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Ethical Considerations and Lessons Learned in a Randomized Controlled Trial of ThinkRx Cognitive Training for Children With Learning Disabilities and/or ADHD

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Abstract

In a randomized controlled trial, we examined the efficacy of 60 hr of ThinkRx, a clinician-delivered cognitive training program delivered to children with learning disabilities and/or ADHD. In this case review, we discuss the ethical considerations for using a waitlist control group instead of a sham intervention in lengthy behavioral interventions with a vulnerable population. We describe the control group options we considered and why we selected waitlist controls. We also discuss lessons we learned in the sampling and assessment stages of our study, including providing clarity in exclusionary criteria, testing technology equipment and Internet access, optimal scheduling, and verifying the validity of testing measures with our specific population. We report our quantitative and qualitative outcomes from two articles published on this study including statistically significant differences in eight of the nine measures, clinically significant changes in IQ score for the ADHD subset, and parent-reported improvements in self-esteem, self-discipline, cooperative behaviors, and school performance.

Learning Outcomes

By the end of this case, students should be able to

- Describe the difference between active and inactive control groups
- Define the strengths and limitations of using waitlist control groups in randomized controlled trials
- Identify the ethical concerns with sham treatment control groups in behavioral intervention studies with children
- Describe potential problems in outcome assessment planning and execution
- Identify a potential problem with incomplete exclusionary criteria

Project Overview and Context

Finding effective interventions for children struggling in school is a priority for educational researchers and practitioners. We have long known that tutoring is one component of academic remediation. Children who do not understand the content taught in class frequently need extra instruction before or after school. But we also know that academic struggles are frequently the result of deficits in cognitive skills such as memory, reasoning, or attention. We see these deficits in children not only with general learning struggles but also with attention deficit hyperactivity disorder (ADHD), dyslexia, autism, and specific learning disability. Therefore, our goal was to explore an intervention that directly targets cognitive deficits rather than re-teaches content to struggling learners—a goal of researchers in neuropsychology, cognitive science, and medicine as well.

ThinkRx is a cognitive training program designed to remediate weak cognitive abilities. The program was originally created in the 1980s by Dr. Ken Gibson, a pediatric eye doctor who specialized in vision therapy for children with dyslexia. It is designed to strengthen weak cognitive skills through repeated engagement in

targeted mental tasks delivered one on one, face to face, by a human trainer. The methodology is distinct from other cognitive training interventions that use a computer interface to deliver brain games. Instead, a clinician can provide dynamic feedback and encouragement, can adjust the intensity and complexity based on the client's level of mastery and frustration, and can individualize the intervention to focus on the specific cognitive deficits of each individual. ThinkRx is offered in 45 countries in LearningRx and BrainRx cognitive training centers and by individual clinicians in private practice. Prior research on the program had revealed statistically significant changes across cognitive skills measured. However, the only published study on ThinkRx at the time of planning this one was a quasi-experimental design from which we could not make causal conclusions.

Section Summary

- Cognitive training is an intervention that targets cognitive deficits through repeated engagement in rigorous mental tasks and should be studied as a potential intervention for children with learning disabilities and/or ADHD.
- For this study, we wanted to know if the clinician-delivered, face-to-face ThinkRx cognitive training method would significantly improve cognitive skills for children with learning disabilities and/or ADHD.

Research Design

Why a Randomized Controlled Trial?

Our research team begins planning every study with the leading question, "What do we want to know?" The answer determines our research design. For this study, we wanted to know if there is a significant difference in cognitive skills for children with learning disabilities and/or ADHD between those who undergo training with the ThinkRx cognitive training program and those who do not. Prior research on this intervention had been conducted using a randomized controlled trial (RCT; Hill et al., 2016), nonexperimental observational studies (Pfister, 2012), qualitative surveys (Musick, 2015), and a pre–post comparison with propensity-matched controls—a quasi-experimental design where a control group is statistically matched to a treatment group (Gibson et al., 2015). However, an RCT on this population had not been conducted prior to this study. A growing and important trend in behavioral intervention research is to assess outcomes across multiple trial designs that point to a convergence of evidence in support of the intervention method. Although several designs would answer our research question, we opted to conduct an RCT comparing a treatment group to a control group. A majority of cognitive training studies in the existing literature had been conducted with this method as it is considered the gold standard in efficacy research. Because an RCT enables causal inference—or the ability to observe that the intervention *caused* the outcomes—we decided an RCT was the best choice for our study.

Section Summary

- We selected an RCT as our research design to draw the strongest conclusions and to align with industry trends in research design.

Research Practicalities

After we selected our research design, there were several practical decisions that had to be made: which type of control group we would use, how large the sample size would be, which outcome measures we should select, and what additional ethical considerations do we have when conducting a study with children who are considered a vulnerable population.

Control Group Selection

The first was to select the type of control group we would use. An RCT always includes a control group. A control group, also called the comparison group, is necessary to determine the "counterfactual," or what would have happened without the intervention. Active control groups receive some type of intervention (a standard treatment or a sham treatment). The comparison between the intervention group results and the active control group results yields a *relative effect*, or the effect of the new intervention relative to the effect of the intervention the control group received. By contrast, inactive control groups do not receive an intervention at all. The comparison between the intervention group results and the inactive control group results yields an *absolute effect*, or the effect of the new intervention compared with receiving no intervention at all.

Why a Waitlist Control Group?

When we were planning our study, there was no current "standard of care" in cognitive training for children with learning disabilities and/or ADHD, so we opted to examine the absolute effect of cognitive training versus no other intervention. In addition, we wanted to avoid the use of a sham intervention for ethical reasons we discuss later, and we wanted the control group to receive the real intervention eventually because children who are struggling to learn due to deficits in memory, attention, and processing speed are considered at risk for school failure and need a timely intervention. Therefore, we chose an inactive, waitlist control group. A waitlist control group serves as the inactive control condition for the initial comparison and then receives the intervention themselves.

Avoiding a Sham Intervention

The biggest advantage of using a waitlist control group is that it eliminates the use of a sham intervention. A sham intervention is a placebo, or a "fake" intervention that is designed to make the participants believe they are receiving a real intervention. In pharmaceutical research, a sham intervention refers to the placebo pill, or a pill with inert or inactive ingredients. The researcher and the participants are blinded and do not know if the pill is the active or placebo ingredient. In behavioral research, however, sham interventions are difficult (if not impossible) to blind. The researchers know if they are delivering an intervention or not, and the participants know if they are receiving an intervention or not.

In our case, there was a significant ethical consideration for weighing the use of a sham intervention. ThinkRx is a 12-week long program that requires three to four 90-min intense training sessions each week in the clinic. The time and effortful commitment plus the commute each way for both children and the parents made it

unethical for us to choose a sham intervention. Because the waitlist control group would then receive the "real" intervention for another 12 weeks at the end of the first 12 weeks, we felt we could not ask children and parents to commit to such an excessive amount of time and effort. In addition, the participants were children with learning disabilities and/or ADHD and dyslexia. Children who have been struggling in school often feel defeated and have low self-esteem from repeated failures in the classroom. We could not justify subjecting these children to 12 weeks of a fake intervention only to then turn around and tell them they will have to start over for another 12 weeks with the "real" intervention. We felt the emotional impact on them would be too great.

Avoiding Expectancy Effects

Despite the ethical justification of avoiding the use of a sham intervention in a behavioral intervention study like ours, the use of a waitlist control group brings up the concern of expectancy effects. An expectancy effect occurs when control group participants perform less than optimally on post-testing because they do not *expect* to do well as they were not given a treatment. (The opposite can also occur when the treatment group expects to do well because they received a treatment.) However, we mitigated the risk of expectancy effects by not telling participants that there was a waitlist control group. Instead, we simply told all of the participants that they would be tested three times during the course of the study and that they would be assigned to either a summer intervention group (the experimental group receiving the intervention in the summer) or a fall intervention group (the waitlist control group receiving the intervention in the fall).

We also knew from prior cognitive training research that there should only be a minimal threat of expectancy effects. There is a robust body of compelling evidence that revealed no significant difference in outcomes between passive and active controls in cognitive training research (Burki et al., 2014; Dunning et al., 2013; Mahncke et al., 2006). Nor had prior research found that the type of control group had any influence on the training effects in the treatment group (Peng & Miller, 2016). Although some cognitive training researchers insist that active control groups are a better choice (Kinser & Robins, 2013) and reduce the risk of inflating the effect of the intervention, we were comfortable that these alternative findings supported our decision.

Sample Size Determination

The next decision we had to make was the sample size for the study. Because we were working within budget limitations, we calculated the cost per participant for the study and then determined how many participants we could accommodate. We determined we could afford to include 40 participants in the trial. We then used our given sample size to run a sensitivity power analysis using G Power software to determine the effect size we would need to reach to achieve enough statistical power to conclude that any statistically significant outcomes were robust. This is in contrast to a traditional power analysis used to determine a needed sample size.

Outcome Measures

Our main consideration in selecting primary outcome measures for the study was to choose the least number of tests that could adequately measure change in cognitive skills. We did not want to fatigue children with

unnecessary testing. Therefore, we selected a standard cognition battery—Woodcock–Johnson III Tests of Cognitive Abilities (WJ-III-COG)—along with a test of attention from the NIH Toolbox. We used pre-intervention, mid-intervention, and post-intervention interview transcripts along with clinician notes as our dataset for qualitative analysis of secondary outcomes, or transfer effects to real-life changes.

Ethical Considerations in Conducting a Study With Children

We know that research with children—who are considered a vulnerable population—requires additional safeguards to protect them. Because cognitive training is typically an intervention that does not involve greater than minimal risk to children, we knew that the primary ethical requirement we needed to ensure was soliciting assent (or agreement to participate) from the children in addition to obtaining consent from parents. (See HHS regulation 45 CFR 46.408.) To do this, we met with the families together and also alone with each to child to ensure they were not feeling pressured to participate. We let them know that they could stop participating at any time during the study without fear of punishment.

Section Summary

- A waitlist control group enabled us to avoid the use of a sham intervention with children who were struggling to learn.
- The decision to use a waitlist control group was based on ethics, logistics, and prior research that indicated no differences in outcomes between types of control groups in cognitive training studies.
- Our sample size was determined based on budgetary constraints. Instead of a traditional power analysis, we conducted a sensitivity power analysis to accommodate a given sample size.
- Outcome measures included a standard cognition battery along with qualitative data.
- Obtaining child assent was a key ethical consideration in planning our study.

Method in Action

Sampling and Recruitment

After we planned our study and obtained Institutional Review Board (IRB) approval, we began recruitment. We sent an email to all families on the mailing list of a local cognitive training center. The list included anyone who had asked for information about the program online, over the phone, or in person in the last 2 years. Recruitment is typically challenging for most research studies, but we received more than 50 responses within 2 days. We screened all of them and enrolled them in the study if they met the inclusionary criteria.

A Sampling Challenge

An unexpected challenge occurred in the sampling process. We had six sets of siblings respond to the recruitment announcement. Because we did not exclude siblings a priori in the research design, we included them in the study if they met the screening criteria. However, we were concerned that if siblings were assigned to different groups in the randomization process, we would risk contamination and attrition. For example, a

sibling in the experimental group may discuss the intervention (contamination) or parents may not want to take part in both phases of the study where the waitlist control group gets the intervention (attrition). So, we responded using block sampling by sibling groups and individuals for randomization. Block sampling, or blocking, is a procedure enabling the researcher to arrange experimental units (or individual participants) into blocks that are similar to one another before random assignment to groups. In our study, we defined our blocks as siblings and individuals.

Procedures

Pre-Testing and Post-Testing

We began and ended the study by administering a battery of cognitive tests to participants in both groups. We measured working memory, long-term memory, visual processing, auditory processing, processing speed, fluid reasoning, and overall IQ score using the WJ-III-COG (Woodcock et al., 2001). To measure attention, we used the Flanker Test from the NIH Toolbox Cognition Battery. Test administrators were blind to the condition of the participants.

Assessment Challenges

We experienced three challenges with assessments in our study. First, although most of our assessments were delivered through traditional paper-and-pencil method, we did select a web-based digital assessment attention task administered on a computer. Because we used Wi-Fi two floors above where the router was located in the building, the tests occasionally experienced delayed response to user input. We opted to use the data anyway as the intermittent conditions were similar at pre-test and post-test. But we learned that it is critically important to have a reliable Internet connection, preferably hardwired, for pre- and post-web-based assessments.

Second, the test administrators had a limited schedule of availability as they held full-time jobs. Therefore, we scheduled assessments back to back over several consecutive days during each assessment period. Several children took longer than the estimated time for completing the assessments which created a backlog in the testing waiting area. We were concerned that the children waiting would become frustrated, bored, or fatigued which might impact their test performance when their assessment turn arrived. We provided some activities in the waiting area and spent a few minutes engaging with them in the testing rooms prior to beginning their testing session to ensure they were motivated to begin. One child had to be rescheduled due to the parent's schedule and another child was rescheduled due to fatigue. In hindsight, we should have spaced out the testing appointments and selected some test administrators with more flexible schedules.

Finally, the third challenge was not related to the delivery of the assessments but to the validity of the attention task in the NIH Toolbox Cognition Battery. When we selected the attention task, we scanned the NIH Toolbox technical manual that reported the aggregated validity coefficients across age groups along with an endorsement of its use with children. It did not itemize the coefficients by age group. As we prepared our own manuscript for publication, we learned from additional literature (Akshoomoff et al., 2014; Zelazo et al., 2013)

that the validity of the test for measuring attention in children was quite low, and that significant ceiling and practice effects were found in the norming studies with children. So, we reported our results along with the caveat to interpret the attention scores with caution due to the issue with validity. Although we chose the test based on the assumption that the test was valid as it was endorsed by NIH, it was ultimately our responsibility to verify the metrics specific to our sample.

Intervention

We delivered 60 hr of ThinkRx cognitive training to the treatment group in three to four 90-min sessions per week for 12 weeks. Using a variety of hands-on manipulatives, a timer, and a metronome, the clinician gives specific, dynamic feedback throughout the training sessions to increase motivation, self-efficacy, and progression through increasingly more difficult training procedures. Based on the Cattel–Horn–Carrol theory of cognition (McGrew, 2009)—the most widely accepted theory of intelligence—the program targets multiple cognitive skills including working memory, long-term memory, visual and auditory processing, processing speed, logic and reasoning, and attention along with a variety of subskills. There are nearly 200 training tasks with thousands of variations from which trainers can individualize from a basic scope and sequence. A unique element of this methodology—besides its delivery by a human rather than on a computer—is the use of deliberate distractions to encourage the development of selective and sustained attention skills. This is in direct contrast to what we typically see in interventions for children with attention disorders. Instead of accommodating the deficits in attention, this methodology targets the remediation of the attention skills by mimicking the stimulus-rich environment found in the real world. There were no challenges that we encountered during the intervention phase, perhaps because the intervention was delivered by clinicians who deliver the intervention to their own clients every day.

Data Analysis

Quantitative data were analyzed using SPSS software. For the first article (Carpenter et al., 2016), we conducted a multiple analysis of variance (MANOVA) which is a statistical test that compared the change scores between the two groups on each variable. To account for the possibility of Lord's Paradox (or another researcher finding a different outcome by adding a covariate), we also ran a multiple analysis of covariance (MANCOVA) with pre-test scores as the covariate. The results were conceptually similar, so we reported the MANOVA results with two exceptions where we reported both methods. In a second article (Moore et al., 2018), we analyzed a subset of the full sample—only the participants with ADHD—using the Jacobsen–Truax method for determining clinically significant change within individual participants, and then we used nonparametric tests to analyze differences between the experimental and control groups as the subset size was small (n = 13). We included a detailed inductive thematic analysis of the qualitative data in the second article as well.

Results

In the full study, MANOVA results indicate an overall significant difference between treatment and control

groups ($F = 15.83$, $p = .00$, partial $\eta^2 = 0.83$), with pairwise comparisons indicating significant differences between groups on eight of nine measures with a very large effect size. The intervention produced statistically significantly greater growth on all measures except attention. As mentioned earlier, we do not believe the lack of significance on the attention measure is an adequate reflection in the difference between the two groups but, instead, reflects the psychometric limitations of the NIH Toolbox Flanker Test measure. However, the Numbers Reversed subtest of the WJ-III-COG is not only a measure of working memory but also a measure of broad attention. (See WJ-III-COG Administrator Manual.) The difference between groups on the test of broad attention was indeed statistically significant.

In the second article, we reported results of the ADHD subset of participants from the full study. Participants in the treatment group showed greater median difference scores on all nine measures as compared with the control group. All treatment group participants obtained a significant clinical change on General Intellectual Ability (GIA)—the composite measure of cognitive skills tested—indicating overall recovery effects from the intervention. Qualitative behavioral improvements were noted in academic performance, confidence, self-esteem, cooperative behavior, self-discipline, sleep, and sports and hobbies; self and parent-reported cognitive improvements included attention, reasoning, memory, processing speed, and visual and auditory processing.

Section Summary

- Block randomization was added to prevent attrition and contamination after six sets of siblings unexpectedly responded to the recruitment email.
- Challenges encountered during the assessment process had to be reported in the study's publications but also informed future planning to prevent technology problems.
- Data analyses revealed both statistically and clinically significant outcomes following 60 hr of cognitive training with ThinkRx with results that transferred to real-life changes as well.

Practical Lessons Learned

Overall, this RCT of ThinkRx, a cognitive training intervention for children with learning disabilities and/or ADHD ($n = 39$), was well planned and executed. We had no attrition and no challenges during the intervention phase of the study. However, we did learn some important lessons about the design, recruitment, and assessment aspects of the study.

Be Prepared to Scientifically Defend the Choice of Control Group

The type of control group used in an RCT is a debated choice with peer reviewers and the scientific community at large. There is a camp that insists that only active control groups (sham or placebo) enable causal inference (Kinser & Robins, 2013). Because we genuinely felt a waitlist control group was the only ethical option for our study, we assumed our choice would be supported by reviewers and other researchers. However, it was effortful to justify our choice, despite the ethical considerations. Fortunately,

there is compelling empirical evidence that evaluated the differences in outcomes between types of control groups in cognitive training research and found none. These findings coupled with a detailed explanation of the ethical reasons for not giving a long sham intervention to children with learning disabilities enabled us to pass peer review. But it is important to have evidence to support the choice.

Clearly Define Exclusionary Criteria

As reported earlier, we had six sets of siblings respond to the recruitment email. Because we had not excluded siblings in the IRB application or research protocol, we had to adjust our randomization method to account for this unexpected occurrence. In the future, we will add an exclusionary criterion that excludes siblings from participating in the same study unless the study is specifically targeting variables related to siblings. In research planning, it is vitally important to consider contingencies when deciding on exclusionary criteria and clearly define them.

Double Check All Internet Connections and Technology Requirements

Because we scheduled three participants at a time for testing, we utilized three empty offices on the third floor of our building. The wireless Internet router is located on the first floor. Unfortunately, we had intermittent problems with the Internet connection during our testing. This created a lag between user input and the computer response. In the future, we would either choose testing rooms closer to the router, hardwire our computers, or only select paper-based assessments. So, it is critical to test and retest all technology before beginning a study.

Confirm Validity of Each Assessment for Use With Our Specific Population

As reported, we did not realize the psychometric limitations of the Flanker Test from the NIH Toolbox Cognition Battery for children ages 8–15 until after our study was complete. We discovered later that the convergent validity of the test with a pediatric population was just 0.34 and there were significant practice effects from repeated testing (Zelazo et al., 2013), and there were significant ceiling effects in older children (Akshoomoff et al., 2014). Therefore, we were not able to make any conclusions about the impact of the intervention on attention skills using this test. In future studies, it will be critical to examine the validity of each assessment tool with the population we are studying. Assuming the test is valid because it has been endorsed by the NIH is not sufficient.

Allow Sufficient Time Between Testing Appointments

The test administrators had limited availability so we booked testing appointments back to back without accounting for differences between examinees in the length of time it would take to complete the assessments. With the Woodcock–Johnson battery, the test takes longer when examinees continue to answer correctly. We did not anticipate that we would have children who would exceed the 90-min time allotted for each. In future research, we will choose test administrators with more flexible schedules and also schedule examinees further apart.

Section Summary

- Provide scientific evidence and ethical considerations to support your choice of control group.
- Clearly define your exclusionary criteria to avoid the need to alter the randomization method.
- Test and retest the time needed, technology requirements, and validity for assessments prior to beginning the study to avoid scheduling conflicts, computer glitches, and psychometric limitations with the outcome assessments.

Conclusion

Testing the efficacy of a behavioral intervention for children has several ethical considerations that we faced in our RCT of ThinkRx cognitive training for children with learning disabilities and/or ADHD. An RCT was the best research design for answering our research question, “Is there a significant difference in cognitive skills after 60 hr of cognitive training with ThinkRx?” We found significant differences between the treatment and control groups on all but one measure. We stand by our choice to use a waitlist control group as it was the most ethical option for conducting a lengthy behavioral intervention with children to avoid using a less-than-ethical sham intervention with a vulnerable population. We also supported that choice with prior research that revealed no difference in outcomes between types of control groups in cognitive training research.

However, we learned several practical lessons from our study that will inform our planning in subsequent research. First, we learned that it is important to consider all contingencies when deciding inclusionary and exclusionary criteria. We also learned that technology is never perfect, so it is vital to test and retest equipment and Internet connections prior to beginning the study. We made the mistake of not verifying the validity metrics of one of our digital tests for use with our age group. In future studies, we will always ensure all the assessment tools have strong validity for use with our specific population. And, finally, we learned that scheduling back-to-back assessment appointments seemed efficient but ended up creating a backlog of bored children in the waiting area. In future research, we will spread out the testing appointments to prevent such overlap.

Section Summary

- An RCT was a successful design for answering our research question.
- A waitlist control group was the most ethical option for testing a lengthy behavioral intervention with a vulnerable population and our choice was supported by prior research.
- We learned practical lessons that will inform our future research planning.

Classroom Discussion Questions

Classroom Discussion Questions

1. What are the key differences between active and inactive control groups?

2. What are the strengths and limitations of using waitlist control groups in randomized controlled trials?
3. Why might it be unethical to use a sham treatment control group in a lengthy behavioral intervention study with children?
4. How can you prevent potential technical difficulties with digital assessments?
5. Why is it important to provide detailed exclusionary criteria in recruitment?

Declaration of Conflicting Interests

Dr. Moore runs the non-profit research institute associated with the intervention studied in this case but her salary is not related to the outcomes of research. Dr. Ledbetter volunteers on the scientific advisory board for the intervention studied in this case but receives no compensation.

Further Reading

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Web Resources

Main website for the intervention used in this study: www.LearningRx.com

LAERD Statistics explanation of MANOVA: https://statistics.laerd.com/spss-tutorials/one-way-manova-using-spss-statistics.php and MANCOVA: https://statistics.laerd.com/spss-tutorials/one-way-mancova-using-spss-statistics.php

American Evaluation Association Blog post by Jeremy Jewell on waitlist control groups: https://aea365.org/blog/jeremy-jewell-on-using-wait-list-control-groups-in-evaluation/

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