



Testing the efficacy of the Nurtured Heart Approach[®] to reduce ADHD symptoms in children by training parents: Protocol for a randomized controlled trial

Velia Leybas Nuño^{a,*}, Betsy C. Wertheim^b, Bridget S. Murphy^a, Richard A. Wahl^c, Denise J. Roe^{b,d}

^a The University of Arizona, Mel and Enid Zuckerman College of Public Health, Department of Health Promotion Sciences, USA

^b The University of Arizona Cancer Center, USA

^c The University of Arizona, College of Medicine, Department of Pediatrics, USA

^d The University of Arizona, Mel and Enid Zuckerman College of Public Health, Department of Epidemiology and Biostatistics, USA

1. Introduction

Attention Deficit Hyperactivity Disorder (ADHD), as currently defined in the Diagnostic and Statistical Manual-5 (DSM-5), is a disorder with a childhood onset, which interferes with normal school and social activities [1]. ADHD has two primary presentations, inattentive type and hyperactive-impulsive type, although a combined type is also recognized. Parents find their child with ADHD extremely challenging to manage using traditional parenting approaches. Most children with ADHD have a difficult time focusing (inattention), act without thinking (impulsive), and/or cannot sit still (hyperactive).

At present, ADHD is a pervasive and costly neurodevelopmental condition [2,3]. According to U.S. parental reports, 6.1 million children, between the ages of two and 17 years, have a diagnosis of ADHD [4]. This is approximately the same as the population of the entire state of Arizona (6.9 million) [5]. Moreover, in 2010, U.S. costs related to ADHD were between \$143 and \$226 billion for adults and children diagnosed with ADHD and their families [3]. These costs are attributable to employment losses, healthcare issues, educational problems, and legal involvement.

As of 2011, to treat ADHD, the American Academy of Pediatrics (AAP) recommends medication approved by the Food and Drug Administration and/or evidence-based parent/teacher behavioral treatment for children ages six to 11 years [6]. The earlier 2007 guidelines published by the American Academy of Child and Adolescent Psychiatry noted that a comprehensive treatment plan which considered both behavioral and parenting interventions was important, although they concluded that available evidence supported pharmacologic treatment as the most effective modality. They did note that parents' preferences were important to developing a final treatment protocol [7].

Many parents have significant concerns about the use of stimulants in children and prefer exploring non-pharmacologic approaches. A recent meta-analysis surveying pharmacologic, psychosocial, and

alternative medicine modalities documented the wide range of ADHD treatment options available to parents, with a lack of any definitive evidence-based treatment recommendation [8].

One non-pharmacologic option is the Nurtured Heart Approach[®] (NHA), a behavioral intervention that aims to improve parent responses to intense (problematic) child behaviors, such as those exhibited by children with ADHD [9]. The purpose of this paper is to document the protocol of the NHA study. To that end, this paper describes the recruitment, screening, and enrollment process; an overview of the intervention; and procedures for the collection and analysis of data.

2. Materials and methods

2.1. Design overview

This one-year intent-to-treat study is a randomized controlled trial designed to test the efficacy of the NHA to reduce inattention and hyperactivity/impulsivity in symptomatic children ages six to eight years old. While the AAP recommends behavioral treatment for children six to 11 years of age, we restricted the age range to simplify this initial study of the NHA by reducing the potential for variability across age. Participants are parents with a child diagnosed with ADHD or suspected of having ADHD. The two arms of the study are an immediate intervention group and delayed intervention group. The intervention is a six-week, online course named the Foundations Course. Data are collected via an online survey at three time points and through course discussion posts and analytics. The primary outcomes are changes in the child's inattention and hyperactivity/impulsivity as assessed by the parent. The secondary outcomes are changes in parental stress and competency. Study hypotheses are:

Hypothesis 1. Parents in the immediate intervention group will report a reduction in inattention and hyperactivity/impulsivity in their child when compared to the delayed intervention group. The Conners 3-

* Corresponding author.

E-mail address: vleybas@email.arizona.edu (V.L. Nuño).

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Parent Short Form [Conners 3-P(S)] measures ADHD behaviors in children [10].

Hypothesis 2. Parents in the immediate intervention group will report a reduction in stress compared to the delayed intervention parents. The Parenting Stress Index 4 Short Form (PSI-4-SF) measures parental stress [11].

Hypothesis 3. Parents in the immediate intervention group will report an increase in their competency when compared to the delayed intervention parents. The Parenting Sense of Competency (PSOC) measures parent competency [12,13].

The University of Arizona Human Subjects Protection Program (UA HSPP) reviewed the study protocol and declared the study exempt due to the low level of risk to participants.

2.2. Data systems

2.2.1. Research electronic data capture (REDCap)

Collection and management of study data is achieved using REDCap software hosted at the University of Arizona [14]. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources. This study uses REDCap for creating the online survey and administering it, real-time screening of potential participants, on-line review and signature of electronic consent, tracking participant enrollments and withdrawals, randomizing participants, and for data management, storage, and export.

2.2.2. Microsoft OneDrive

Secure file storage and organization is the main purpose for OneDrive. The shared drive stores, secures, and organizes study documents such as UA HSPP forms/approvals, study progress and/or decisions (e.g., participants who withdraw; changes in surveys), locations of recruitment sites, and participant communications (e.g., survey invitation templates, reminders to complete surveys or login in to course shell).

2.2.3. Microsoft excel

Excel organizes and codes qualitative data from course discussion posts. Separate worksheets are available for the immediate and delayed intervention groups that sequentially list the verbatim discussion posts along with other items (e.g., date, interaction type). Data are coded for common themes and participation milestones.

2.3. Intervention—Nurtured Heart Approach (NHA) Foundations Course

The core principles of the Nurtured Heart Approach are: (1) refusing to energize negativity, (2) purposefully energizing success, and (3) establishing and applying clear rules and consequences [9,15]. This goal is to give children a sense of structure and the opportunity to manage emotions successfully. The NHA has a strong theoretical and empirical foundation [15]. More specifically, the NHA trains parents to focus on positive behaviors, create opportunities for success, establish clear boundaries, reduce focus on negative behaviors, and provide immediate and consistent consequences, which are evidence-based elements for improving children's behavior [15]. Due to its potential promise and the need for more evidence-based behavioral therapies for children with ADHD, this study tests whether the NHA reduces children's ADHD symptoms, reduces parental stress, and increases sense of competency among parents of children with ADHD.

The study intervention is the Nurtured Heart Approach taught through the Foundations Course available through the Children's

Success Foundation. Parents, educators, clinicians, and specialists have been accessing the Foundations Course since 2010. It spans six weeks, with each week building on the previous week's content. The Foundations Course takes approximately 16 h to complete and comprises recorded lessons, readings, skills practice and a live session. A description of each component follows.

- **Recorded lessons.** Howard Glasser, the developer of the Nurtured Heart Approach, narrates six recorded PowerPoint lessons. Each lesson is 60–100 min in duration. The six topics are introduction, foundational pieces, techniques, limit setting, inspiring and igniting greatness, and notching up the NHA.
- **Readings.** Participants receive excerpts from the Transforming the Intense Child Workbook [16] to complement the recorded lessons. The workbook offers real-life scenarios and practical language participants can apply.
- **Skills practice.** Participants practice applying the skills learned through the recorded lessons and readings then post their experience(s) on the training discussion forum. Advanced Trainers in the NHA read the posts and respond to the comments. Advanced Trainers synthesize the posts for the week to generate a set of themes for preliminary discussion during the live session.
- **Live sessions.** Each week culminates with a live session where Glasser, along with NHA Advanced Trainers, host a 60-min live forum online to address the themes for the week based on the posts and to answer questions. The session is recorded and accessible within 24 h for parents that could not participate or for those who want to review the content.

Dissemination of course material begins on Thursdays for the immediate intervention group and Wednesdays for the delayed intervention group. The difference in the start day had to do with accommodating a holiday and wanting to keep the materials release date consistent throughout the course. Participants can return to previous weeks' content, but cannot advance to future lessons until they are released. All material remains available to participants for the entire six weeks of the course and for 30 days following the last live session.

2.4. Eligibility

A parent, guardian, or caregiver is eligible to participate. Inclusion criteria are adults with a child age six to eight years (at the time of screening) diagnosed with or suspected of having ADHD. For those without a formal ADHD diagnosis, eligibility is contingent on the participants' self-report of another adult (e.g., teacher; spouse/partner) noticing ADHD symptoms in the child. An email address and access to the Internet is required. Exclusion criterion is a diagnosis of autism, which is in alignment with the exclusion criteria for a similar study by Webster-Stratton et al. [17].

2.5. Recruitment

Major efforts in recruitment begin in Pima county and then expanded to the state of Arizona and ultimately nationwide. Four individuals contribute time to the dissemination of fliers to local agencies, schools, clinics, churches and community centers.

2.5.1. Local

Various recruitment methods are employed including mailings, emails, and web and social media postings. Mailings through the United States Postal Service or email include an introductory letter and flier(s). Mailings are sent to specific entities including health clinics, such as pediatric and family practice offices, behavioral health agencies including non-profit organizations, Medicaid funded agencies, private practice offices, private schools, religious/spiritual organizations, and community organizations such as Parks and Recreation centers, Boys

and Girls Clubs, libraries, child care centers, and community centers. The introductory letter describes the study as a training opportunity to help primary caregivers (e.g. parents, guardians, foster parents, etc.) of children with ADHD. It lists criteria for eligibility and requests the recipient to disseminate fliers and study contact information. Fliers include information for participant compensation (\$20 for each completed survey, up to \$60 for three total surveys, to be paid at study completion).

To recruit within local public schools, the study requires approval from districts. Study investigators applied for and were provided approval to recruit students in grades first through third in two of the largest local districts.

2.5.2. State and nationwide

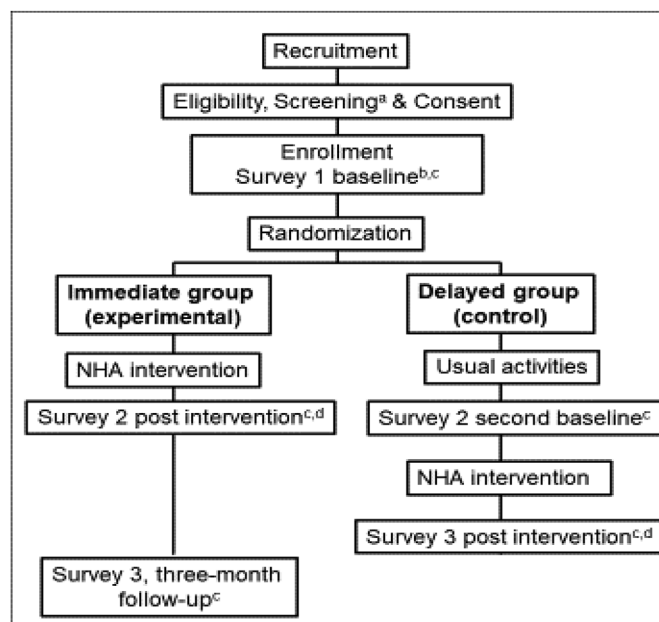
Websites and social media posts are primarily used to recruit participants from across the county. The Children's Success Foundation shares electronic fliers with its national trainers. Additionally, the Children's Success Foundation posts on its Facebook page and subsequently on other organizational and individual Facebook pages. Individuals associated with NHA who have professional websites post the flyer as well.

2.6. Screening, consent, and enrollment

Potential participants interested in the study initiate contact by phone or email (Fig. 1). Each inquiry is assigned to one of two study investigators. Those sending an email receive an email response thanking them for their interest and inviting them to select a time for a screening call. Those that call and leave a voice message receive a return call. If the potential participant answers, they are asked if they can complete the screening at that moment. If not, another time is scheduled. If there is no answer, the investigator leaves a voice message.

Screenings are divided into three parts. First, the investigator describes the study, answers questions, and asks if the caller is interested in participating based on the information presented.

The consent form is verbally reviewed with the participant by: (1) revisiting the overview and purpose of the study; (2) describing the study procedures including randomization to one of two groups, participation in a six-week online Foundations Course, completion of three



Data Collected:

^aCDC ADHD Checklist, ^bDemographics, ^cConners 3-P(S), PSI, PSOC,

^dLevel of participation

Fig. 2. Intervention delivery and data collection.

surveys, and payment for completed surveys; (3) acknowledging the option to refuse or withdraw from the study at any time; (4) discussing potential benefits and risks; (5) confirming confidentiality; and (6) discussing dissemination of the results. Subsequently, the investigator requests verbal permission to register participants in the study.

If the participant agrees to register, REDCap sends an email with a link to the electronic consent page. This page shows the consent form and allows electronic signature and submission. Also, included on the REDCap site is a PDF copy of the consent form should the participant wish to share and review with others before signing. After the participant signs the electronic consent form, the participant is sent a PDF

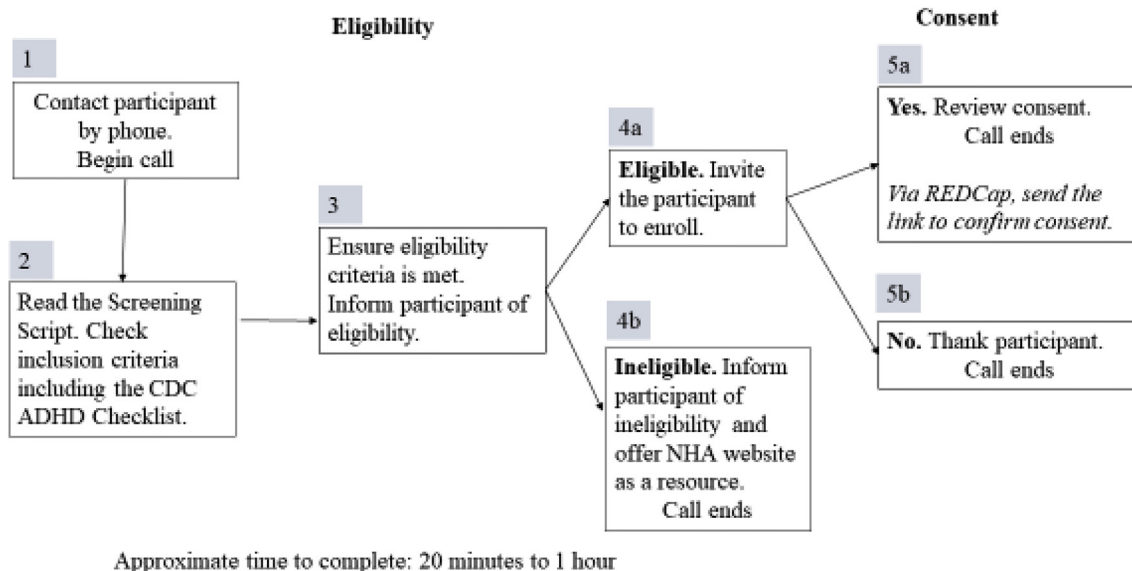


Fig. 1. Eligibility Determination and Consent sent so far. Second, the investigator asks about suspected or diagnosed ADHD, completes the Centers for Disease Control and Prevention (CDC) ADHD Checklist [18], and then asks if the child has a diagnosis of autism. If the caller meets the inclusion criteria, the investigator asks if the potential participant can commit approximately 20 h of time to complete surveys and participate in the intervention, if they have regular access to a computer with internet, and for their contact information. Third, if eligible and still interested, the investigator reviews the consent form and asks if the potential participant would like to register for the study.

copy of the consent via email. This indicates formal enrollment in the study.

2.7. Study procedures

Given the available funding, study procedures take place over one year (Fig. 2). Study recruitment occurs for six months starting in August and ending in mid-January. Between the end of January and June all other study activities occur. The immediate intervention group completes the Foundations Course February to March, followed by the delayed intervention group from March to May, with no overlap in intervention times.

2.7.1. Survey 1 - baseline

All enrolled participants are sent a link to the baseline survey in January, with instructions to complete it within two weeks. The first survey is administered prior to randomization and contains four main headings: demographics, participant's report of ADHD behaviors in their children as measured by the Conners 3-P(S) [10], participant stress as measured by the PSI-4-SF [11] and perceived parenting skills as measured by the PSOC [12,13]. Instructions on the survey explicitly direct parents to answer survey questions based on the child they identified for this study. Participants who complete the baseline survey are randomized; all others are withdrawn from the study. Participants are allocated into groups using block randomization (block size = 6) to either the immediate or delayed intervention group.

2.7.2. Survey 2 – post-intervention and second baseline

After the immediate intervention completes the Foundations Course, participants in both groups are sent a link to Survey 2, with instructions to complete it within two weeks. This survey includes the three study measures (Conners 3-P(S); PSI-4-SF; PSOC). The immediate intervention group had additional questions about their participation in the Foundations Course.

2.7.3. Survey 3 – post-intervention and follow up

Participants in the delayed intervention group complete Survey 3 (post-intervention) at the end of their Foundations Course. All delayed intervention participants are invited to complete the survey regardless of their level of participation. The same as the immediate intervention group's post-intervention survey, it includes the three study measures plus questions about participation in the Foundation Course.

Participants in the immediate intervention group complete Survey 3 later, approximately three months after the end of their Foundations Course. It contains only the three study measures. All immediate intervention participants complete the survey regardless of their completion of whether they completed Survey 2 and participation in the Foundations Course.

2.8. Study measures

2.8.1. CDC ADHD checklist

The basis for the checklist is DSM-5 criteria for diagnosing ADHD and asks a participant to indicate “yes or no” if an ADHD symptom has been present for at least six months at a level that it is inappropriate for the child's developmental age. There are two scales with nine items each. The first scale measures inattention and the second measures hyperactivity/impulsivity symptoms. A score of six or more on either scale indicates possible diagnosis of ADHD.

2.8.2. Demographics

The first survey collects information on the adult participant, the spouse/partner of the participant (if applicable), the child with ADHD, and the household. Participant-focused questions include age, gender, education, race/ethnicity, relationship to child, and marital status. Child-focused questions include date of birth, sex, race/ethnicity,

school type (public, private, home school), academic performance and behavior (passed subjects, Individualized Education Plan, referrals, and suspensions), and medication use. Household-focused questions include number of children, income, and primary language.

2.8.3. Conners-3 Parent Short Form (Conners 3-P(S))

The primary outcome measures are changes in inattention and hyperactivity/impulsivity. These are measured using the Conners 3-P(S), a standard instrument used for diagnosing ADHD [10], which comprises 45-items. Items ask participants to describe the trueness/frequency of specific behaviors within the past month. The response range from 0 to 3. Answers to each of 43 questions contribute to the score of one subscale. The six content and two validity subscales are inattention, hyperactivity/impulsivity, learning problems, executive functioning, defiance/aggression, peer relations, and positive and negative impression. The validity subscales determine whether participants might be responding overly positively or negatively. The last two questions are open-ended querying about any other concerns a participant might have about their child and the child's strengths and/or skills. These two questions do not contribute to subscale scoring. Raw scores are converted into standardized T-scores using age- and sex-specific conversion standards. The Conners 3-P(S) has good to very good psychometric properties. More specifically, internal consistency shows a mean Cronbach's alpha of 0.89 (sub-scales range from 0.85 to 0.92), mean adjusted test-retest correlation is 0.86 (sub-scales range from 0.73 to 0.97), and standard error of measurement ranges from 2.83 to 3.87 [10].

2.8.4. Parenting Stress Index-4 Short Form (PSI-4-SF)

The 36-item PSI-4-SF [11] asks participants to select the response that best represents the participant's opinion. For most questions, response options include strongly agree, agree, not sure, disagree, and strongly disagree. Three questions have different response options, two are five point Likert-type scales and the third is a categorical count of the participant's perception of problematic behaviors in the child. Answers to each question contribute to the score for one of the three subscales as well as a total score. The three subscales are parental distress, parent-child dysfunctional interaction, and difficult child. Raw scores can be converted into a percentile profile for each subscale and total score. Higher scores are worse and suggest higher levels of stress. The PSI-4-SF has very good internal consistency with a mean Cronbach's alpha of the total scale of 0.95 (subscales range from 0.88 to 0.90).

2.8.5. Parenting Sense of Competence (PSOC)

The PSOC [12,13] asks participants to rate the extent to which they agree or disagree with each of the 17 statements using a six-point scale from strongly disagree to strongly agree. Answers to questions form two subscales: satisfaction (9-items) and efficacy (7-item) with a combined total score that uses the two subscales. One item is not included in the scoring. Higher scores indicate greater sense of parenting competency. The PSOC has acceptable internal consistency of 0.80 for mothers (both satisfaction and efficacy scales) and 0.88 for satisfaction and 0.77 for efficacy for fathers [19]. The six-point scale [12] puts “somewhat disagree” in between “strongly disagree” and “disagree” (and “somewhat agree” in between “agree” and “strongly agree”), which has the potential to raise confusion for study investigators and participants alike.

2.8.6. Level of participation

The post-intervention survey includes a series of questions designed to measure level of participation in the Foundations Course. Participants report how many lessons, readings, and live sessions they engaged with in addition to an overall self-rated level of participation. Platform analytics also allow study staff to export computer usage data to help reflect the types and level of participation for each participant.

2.9. Sample size justification

The power calculation is based on change in inattention as reported in a study on training for children with ADHD [20]. Comparing a change of zero (delayed intervention) to a change of 8.7 points (immediate intervention group), with a common standard deviation of 10.875, a total of 52 participants (26 in each group) are required for 80% power with two-sided alpha of 0.05. Study enrollment will continue throughout the recruitment period, which may result in additional participants being consented and randomized.

2.10. Statistical analyses plan

The primary analyses are changes in the child's inattention and hyperactivity/impulsivity as measured by Conners 3-P(S). For all primary and secondary endpoints, baseline (first survey – all participants) and post-intervention (immediate group) or second baseline (delayed group) scores are compared using paired *t*-tests in each randomized group separately. Changes in scores (second minus first survey) are compared between the two groups using two-sample *t*-tests. Analysis of covariance is used to adjust for baseline scores in a sensitivity analysis. Similarly, any baseline characteristic that is different between the two groups (by chance) is adjusted for in a separate sensitivity analysis. If no significant effect on the primary endpoints is detected, another sensitivity analysis restricts the sample to participants with substantial levels of participation in the NHA Foundations Course. No imputation will be performed for missing data. Conners 3-P(S) and PSI allow only one missing question per subscale. No instructions were found regarding the number of allowable missing questions for scoring PSOC, so complete data are required for that instrument.

Stratified analyses will investigate potential differences in each primary endpoint according to the child's sex (girls, boys), child's age (6, 7, 8 years old), and child's ADHD medication (none, any). Interactions between these variables and the primary endpoints are tested using likelihood ratio tests of nested linear regression models, using change in inattention (or hyperactivity/impulsivity) as the continuous outcome variable.

2.11. Qualitative study measure

One qualitative source is used to provide understanding of the application of the NHA principles, timing of milestones that occur during the Foundations Course, and participant engagement.

2.11.1. Discussion boards

During the intervention, participants use online discussion boards to share success and challenges related to the intervention. This allows for participants to receive feedback and support from NHA Advanced Trainers and other study participants. The Microsoft Excel worksheets are used to document the participant identification number, the week the post was submitted, its relationship to other posts (e.g., initial general comment; response to/from trainer or peer), and the actual text. A coding scheme is developed to look for (1) key words and phrases that reflect application of the NHA elements and (2) if there are key milestones that are evidenced each week. Subsequently, a minimum of two study staff review and code the text.

3. Discussion

This protocol was developed to determine the efficacy of the NHA to reduce ADHD symptoms in children ages six to eight years. If found efficacious, it would provide initial evidence of NHA's ability to reduce ADHD symptoms. Such results might provide options for parents, medical providers, and educational professionals searching for alternatives to medication and/or complimentary treatments with medication.

3.1. Study significance

Parents seek options for ADHD treatment. Reputable associations such as the American Academy of Pediatrics and the American Psychiatric Association identify parenting and/or evidence behavioral interventions as treatment options. This study has the potential to contribute to the evidence-based options for ADHD treatment thereby providing parents and practitioners alternatives.

3.2. Study strengths

The inclusion criteria are a strength. It is important to note that participants do not need to have a clinical diagnosis of ADHD in order to participate, a suspected diagnosis is sufficient. In cases where the child is suspected of having ADHD, but lacks a formal diagnosis, we will ask if another adult has observed ADHD symptoms in the child. Subsequently, all participants are administered the CDC ADHD checklist. Children that meet the CDC ADHD checklist criteria for ADHD may or may not have a diagnosis of ADHD by a health care professional. We selected the CDC ADHD checklist to have a brief and credible measure for determining ADHD.

While it may seem counterintuitive, another strength is the limited timeframe from recruitment to intervention and data analysis. The study funding is for one-year with the goal to determine NHA's efficacy. While this brevity may seem unreasonable, the investigative team modeled the design after other studies that used waitlist control methods. This design has been used in other studies, but this study it is the first to investigate the impact of NHA on ADHD symptoms. Given the brevity of the study, it has the potential to expedite evidence-based outcomes particularly for behavioral interventions.

Finally, the multidisciplinary investigative team is a strength. The team is diverse in its experiences and perspectives, which should result in a robust research methodology implemented in a relatively short period. The team has the content and technical expertise to manage multiple aspects of the study (e.g., approvals, intervention delivery, course platform, data systems/analysis) and test the study hypotheses in a one-year period.

3.3. Implications for future studies

Given the Nurtured Heart Approach has been available for two decades and has a broad reach with individuals trained throughout the United States and in other parts of the world, the protocol provides a step by step guide for future studies.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2018.100312>.

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