpaired), within-subject (paired), or mixed design? Describe any counterbalancing required. Typical study designs for observation studies include cohort, cross sectional, and case-control studies.

Sequential, non-randomized design. The BPT sample was recruited while PI Kofler was at the University of Virginia. Data collection continued, led by co-PI Schaefer, when PI Kofler changed institutions to Florida State University in August, 2014. The CET sample was collected at FSU (co-PI Holland for 2015-2016, co-PI Austin for 2016-present). Identical procedures were used for both samples. Both treatments were delivered in small group format (2-4 families) or individually as needed to accommodate families' schedules. Schedule changes were accommodated to the extent possible (e.g., make-up sessions the same week). Families recruited between June 2013 and December 2014 were offered behavioral parent training (BPT). The final BPT post-treatment session was completed in June 2015. Families recruited between June 2015 and December 2016 were offered central executive training (CET). The final CET post-treatment session was completed in [TBD, likely May/June] 2017. Recruitment to CET was closed when the software for the active comparator was completed. We are currently conducting a pilot randomized trial of CET versus this active comparator (inhibition training) that is registered at clinicaltrials.gov (NCT03042338).

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Randomization

If you are doing a randomized study, how will you randomize, and at what level?

Participants are not randomized because the CET intervention was in development. Recruitment to BPT was closed when CET was ready for testing. Recruitment to CET was closed when the active comparator was ready for testing.

Analysis Plan

Statistical models

What statistical model will you use to test each hypothesis? Please include the type of model (e.g. ANOVA, multiple regression, SEM, etc) and the specification of the model (this includes each variable that will be included as predictors, outcomes, or covariates). Please specify any interactions that will be tested and remember that any test not included here must be noted as an exploratory test in your final article.

Covariates and Data Handling

1. To describe the samples, the BPT and CET samples will be compared at pre-treatment on gender, age, SES (Hollingshead scores), WASI-II/WISC-IV Verbal Comprehension Index IQ standard scores, medication status (no/yes), race/ethnicity (US Census categories), comorbidities (no/yes), teacher reported ADHD symptoms (BASC-2 attention problems and hyperactivity T-scores), parent reported ADHD symptoms (BASC-2 attention problems, hyperactivity T-scores, CSI-IV raw severity scores for attention problems and hyperactivity/impulsivity), parent reported ODD symptoms (CSI-IV raw severity scores). Variables showing significant between-group differences at p = .05 or less, corrected for multiple comparisons, will be used as covariates in all above analyses (simultaneous entry). We decided to sacrifice power if needed to control for any pre-treatment differences.
2. The CET vs. BPT pre-treatment descriptive analyses will also be conducted for the treated vs. untreated samples. For the purposes of these analyses, the BPT and CET participants will be combined as the 'treated' sample, and those who declined or otherwise were offered but did not participate in BPT and CET will be combined as 'untreated.' We will not conduct treated vs. untreated analyses separately for the BPT and CET groups due to low n. The same significance

criteria and correction for multiple comparisons will apply as for BPT vs. CET.
3. All hypothesized interactions are expected to look like Figure 1 in Redick (2015). In other words, the expected interaction pattern would be due to no pre-treatment group differences, and differential improvements favoring the group hypothesized to improve.

Unless otherwise specified below, all omnibus tests will be 2 (group; between) x 2 (variable; within) x 2 time points (pre, post; within) mixed-model ANOVA or ANCOVA. ANOVA vs. ANCOVA decision will be based on whether there are significant p =.05 (or lower) group differences on any pretreatment variables as detailed in previous section. Tests that specify independent-samples or paired-samples t-tests will be run as between-group and within-group ANCOVAs, respectively, if covariate adjustments are needed based on analysis of pretreatment characteristics described in previous section.

Analyses will be run using JASP 0.8.1 (or current version).

Primary Outcome
1. Near-transfer: 2 group x 2 task x 2 time points (pre, post). Tasks are Rapport phonological (PH) and visuospatial (VS) working memory tests. Critical test is the group x time interaction. The 2 tasks are included in the omnibus ANOVA to (1) address recommendations to probe cognitive abilities using multiple tests, and (2) maximize power for the critical group x time interaction. The 2 working memory tests are considered to tap the same 'central executive' working memory; they differ in whether that central executive is processing phonological or visuospatial information. If the group x time interaction is significant at p =.05 (or lower), it will be followed by Bonferroni-corrected within-group post-hocs for each task and ANCOVA of post-treatment covaried for pre-treatment separately for each task (i.e., residualized gain scores). These post-hocs will also be performed if the main effect of time is significant (but not the group x time interaction) to allow us to better characterize change within each group (i.e., did each treatment produce significant change?). Stimuli correct per trial will be used.
Secondary Outcomes
2. Far-transfer subjective ADHD symptoms: Two scales are used: the norm-referenced BASC-2 (T-scores based on age and gender norms) and CSI-IV (raw symptom severity scores). Both have separate Attention Problems and Hyperactivity/Impulsivity subscales. Both will be tested via 2 group x 2 subscale x 2 time point mixed-model ANOVA. Critical test is the group x time interaction for both. Post-hoc plan follows #1 above.
3. Far-transfer objective (proximal) ADHD symptoms: Same 2 group x 2 task (PH-actigraphy, VS-actigraphy) x 2 time points approach as above; same post-hoc plan. Critical test is the group x time interaction. Actigraph data will be PIM intensity scores collected while the child was completing the PH and VS tests described above. Each data point reflects total hyperactivity score (Rapport et al., 2009), which is computed by summing the PIM activity counts for each of the 3 actigraphs (non-dominant wrist, left ankle, right ankle).
4. Far-transfer objective (distal) ADHD symptoms: Same 2 group x 2 task (PaintBeginning-actigraphy, PaintEnd-actigraphy) x 2 time points approach as above; same post-hoc plan. Critical test is the group x time interaction. Actigraph data will be PIM intensity scores collected while the child was completing the beginning of session and end of session Paint activity (drawing using Microsoft Paint). Each data point reflects total hyperactivity score (Rapport et al., 2009), which is computed by summing the PIM activity counts for each of the 3 actigraphs (non-dominant wrist, left ankle, right ankle).
5. Far-transfer subjective oppositional-defiant symptoms: Included as fidelity check based on evidence that BPT may produce greatest effects on oppositional defiant symptoms. Analysis will be 2 group x 2 timepoints mixed-model ANOVA (only one measure of ODD symptoms was collected). Critical test is the group x time interaction. CSI-IV raw symptom scores for the ODD dimension will be used as dependent variable. Bonferroni-corrected paired-sample t-tests for each group separately (pre vs. post), and between-group at post covaried for pre-treatment ODD symptoms are tested because of compelling evidence that BPT improves these symptoms (manipulation check; if no significant reductions in BPT group, may indicate limited BPT efficacy).

Feasibility/Acceptability Outcomes
6. Client Satisfaction Questionnaire-8 (CSQ-8) parent report at post-treatment (total scores) will be compared across groups (BPT vs. CET) using independent samples T-test.
7. Barriers to Treatment Participation Scale (BTPS) parent report at post-treatment (total scores and all subscales). Independent samples t-tests. The Relevance of Treatment subscale will be interpreted as evidence of intervention expectancies.
8. CET only: System Usability Scale (SUS). Child reported feasibility of CET system. Expected to be high (mean of at least 3.5 on 5-point Likert scale, where higher scores indicate better usability). Descriptive statistics only.
9. CET training duration. Total minutes trained and total training games completed will be reported. Descriptive statistics only.

Recommended elements
10. All hypothesized interactions are expected to look like Figure 1 in Redick (2015). In other words, no pre-treatment group differences, and differential improvements favoring the group hypothesized to improve. Should pre-treatment group differences be observed, differential improvements favoring the group hypothesized to improve would be observed when using post-treatment covaried for pre-treatment analysis (residualized gain scores). No differences in this test indicate equivalence between interventions.
11. P-values and Bayes Factors will be reported. P-values will be considered primary in cases of discrepant results (to follow current conventions in the field). P-values = .05or lower will be considered significant (after Bonferroni corrections for post-hoc tests). Bayes Factors = 3 or greater will be considered significant.

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Transformations

If you plan on transforming, centering, recoding the data, or will require a coding scheme for categorical variables, please describe that process.

No transformations are planned. If needed, categorical variables will be dummy coded as n-1 predictors. Reference categories would be: Medication changes (no change), race/ethnicity (Caucasian/Non-Hispanic), ADHD presentation (Combined Presentation). All other categorical variables are dichotomous and therefore would not require dummy coding.

Follow-up analyses

If not specified previously, will you be conducting any confirmatory analyses to follow up on effects in your statistical model, such as subgroup analyses, pairwise or complex contrasts, or follow-up tests from interactions? Remember that any analyses not specified in this research plan must be noted as exploratory.

Planned contrasts/post-hocs are described under the statistical model question above. Unless otherwise specified, significant main effects/interactions in the omnibus model will be followed by Bonferroni-corrected post hocs/contrasts to characterize the omnibus effects.

Inference criteria

What criteria will you use to make inferences? Please describe the information you'll use (e.g. specify the p-values, Bayes factors, specific model fit indices), as well as cut-off criterion, where appropriate. Will you be using one or two tailed tests for each of your analyses? If you are comparing multiple conditions or testing multiple hypotheses, will you account for this?

P-values and Bayes Factors will be reported. P-values will be considered primary in cases of discrepant results (to follow current conventions in the field). P =.05 or lower and BF =3 or greater will indicate significant effects.

For the Bayes Factors, BF10 or BF01 will be reported based on which value is greater than 1 as recommended.

Post-hoc tests will be corrected using Bonferroni corrections for multiple comparisons. No corrections will be made for the omnibus tests. These omnibus tests already include 2 variables per outcome to minimize the number of tests.

Data exclusion

How will you determine which data points or samples (if any) to exclude from your analyses? How will outliers be handled?

Outliers (3 SD or more beyond group mean) will be windsorized relative to the group mean. Group = BPT or CET.

Attrition: If available, mid-treatment data will be substituted for missing post-treatment data. If not available, the most proximal (non-pre-treatment) data point for that child will be substituted. If not available, single imputation will be used based on all available demographic and performance data.

Duplicate Data: In cases of duplicate data with different administration dates, the first administration will be used unless there is compelling reason to select differently. If a child has duplicate task data from the same date, the file will be checked for notes (e.g., first administration was invalidated by fire alarm/child had to go to the bathroom). The first administration will be used unless there is a clear documented reason to select otherwise. If a participant has duplicate rating scale data from the same date (e.g., mom and dad filled out forms separately), we will select the rater who completed forms at the other time point. Priority will be given to ratings from the caregiver involved in treatment. Maternal ratings will be prioritized if no other distinguishing criteria are met. All decisions will be made without looking at the scores.

No checks will be performed to determine eligibility for inclusion in data analyses besides verification that each participant was consented and enrolled.

Missing data

How will you deal with incomplete or missing data?

Missing data: Patterns of missingness will be explored to identify potential reasons and determine whether a missing at random (MAR) assumption is reasonable. The steps outlined above for missing data due to attrition will be followed.

In the case of unanticipated data handling situations, decisions will be made by co-PIs without access to the data and without knowledge of the effects of those decisions on the subsequent analyses.

Exploratory analysis

If you plan to explore your data set to look for unexpected differences or relationships, you may describe those tests here. An exploratory test is any test where a prediction is not made up front, or there are multiple possible tests that you are going to use. A statistically significant finding in an exploratory test is a great way to form a new confirmatory hypothesis, which could be registered at a later time.

None specified.

Scripts

Upload an analysis script with clear comments

This optional step is helpful in order to create a process that is completely transparent and increase the likelihood that your analysis can be replicated. We recommend that you run the code on a simulated dataset in order to check that it will run without errors.

no file selected

Other

Other

If there is any additional information that you feel needs to be included in your preregistration, please enter it here.