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Support for Advanced Scientific Research

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The Eppley Foundation is particularly interested in supporting investigations where federal or other conventional sources of funding are not available. The foundation rarely supports research into diseases for which considerable funds are available, such as cancer, HIV, diabetes and heart disease. We consider the most effective use of our funds to be research-initiation grants.

Today the foundation funds projects in medicine, life sciences and the physical sciences. Particular areas of interest include innovative medical investigations and applications, endangered animals and ecosystems, and climate change. Proposals from newly awarded Ph.Ds and M.Ds rarely meet the foundation's standards for advanced research. We do not make grants to individuals, but only to charitable or educational organizations with nonprofit status. Foreign nationals are supported only when affiliated with a US institution.

The Foundation does not provide operating funds. We prefer to fund a specific project or a specified part of a larger project. In the case of the latter, the Foundation requires assurance that all funds will be in hand at the time the research begins. Similarly, when the Foundation is asked to fund the first year of a multiple-year investigation, all funds must be raised at the time of initiation in order to ensure the work can be sustained until it is completed.

Letters of inquiry may be sent at any time up to March 15th and September 15th. Invited proposals are due April 15 and October 15. This questionnaire is intended to supplement your grant proposal. Your request should include a c.v. for all participating researchers, at least two supporting letters from professionals familiar with the work you are proposing, and an itemized budget. The foundation will pay a maximum of 15 percent overhead to the sponsoring institution; we do not pay overhead for travel or employee benefits. Attach additional pages to this questionnaire if necessary. Visit our web site, above, for more information.

Two printed copies of your grant proposal and all attachments should be sent to the address above and simultaneously email all to Ingrid Eisenstadter at ingrid.e [at] earthlink.net. The e-mailed proposal should be a pdf, preferably with all documents included in a single file.

Name **Bessel van der Kolk, MD** Year degree received **__1970_** Date**__July 1_____**

Address **1269 Beacon Street, Brookline MA** Zip **02446**

Organization name **The Trauma Center at JRI** Your position **Medical Director**

Proposal title **__Neurofeedback to enhance executive functioning in children with histories of severe abuse and neglect: Applying the lessons from neuroscience research**

Duration of proposed research **June 2017- June 2018** Number of current investigations underway, funded **1** unfunded **1**

Percent of time currently spent on research **30**%

Teaching **30**%

Administration **10**%

Other **30**% (**clinical**)

1. If the above ratio will change if your proposal is funded, please explain:

None

2. Describe the significance of what your work will reveal, explaining how it may be used by others in science or industry:

According to the Centers for Disease Control the consequences of child abuse and neglect are thought to be the largest public health issue in the US. The current proposal aims to study whether EEG biofeedback (Neurofeedback – NF) can reverse the well-established brain abnormalities resulting from early abuse and neglect and evaluate it effects on reducing externalizing symptoms that impede a child's ability to successfully engage in the school setting and build relationships.
Potential underlying change mechanisms (executive function, emotion regulation, self-concept, and neuroimaging measures of threat detection, spatial memory and reward anticipation) will also be explored. A further feature of this proposal includes an additional exploratory component of the impact of caregiver NF on youth functioning. This project represents collaboration between experts in the fields of traumatic stress treatment (Dr. van der Kolk) and experts on the effects of environmental and experiential factors on brain development (Dr. Teicher). In addition, the inclusion of NF for primary caregivers will be explored as relevant to child outcomes.

3. Explain how your work overlaps with or relates to work underway elsewhere:

To our knowledge no one has formally studied the effects of neurofeedback on helping abused and neglected children be able to self-regulate, focus and pay attention, though our previous studies have demonstrated that NF is capable of doing so in adults with histories of abuse and neglect.

4. Do you qualify for federal or state funds? Yes **X** No _____ Explain:

The Trauma Center at JRI has 503c status and is qualified to receive state and federal funds.

5. Briefly, when the project for which you are seeking funds is complete, what will be the next phase in your research?

Following the completion of this project, we plan to apply for federal funds from NIH. To be considered for these funds through a new NIMH funding mechanism (RFA-MH-17-604: Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders; R61/R33), we require preliminary data to support the application for a larger randomized control trial. This will allow for the creation of a solid research base and will support our efforts to include NFT for trauma in the National Registry of Evidence-Based Programs and Practices (NREPP), allowing for youth and families to receive insurance reimbursement for NFT for trauma.

6. Your additional comments:

Please see attached document for further details of the proposed study.

Neurofeedback to enhance executive functioning in children with histories of severe abuse and neglect: Applying the lessons from neuroscience research

Statement of Significance

This study proposes to study the effectiveness of an intervention (neurofeedback) to reverse the pervasive long term damage of child abuse and neglect (child maltreatment), that affects over a million children each year in the US. The Centers for Disease Control has identified maltreatment as the costliest public health issue in the US in terms of mental health, lost income, long term medical and drug abuse complications, lost educational attainments, incarceration etc. Early abuse, neglect and abandonment re-organize core neurobiological, perceptual and integrative patterns in the brain that are expressed in difficulties in relationships between oneself and others, as well as in a person's self-regulatory capacities, ability to focus and concentrate, being able to complete a task, and being able to successfully negotiate intimacy and care of children[1].

In the past thirty years neuroimaging studies, including some stemming from the Trauma Center (and from former students who graduated from our program), have shown that terrifying attachment experiences often result in impaired functioning of brain areas devoted to self-reflection (the medial prefrontal cortex), being able to distinguish between what is dangerous from what is safe or pleasurable (the amygdala), the capacity to be aware of the consequences one's actions over time, and the notion that feelings and experiences have a beginning, middle and end (the dorsolateral prefrontal cortex); the capacity to filter out relevant from irrelevant stimuli (the anterior cingulate), as well as having an integrated relationship with the demands, warnings, and comfort of one's bodily sensations (the insula)[2].

The great treatment challenge is to find ways to re-normalize these brain functions, all of which are necessary for having a self that is in a harmonious relation to others, and to be some-body who is in charge of one's actions and emotions. **Neurofeedback** offers the unique potential to specifically target thee brain areas affected by child maltreatment. We are in the process of studying 1) to what degree neurofeedback can change in activity of those brain areas, 2) correlate changes in those brain areas with changes in overall psychological functioning[3].

Tens of thousands of mental health professionals are currently involved in the treatment of this population, but current approaches tend to focus on behavioral control, and none of them address the pervasive neurobiological and cognitive impairment. Last year, children in the US received over $18 billion worth of psychotropic agents; the poorer the child, the more medications were prescribed. Psychotropic agents tend to calm children down but they also interfere with motivation, attention and the capacity to feel pleasurably engaged. Given the magnitude of this public health problem we are in dire need to develop interventions that are 1) cost effective, 2) easily tolerated, and 3) can been applied on a large scale.

Neurofeedback training. At the JRI Trauma Center we now have completed three neurofeedback studies, two of which have been published[4, 5], and one was recently submitted for publication. Our data suggest that NF can produce significant improvement in measures of affect regulation, executive functioning (EF) and PTSD symptoms both in children with histories of severe abuse, and in adults with histories of severe intra-familial abuse[4]. NF training helps individuals acquire self-regulation skills by stabilizing EEG activity, and thereby improve focus and attention[6]. In the proposed study, we will examine the dosage of NF necessary for sustained improvement in affect regulation, EF & PTSD symptoms in abused children, aged 7-12.

In NF training, neural activity is recorded from scalp electrodes and fed back in real time to subjects in a readily understood, visual format (simple computer games). NF is thought to change behavior by changing neuronal connectivity patterns in the central nervous system (CNS) via operant conditioning. NF associated EEG changes have been correlated with changes in various functional outcomes, including cortico-motor excitability, memory, cognition, sleep, and mood, as well as increases in affect regulation and executive function, sustained attention, and working memory[7-9]. Up to now, NF research has focused mainly on performance enhancement and on clinical conditions such as Attention Deficit Hyperactivity Disorder (ADHD)[10-12], depression[13, 14] and

substance abuse[15]. However, the evidence to date remains controversial. In the proposed study, we plan to follow up on our extensive pilot investigations to study whether NF can enhance affect dysregulation and impaired executive functioning in maltreated children, enhance psychosocial outcomes, and lay the groundwork for elucidating mechanisms of action.

Preliminary studies:

1) *Phase 1 of our research program was a pilot study of NF for chronic PTSD[4]* whose primary purpose was to demonstrate the feasibility of NF as an intervention technique. We recruited 17 individuals with chronic PTSD who endorsed an average of 6.59 lifetime traumatic events. 100% had experienced trauma prior to age 18; 15/17 identified childhood physical, sexual, and /or emotional abuse as their index trauma. Participants completed 40 sessions of NF 2x per week. Using standard growth curve modeling, we found significant decreases in PTSD symptoms associated with a medium effect size ($pr^2 = 0.48$) and stronger decreases in affect dysregulation ($pr^2 = 0.65$). Multilevel growth curve analyses showed that NF significantly reduced PTSD symptoms (DTD scores 69.14 to 49.26), and improved affect regulation (Inventory of Altered Self-Capacities (IASC)). The effect size associated with the change from the pre to follow-up assessment indicated a large effect size decrease ($d = -1.01$) with time accounting for 25% of the within subjects variance resulting in an average IASC-AD score of 17.20 at the final assessment.

2) *Phase 2 was a Randomized Control Trial of 52 adults between 18 and 65* with histories of chronic childhood trauma and current PTSD[5]. We randomized participants into two groups: NF (n = 28) and waitlist (WL) (n = 24). Participants had an average of 9.29 (SD = 2.90) different traumatic events, all starting in childhood. There was a significant treatment condition x time interaction (b = -10.45, t = -5.10, p< .001). Both the WL ($d = -.62$) and NF ($d = -2.33$) conditions exhibited significant decreases from the pre-treatment to the second (1 month) post treatment assessment; however, this decrease was substantially larger for the NF condition ($d = -1.71$). The average decrease in CAPS score from the pre-treatment to the 1-month post treatment assessments was 40.35 for the NF condition and 10.78 for the WL group. Mirroring the CAPS severity score findings, a significant treatment condition x time interaction emerged for the DTS ($b = -1.52$, $t = -3.89$, $p< .001$). The NF condition exhibited a large decrease ($d = -1.23$); there was a large effect size difference between WL and NF conditions ($d = -.97$). Four of the IASC subscales (tension reduction activities, affect dysregulation total, affect skill deficits, affect instability) exhibited significant Time x Condition interactions. The effect size for tension reduction activities pre- to the post-treatment was -.75.

3). Phase 3: *NFB versus WL/TAU for children ages 6 - 13* years of age, an ongoing pilot study at the Trauma Center for children who have experienced multiple traumas and exhibit clinically significant emotional and behavioral problems. We analyzed data on 37 subjects (20 NFB; 17 Waitlist / TAU) utilizing multilevel regression to examine decreases in internalizing and externalizing symptoms measured by the CBCL and executive dysfunction as measured by the BRIEF-parent report across four evaluation time points (pre-, mid-, post-treatment and 1-month follow up). Subjects in the NFB group, but not the control group, displayed change over time on the CBCL with a large effect size in the expected direction (internalizing $d = -0.81$; externalizing $d = -0.74$). The same pattern was observed for the two primary subscales of the BRIEF, with subjects in the NFB group exhibiting change over time in the expected direction indicative of a moderate (Metacognition $d = -0.51$) to large (Behavioral Regulation $d = -0.93$). Further, the endpoint assessment showed a significant difference between the treatment groups in terms of clinically significant PTSD symptoms, where the NF group endorsed significantly lower rates of PTSD. However, in one-month follow up, these abused children did not maintain their treatment gains (unlike the adults in the previous NF studies), suggesting that they need a lengthier intervention.

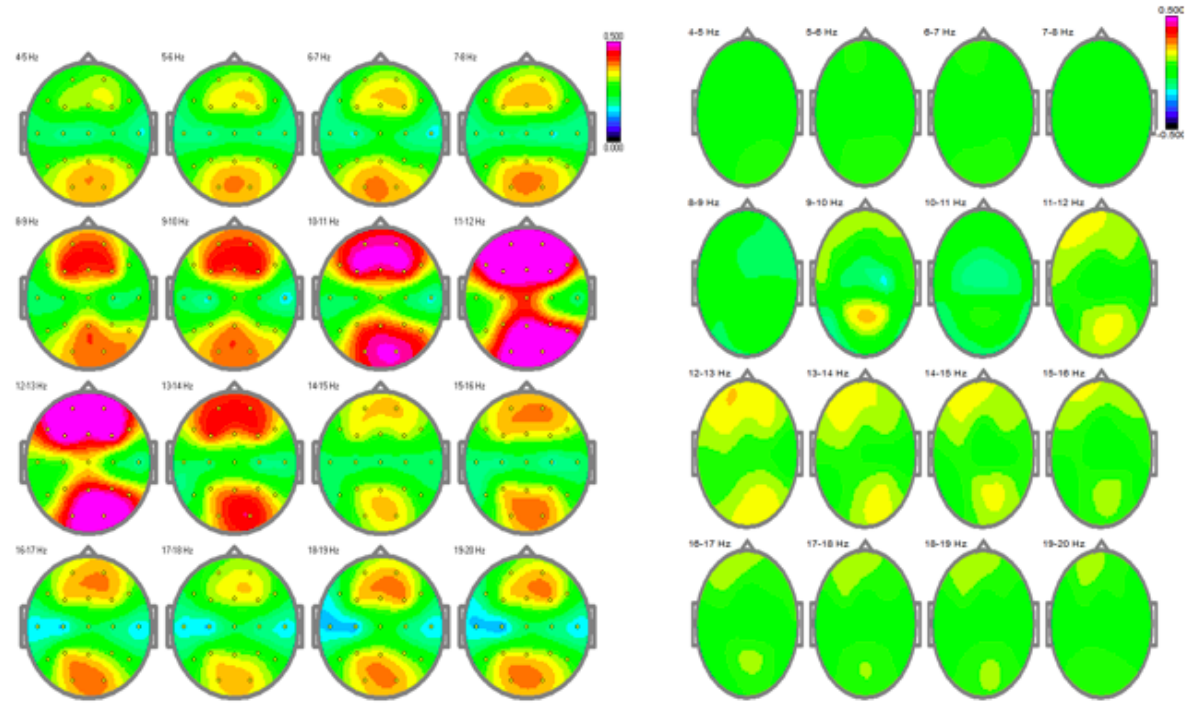
In summary, the NFT has been shown to be effective for adults with histories of trauma exposure, and initial pilot data for children indicates promising results for trauma exposed youth. In the above cited studies, adults receiving NF presented with a significant decrease in PTSD symptoms following their treatment course. Based on these studies and the initial findings of the child neurofeedback study, the logical next step for the research community involves further exploring the impact of the number of NF sessions on youth functioning.

Objectives

The current proposal aims to conduct a pilot study to collect enough data to prepare ourselves for a new funding source through NIMH (RFA-MH-17-604: *Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders; R61/R33)*. The proposed pilot study will be a single arm design in order to 1) evaluate the number of sessions it takes for children with histories of abuse and neglect to maintain improvement in externalizing symptoms that impede a child's ability to successfully engage in the school setting and build relationships. 2) to measure changes in executive function, emotion regulation, self-concept, 3) to collect pilot data of Evoked Response Potentials (ERPs) to explore whether that is an appropriate biological marker of deficits in executive functioning in maltreated children.

All children will receive pre-post quantitative EEGs (qEEGs), and the particular NF protocol will be determined by neural connectivity abnormalities in the qEEG. The following graphic shows an example of qEEG pre and post intervention.

Coherence maps pre and post intervention.



The following aims address the functional improvements that are anticipated:

Aim 1. Test the hypothesis that NFT will lead to clinically significant outcomes in the area of social functioning, executive function, and school engagement / performance.

Aim 2. Test the hypothesis that changes in ERPs will be reliable biomarkers of improvement in executive functioning capacities.

Methods

Participants. The study will include 30 children ages 8 through 12 with a history of developmental trauma (including neglect, emotional, physical and sexual abuse, or medical trauma) and have experienced two or more traumatic experiences .

Inclusion Criteria. Children ages 8 to 12 who meet the following criteria will be considered for the study: (1) the child has been in weekly individual therapy with the same therapist for at least 3 months prior to study commencement; (2) the child has no medication or treatment changes in the past 3 months; and (3) structured assessments indicate clinically significant posttraumatic stress, presented clinically significant symptoms on the Child Behavioral Checklist (CBCL) (internalizing or externalizing scales) or posttraumatic stress symptoms as manifested in pre-determined trauma symptom checklists.

Exclusion Criteria. Children will be excluded from the study if they meet the following exclusion conditions: (1) the child has a history of epilepsy, seizure or head injury, (2) the child had received prior NFT within the past 5 years, (3) the child is currently on benzodiazepine medication, (4) there are ongoing safety concerns at home, the child has had a suicide attempt, serious self harm behavior and psychiatric hospitalization in the past 6 months or (5) children live more than 65 miles from the Trauma Center.

Procedure. The enrollment process will include three steps: (1) initial phone conversation with the caregiver to exclude demographic conditions, (2) phone screening with caregiver, and (3) baseline assessment with the child and his/her caregiver. During the baseline assessment, all caregivers will receive a detailed explanation regarding the study and its course, and be asked to sign an informed consent. Assessments will be conducted at baseline, midpoints (every 10 sessions), endpoint, and at follow up (approximately 10 weeks post study).

The following assessments will be performed in all the assessments: The caregivers will complete CBCL, BRIEF, CAM, CDC and the child will complete the CDI2, PTSD-RI, and NIHToolbox Cognitive Battery. Further, caregivers will be asked to complete measure to assess their overall functioning, including the BSI, PSI, IASC, NIHToolbox, and the TESI. The Baseline assessment also includes PTSD-RI history and child's demographics. During the NFT periods, and after every NFT session, both the children and their caregivers will fill out a self-report NFT Symptom Checklist questionnaire to track the NFT changes. Quantitative EEG or brain mapping will be performed pre and post NFT.

Compensation. All caregivers will receive a compensation of $25 per self-report / psychological screening assessment and $100 per qEEG assessment. The children will receive a gift card for $5 upon completing the study. During the NFT period, the children will receive reinforcement prizes based on their NFT performances.

Measurement tools. The following list includes the measurement tools proposed to assess child functioning:

- *CBCL:* The Child Behavior Checklist is a well-validated questionnaire which assesses emotional and behavioral problems in school-age children[16].
- *BRIEF:* The Behavior Rating Inventory of Executive Function (BRIEF) is a commonly used assessment of executive functions and self-regulation[17].
- *PTSD-RI:* The PTSD Reaction Index (PTSD-RI) is a semi-structured interview that measures a child's trauma history, and determines whether a child's symptoms fulfill the DSM-5's diagnostic criteria for PTSD[18]. PTSD-RI will be completed separately by the caregiver and the child.
- *CAM:* The Children's Alexithymia Measure (CAM) is a measure used to screen children with alexithymia or difficulty in recognizing and expressing one's feelings[19].
- *CDC:* The Child Dissociative Checklist is a questionnaire that measures the presence of dissociative symptoms in children[20].

- *NIH Toolbox Cognitive battery* includes four tests to measure executive function, attention, episodic memory, language, processing speed, and working memory. Both the assessor and the child use computers and keyboards; see [21] for reliability and validity of measure.
- *Caregiver NFT Symptom Checklist:* A self report questionnaire to track the impact of the NFT. The NFT Symptom Checklist was developed at the Trauma Center to address the need to accurately and quantitatively measure the impact of the NFT. It consists of symptoms from the following categories: Attention/focus, Mood, Sleep, Communication/ Connection Energy, Physical symptoms and Individual symptoms.
  Each symptom includes three scales:
  - Intensity: the impact of the symptoms on the child's life. The score is 0--4 where 0 is no impact and 4 has extreme impact.
  - Frequency: how often the child experienced this symptom during the week. The values are 0--4 where 0 is never and 4 is every day.
  - Change: how did the child experienced of this symptom changed compared to the last week. The values are Better, Same, or Worse.
- *Child NFT Symptom Checklist:* A self report checklist that was developed at the Trauma Center to address the need to accurately and quantitatively measure the impact of the NFT.

To assess caregiver functioning, the following tools will be used. Measures will be administered at baseline, 10 weeks, 20 weeks, and follow-up.

- *BSI (Brief Symptom Inventory)* - BSI or Brief Symptom Inventory is an instrument that evaluates psychological distress and psychiatric disorders in people. The test can be used for areas such as patient progress, treatment measurements, and psychological assessment [22] .
- *IASC (Inventory of Altered Self-Capacities)* - The IASC is a self-report measure of an individual's psychological functioning capacity in the areas of forming and maintaining meaningful relationships, creating a stable sense of personal identity and self-awareness, and the ability to modulate and tolerate negative affect. This instrument is particularly useful with adults who have experienced significant childhood abuse or trauma [23].
- *PSI/SF (Parenting Stress Index Short Form)* - The PSI Short Form is a direct derivative of the Parenting Stress Index (PSI) full-length test for parents of children 12 years and younger. The PSI/SF yields a Total Stress score from three scales: Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child [24].
- *NIH Toolbox Cognitive battery* includes four tests to measure executive function, attention, episodic memory, language, processing speed, and working memory. Both the assessor and the child use computers and keyboards. See Weintraub, Dikmen, Heaton, & al., 2013 for reliability and validity of measure.
- *TESI (Traumatic Events Screening Inventory)* – The TESI is an inventory assessing adults' exposure to traumatic event / experiences across the life span.

Treatment groups. As we are proposing a feasibility study, we will focus our research on one treatment group, where we propose to provide children 40 sessions of NFT.

Expectations of Success

Despite 30 years of sustained research support for the PI, previous efforts to receive federal funding for NF have not yet yielded positive results. The research team at the Trauma Center will continue to seek funding from federal sources, but to do so, it is necessary to collect additional pilot data to demonstrate the capacity of NFT to positively affect traumatized youth. The Principal Investigator, Dr. Van der Kolk, has an extensive track record in the development, implementation, fidelity monitoring and dissemination of grant funded randomized control trials for trauma-informed interventions and will be actively involved in all stages of this project.

Potential Impact. Success federal application will require pilot data to present a solid rationale for the proposed research study. However, new mechanism of NIMH (described above) indicates a significant move toward prioritizing research on novel treatment approaches and technologies. Thus, we are seeking to explore and identify data to demonstrate the potential efficacy of NFT for childhood trauma.

We hypothesize that 40 sessions of NFT will result in: a) significant reduction in externalizing behavior problem that are impeding a child's ability to successfully engage in the school and social settings as measured by the CBCL externalizing behavior scored; b) significant reductions in PTSD symptom severity as measured by the PTSD-RI; c) significant reductions in severity of co-morbid symptoms and problems, including depression, alexithymia, anxiety, and anger / aggression; and d) enhanced executive function reflected across three levels of analysis – 1) reductions in severity scores on a parental report, behavioral measure of EF (Behavior Rating Inventory of Executive Function (BRIEF)), 2) improvement on performance based measures of attention, inhibition, cognitive flexibility and working memory as measured by tasks in the Cognition domain of the NIH Toolbox, and 3) changes in ERPs.

Broader Ramifications

There are hundreds of thousands of children in the US who have been exposed to chronic maltreatment. This results in devastating consequences on their capacity to learn, attend to new information, make wise decisions about their lives and deal with interpersonal conflict. We desperately need to find ways of reversing the resulting damage and help them to grow up to be competent individuals who can contribute to the welfare of society at large, rather than be dependent on the government for sustenance and control.

In addition to the research in our Clinic, we have been using neurofeedback in the residential treatment programs affiliated with our parent organization, JRI, to good effect. However, to disseminate this modality, more solid research is needed to prove its efficacy. For example, recently I received a request from the Pine Ridge Indian Reservation in South Dakota to help support them in acquiring funding to start neurofeedback in their system, but we concluded that this would not be a feasible at this point, since they would be unable to support their application with solid evidence as to its efficacy in affected children.

This study is part of a larger effort to collect precisely those data, with the hope that, if proven to be as efficacious as our pilot studies indicate, neurofeedback can become a widely available intervention for traumatized youth-- in schools, and in mental health and in juvenile justice systems, to help traumatized youth to focus, pay attention and grow up as contributing members of society.

Insurance companies will not reimburse for treatment that are not considered "evidence based," i.e., have several studies showing efficacy of treatment approaches for particular target groups. Thus, a goal of this project is to publish manuscripts and data on the effectiveness of NFT for trauma impacted children to ultimately apply to the National Registry of Evidence-Based Programs and Practices (NREPP). This will allow for youth and families of lesser means to have access to effective treatment for trauma.

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YEAR ONE BUDGET

OBJECT CLASS CATEGORIES

A. Personnel

Job Title	Name	Annual Salary	Level of Effort	Salary Requested
Principal Investigator	B. van der Kolk	$150,000	10.0%	$15,000
Project Coordinator	A. Rogel	$ 50,000	50%	$25,000
NFB Technician (1 Part Time)	TBD	$ 40,000	50%	$20,000
Research Assistant, 50% effort	TBN	$ 36,000	50%	$18,000
Personnel Subtotal				**$78,000**

B. Fringe Benefits	34.50%	**$26,910**

C. Travel	**Request**
No Travel costs required for this project	
Subtotal Travel	**$ -**

D. Equipment

Equipment Subtotal

E. Supplies

General Office Supplies	Paper, postage, data storage/protection supplies, etc. ($50/month)	$600
Psychometric Assessments		$996
QEEG Supplies		$1,500
Subtotal Supplies		**$3,096**

F. Construction

No construction costs required for this project.

Construction Subtotal	**$ -**

G. Consultants/Contracts

Consultant Costs: Name/Role	Rate	Days/Year	Total
E. Hamlin: NFB Consultant	$100 / hour x 48 weeks		$ 4,800
			$ 4,800

H. Other Costs	**Total**
Office Rental/Utilities (1 dedicated office, 200 sq ft ea @ $62.5 per sq ft)	$ 12,500

Subject Compensation		$ 10,235
Advertising		$ 4,500
Subtotal Other Costs		**$ 27,235**
		Request
Total Direct Costs		**$ 140,041**
Indirect Costs	9.4% Federal Indirect Rate (Trauma Center)	**Request**
	DHHS	**$ 11,988.82**
		Request
TOTAL COSTS		**$ 152,030**

Subject cost calculation

Total N: Baseline	40
Total N: Mid / Post	30
Total N: Completion	27

	Compensation			Measures		
Timpoint	**Cost Per Eval**	**Total Cost**	**# of Subjects**	**Cost per Eval**	**Total Cost**	**# of Subjects**
Baseline	$25	$1,000	40	$8	$314	40
QEEG 1	$100	$4,000	40			40
Week 10	$25	$750	30	$8	$235	30
QEEG 2	$100	$3,000	30			30
Week 20	$25	$675.00	30	$7.84	$235.20	30
Gift Card	$5	$135.00	30			30
Follow Up	$25	$675	27	$8	$212	27
Total	**$305**	**$10,235**	**227**	**$31**	**$996**	**227**

Evals per week	Eval hours per week
5	14

	# of Subjects	# of Sessions / Evaluations per Year	# of Sessions / Evaluations per Week	Staff Time per week
NFB Child	30	1200	25	12.5
Evaluation	30	120	2.5	5
QEEG	30	60	1.25	3.75
				21.25

	Cost per Administration
Assessment	
CDI	2.2
TSCC	2.8
BRIEF	2.24
CBCL	0.6
CAM	0
CDC	0
PTSD RI	0
	7.84

Budget Justification

Principal Investigator

Dr. Bessel A. van der Kolk (Effort: 1.2 calendar months (CM)) will serve as a Principal Investigator on this project. Dr. van der Kolk has been continuously funded to study various aspects of trauma and its impact on development since 1991. He has published over 100 peer-reviewed articles in this area and is considered one of the preeminent figures in his field. Dr. van der Kolk is also the founder and medical director of the Trauma Center, one of the first clinics devoted solely to treating the sequelae of chronic trauma exposure. Dr. van der Kolk has served as the PI for numerous studies including investigating the efficacy of several treatment approaches including Eye Movement Desensitization and Reprocessing therapy, yoga, neurofeedback and theater programs. Dr. van der Kolk is currently the PI on a RCT examining the efficacy of neurofeedback for maltreated children with emotional and behavioral disorders. Under Dr. van der Kolk's leadership, the Trauma Center has completed all grant funded research projects on-time and within budget. Dr. van der Kolk will hold primary responsibility for the daily operations of the project, including; coordination of training, supervision and fidelity monitoring of neurofeedback, oversight of database development and management, training on study measures and subject recruitment. He will be available to staff in the event that any adverse events arise. He will also be responsible for reviewing data on a weekly basis. Additionally, Dr. van der Kolk will oversee changes in the direction of the research projects and the reprogramming of funds, if necessary. he will also oversee and be directly involved with data analysis and reporting, as well as manuscript preparation.

Research Coordinator

Ainat Rogel (Effort: 6 CM) will serve as the project coordinator. The Project Coordinator, working closely with the PIs, will be primarily responsible for administrating the day-to-day activities of the study. She will manage communications with the Institutional Review Board and assure adherence to all ethical guidelines. She will be responsible for assuring that materials and space are available for assessment sessions, and for scheduling and overseeing the assessors. The Project Coordinator will conduct study assessments and treatment sessions as needed. She will collect data from study participants on a weekly basis and will be responsible for maintaining confidentiality.

Intervention Staff

Neurofeedback Technicians

Two TBN intervention technicians (Effort: 3 CM each) will be employed to conduct NF. Both technicians will undergo a 40 hour NF implementation training program. They will conduct all neurofeedback sessions onsite, review between-session assessment materials, document session activities, attend weekly supervision, and attend research meeting. Each clinician will provide neurofeedback at the Trauma Center.

Research Assistants / Clinical Interviewers

One TBN Research Assistant (Effort: 6 CM) will be employed to conduct study assessments, enter study data and conduct administrative duties for the study. Prior to study onset, RAs will receive training on implementation of measures to be used in this study. The RA will attend weekly research meetings.

NFB Supervisor and Consultant: Dr. Ed Hamlin will serve as the direct clinical supervisor for the NF intervention. Dr. Hamlin is the founder and director of the Institute for Applied Neuroscience and has been a NF practitioner, supervisor, consultant and trainer for over 30 years. Dr. Hamlin will provide primary clinical supervision of the staff clinicians delivering the NF intervention. He will run a weekly supervision with the study clinicians, and will also be involved in decision-making for any adjustments necessary for the treatment protocol. He will review NF technician session fidelity checklists. Clinicians will meet weekly with Dr. Hamlin to go over the specifics of each NF session

and to review individual patient logs, session fidelity checklists, and adjustments to the protocol. Twenty percent of sessions will be randomly selected for review to assure that they match adjustments dictated by the supervisory staff. Dr. Hamlin will also communicate weekly with Dr. van der Kolk to discuss the progress of treatment. Funding is requested for one hour of weekly supervision at the rate of $100/hour for 48 weeks, for a total of $4,800.

***Fringe Rate**
The JRI agency fringe rate, which covers taxes, benefits, vacation time, and insurance, is 34.5%. Thus the funding requested to cover fringe costs total $26,910 FTE.

Equipment
No equipment funds are required for conduct of this project. Our research laboratory already possesses the three neurofeedback systems required for implementation of this project (hardware, software, amplifiers, sensors and monitors).

Travel
No funds are requested for travel.

Supplies
We request funds for the purchase of psychometric instruments; data storage and protection supplies; and consumable project supplies. The majority of psychometric instruments to be used in this study are public access and thus available at no cost. Aside from these, costs for manuals and score sheets are as follows:

- Child Depression Inventory - $2.20 per administration.
- Trauma Symptom Checklist for Children - $2.80 per administration.
- Behavior Rating Inventory of Executive Function - $2.24 per administration.
- Child Behavior Checklist - $.60 per administration.
- Total of $7.84 per subject, per assessment for a total of $996.

In addition to these costs, we are requesting;

- $600 for data storage and protection supplies (locked file cabinets; hard drive backups).
- $1,500 for consumable project supplies (e.g., electrodes, cotton swabs, electrode paste, paper, file folders, etc.).

Subject Compensation
Breakdown of participant compensation is as follows:

	Compensation		
Timpoint	**Cost Per Eval**	**Total Cost**	**# of Subjects**
Baseline	$25	$1,000	40
QEEG 1	$100	$4,000	40
Week 10	$25	$750	30
QEEG 2	$100	$3,000	30
Week 20	$25	$675.00	30
Gift Card	$5	$135.00	30
Follow Up	$25	$675	27
Total	**$305**	**$10,235**	**227**

Thus we are requesting $10,235 in subject compensation costs.

Other Expenses
Recruitment Costs
The majority of recruitment efforts for this study will not entail additional expense aside from Project Coordinator time involved in outreach to the extensive network of social services organizations our Center has cultivated over the past 30+ years, including victim assistance

agencies, local colleges and therapists' offices, local Health Maintenance Organizations, state mental and public health organizations, professional peer support groups, Rape Crisis Centers, mental health centers, private practitioners, and Victim Assistance Programs. However, to ensure sufficient enrollment we have found there to be significant benefit in strategic placement of a series of announcements in local newspapers. Advertising fees associated with this aspect of study recruitment are estimated at $4,500.

Facility Rental

Our agency indirect costs do not cover facility costs (i.e., office rental and utilities). Successful conduct of this project requires that we expand our existing office rental lease to add two small offices (100 square feet each) which will be devoted to administration of study interventions and assessments. The additional cost/year of this office space rental is computed as follows: 200 square feet x $62.5 square/foot 2011 building lease rate + prorated utility costs (office electricity, DSL, telephone, cleaning, maintenance) =$12,500/year.

Indirect Costs

The JRI federally-established indirect rate is used to cover administrative costs associated with human resources and administration. The indirect rate does not include facility rental. Our federal DHHS indirect rate is 9.4%, which amounts to $11,989**.**

Biographical Sketch: Bessel van der Kolk

BIOGRAPHICAL SKETCH			
NAME Bessel A. Van der Kolk	POSITION TITLE Medical Director, Trauma Center Principal Investigator		
eRA COMMONS USER NAME Vanderkolk			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as			
INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
University of Hawaii	B.A.	1965	Pre-med/ Polit Sc.
University of Chicago, Pritzker School of Medicine	M.D.	1970	Medicine
Queen's Medical Center, Honolulu, Hawaii		1970-1971	Medical Intern
Massachusetts Mental Health Center/Harvard		1971-1974	Psychiatry

A. Personal Statement

I have spent my career studying how children and adults adapt to traumatic experiences, and have tried to translate emerging findings from pharmacology, neuroscience and attachment research to develop and study potentially effective treatments for traumatic stress in children and adults. In 1984 I set up one of the first clinical/research centers in the US dedicated to study and treatment of traumatic stress in civilian populations, which has trained numerous researchers and clinicians specializing in the study and treatment of traumatic stress, and which has been continually funded to research the impact of traumatic stress and effective treatment interventions. I did the first studies on the effects of SSRIs on PTSD; was a member of the first neuroimaging team to investigate how trauma changes brain processes, and did the first research linking BPD and deliberate self-injury to trauma and neglect in early childhood. Much of my research has focused on how trauma has a different impact at different stages of development, and that disruptions in care-giving systems have additional deleterious effects that need to be addressed for effective intervention. In order to promote a deeper understanding of the impact of childhood trauma and to foster the development and execution of effective treatment interventions I initiated the process that led to the establishment of the National Child Traumatic Stress Network (NCTSN), a Congressionally mandated initiative that now funds approximately 150 centers specializing in developing effective treatment interventions, and implementing them in a wide array of settings, from juvenile detention centers to tribal agencies, nationwide. Based on data on 20,000 children followed within the Network we proposed to include a diagnosis Developmental Trauma Disorder within the DSM5. While that effort failed, we continue to systematically study the differential adaptation to trauma in children, in the expectation that this will eventually lead to a more precise diagnostic system that incorporates the effects of early experience on RDoC-related neurocircuits, and provide more precise targets for intervention. Following in the footsteps of Abram Kardiner who called traumatic stress a "physioneurosis" I have focused on studying treatments that stabilize physiology, increase executive functioning and help traumatized individuals to feel fully alert to the present. This has included an NIMH funded study on EMDR and NCCAM funded study of yoga, and, in recent years, the study of neurofeedback to investigate whether attentional and perceptual systems (and the neural tracks responsible for them) can be altered by changing EEG patterns. Having an well-trained clinical team that specializes in the treatment of children and adults with histories of child maltreatment, a treatment model that already is widely taught and implemented nationwide, a research lab that studies the effects of neurofeedback on behavior, mood, and executive functioning, and numerous training opportunities nationwide to a variety of mental health professional, educators, parent groups, policy makers, and law enforcement personnel, puts us in an excellent position to lead the treatment and dissemination parts of this effort.

B. Positions and Honors

Positions and Employment

1982-2000	Founder and Director, Trauma Center
1992-1997	Associate Professor of Psychiatry, Harvard Medical School
1997-1999	Professor, Harvard University Graduate School of Education
1996-	Professor of Psychiatry, Boston University School of Medicine
2000-	Research and Medical Director, Trauma Center
2008-	Vice President of Research, Justice Resource Institute
2012-	Co-Director, Complex Trauma Treatment Network, National Child Traumatic Stress Network

Honors (Sample)

1984, 1988, 1989 1st prize, Solomon Award, Harvard Dept of Psychiatry 1990-91; President, International Society for Traumatic Stress Studies; 1994 Eli Lilly Lecturer, Royal College of Psychiatrists, London; 1996 Cohen Chair in Child Mental Health, NY Jewish Board of Family and Children's Services; 1998 Lifetime Achievement Award, International Society for Traumatic Stress Studies ; 1999 Benjamin Rush Award, American Psychiatric Association; 2001 Ben Wiesel Visiting professor, Institute for Living, Hartford. CT; 2001 Visiting professor, University of Salamanca, Spain 2002; Distinguished Life Fellow, American Psychiatric Association; 2006 Bowlby Memorial Lecture, University of London; 2006 Richard Lederman Lecturer. Performing Medicine Association Aspen CO; 2008 McNamee visiting professor Dartmouth University 2013 Reiss Davis distinguished professor, Los Angeles, 2014 Visiting professor, Center for Consciousness Science, University of Virginia; 2013 Visiting professor, University of Bahia, Brazil, 2014 Keynote, International Society for the prevention of child abuse, Nagoya. Japan; 2016 Wallerstein Lecturer UCSF, Keynote, Royal College of Psychiatry, London.

C. Contributions to science (from 150 peer reviewed publications)

A. Basic mental and biological parameters of PTSD. Since PTSD was just becoming a DSM diagnosis as I started my career I began investigating basic processes involved in traumatic stress, including the nature of nightmares in PTSD, as well as basic mental and biological processes, including the first biological model of PTSD, and the first neuroimaging studies of PTSD and Dissociative Disorders, and the first study to confirm immunological abnormalities related to childhood trauma:

Van der Kolk BA, Blitz R, Burr WA, Hartmann E (1984). Nightmares and trauma: Life-long and traumatic
nightmares in veterans. Am J Psychiatry 1984;141:187-190.

Van der Kolk, BA & Ducey, CP (1989). The psychological processing of traumatic experience: Rorschach patterns in PTSD. *Journal of Traumatic Stress*, *2*(3), 259-274.

Van der Kolk BA, Greenberg M, Boyd H, Krystal J (1985): Inescapable shock, neurotransmitters, and addiction to trauma: toward a psychobiology of post traumatic stress. Biol Psychiatry 20:314-325 *(the first published biological model for PTSD)*

Van der Kolk BA, (1985) Adolescent vulnerability to post traumatic stress. Psychiatry, 48: 365-370. *(one of the first studies to elucidate the role of committing atrocities, "moral injury", for developing PTSD).*

Van der Kolk BA, Greenberg MS, Orr S, Pitman RK (1989): Pain Perception and endogenous opioids in Post Traumatic Stress Disorder. Psychopharm Bull 25: 117-121.

Pitman RK, **Van der Kolk BA**, Orr S, Greenberg MS (1990): Naloxone reversible Stress Induced Analgesia In Post Traumatic Stress Disorder. Arch Gen Psychiat. 47:541-547,.

Rauch S, **Van der Kolk BA**, Fisler R, Alpert N, Orr S, Savage C, Jenike M, Pitman R (1996): A symptom provocation study using Positron Emission Tomography and Script Driven

Imagery. Arch Gen Psychiatry, 53, 380-387. (*the first PET study of PTSD*)

Saxe GN, Vasile RG, Hill TC, Bloomingdale K, **Van der Kolk BA** (1992): Temporal lobe changes in Multiple Personality Disorders demonstrated by rCBF and SPECT imaging. J Ment Nerv Dis, 1992. *(the first neuroimaging study of dissociative disorders)*

Wilson, S N; **Van der Kolk, B A**; Burbridge, JA; Fisler, R E; Kradin, R (1999). Phenotype of blood lymphocytes in PTSD suggests chronic immune activation. Psychosomatics, 40, 222-225.

Hopper JW, Spinazzola J, Simpson WE, **Van der Kolk BA. (**2006). Preliminary Evidence of parasympathetic influence on the basal heart rate in posttraumatic stress disorder. J Psychosom Res 60: 83-90.

Hopper, JW; Frewen, PA; **Van der Kolk, BA;** Lanius, RA (2007). Neural correlates of reexperiencing, avoidance, and dissociation in PTSD: symptom dimensions and emotion dysregulation in response to script-driven trauma imagery. J. Traum. Stress. 20, 5, 713-725,.

B. Psychopharmacology. With the promise of psychopharmacology to be a potential solution to PTSD I was the PI/co-PI of the first two teams to study the capacity of fluoxetine and sertraline, respectively, to ameliorate PTSD symptomatology:

Van der Kolk BA, Dreyfuss D, Berkowitz R, Saxe G, Shera D & Michaels M (1994): Fluoxetine in Post Traumatic Stress. J Clin Psychiat, 517-522.

Davidson, J.R., Rothbaum, B.O., **van der Kolk, B.A**., Sikes, C.R. and Farfel, G.M., (2001). Multicenter, double-blind comparison of sertraline and placebo in the treatment of posttraumatic stress disorder. *Archives of General Psychiatry*, *58*(5), pp.485-492.

C. Memory. Our studies of traumatized populations inevitably confronted us with the central issue of memory in traumatic stress – whether conscious (verbal) memory of the event(s) may be absent; the physiological arousal (and dissociation) in response to traumatic reminders, and the unusual fragmentary and sensory nature that accompanies recall of traumatic events:

Van der Kolk BA, Van der Hart O (1989): Pierre Janet and the breakdown of adaptation in Psychological Trauma. Am J Psychiat, 146:1330- 1342.

Van der Kolk, BA (1994): The Body keeps the Score: Memory and the evolving Psychobiology of Post Traumatic Stress. Harvard Review of Psychiatry 1; 253-65.

Van der Kolk BA, Fisler R (1995): Dissociation and the fragmentary nature of traumatic memories: background and experimental evidence. J Traumatic Stress, 9, 505-525.

Osterman JE, Hopper J, Heran, WJ, Keane TM, **Van der Kolk BA** (2001). Awareness under anesthesia and the development of posttraumatic stress disorder, Gen Hosp Psychiatry, 23 (4): 198-204.

Hopper J. W. **Van der Kolk B**. (2001): Retrieving and Assessing traumatic Memories. Exploring the nature of traumatic memory, Journal of Aggression, Maltreatment, and Trauma, 4: 33-71.

D. The pervasive role of trauma in psychiatric disorders. As some of the psychological and biological parameters of traumatic stress were getting elucidated, my colleagues and I became curious about the potential role that childhood trauma plays in various psychiatric disorders, including:

Beck J, **Van der Kolk BA**: Reports of Childhood Incest and Current Behavior of Chronically Hospitalized Psychotic women. Am J Psychiatry 144:1474-1476,1987.

Herman JL, Perry JC, Van der Kolk BA (1989): Childhood Trauma in Borderline Personality Disorder . Am J Psychiat 146: 490-495.

Van der Kolk BA, Perry JC Herman JL (1991): Childhood origins of self- destructive behavior. Am J Psychiat 148: 1665-1671,

Moleman N, Van der Hart O, **Van der Kolk BA** (1992): The Partus Stress Reaction: a

neglected aspect of post partum psychopathology. J Nerv Ment Diseases, 180 271-272.

Saxe G, **Van der Kolk BA**, Chinman G, Berkowitz R: Dissociative Disorders in the Mental Hospital. (1993) Am J Psychiatry; 150: 1037-1042.

Herzog DB, Staley JE, Carmody S, Robbins WM, **Van der Kolk BA** (1993**)**: Childhood sexual abuse in anorexia nervosa and bulemia nervosa. J Am Acad Child Adolsec Psychiat; 32. (5): 962-966

E. Complex PTSD, Disorders of Extreme Stress, and Developmental Trauma

Our studies of psychiatric populations paved the way to study the differential impact of traumatic experiences depending on stage of development and relationship to the perpetrator. Much of this work was done in my role as the co-PI of the DSM IV Field Trials for PTSD.

Van der Kolk, BA, Pelcovitz D, Roth S, Mandel F, McFarlane AC, Herman, J (1996): Dissociation, somatization and affect dysregulation: the complexity of adaptation to trauma. Am J Psychiat 153: 83-93.

Roth SH, Newman E, Pelcovitz D, Mandel FS, **Van der Kolk BA**. 1997. Complex PTSD in victims exposed to sexual and physical abuse: results from the DSM IV Field Trial for Post Traumatic Stress Disorder. J Trauma Stress 10(4): 539-555.

Van der Kolk BA. (2005). Developmental Trauma Disorder: toward a rational diagnosis for children with complex trauma histories. Psychiatric Annals 35: 401-408,.

Van der Kolk, BA, Roth S, Pelcovitz D, Sunday S, Spinazzola J. (2005). Disorders of Extreme Stress: The Empirical Foundation of a complex adaptation to Trauma. J Trauma Stress 18 (5) 389-399.

Spinazzola J, Blaustein ME, **Van der Kolk BA.** 2005. Posttraumatic Stress Disorder Treatment Outcome Research: The Study of unrepresentative samples? J trauma Stress 18; 425-436.

D'Andrea, W., Ford, J., Stolbach, B., Spinazzola, J. **Van der Kolk, B. A** (2012). Understanding Interpersonal Trauma in Children: Why We Need a Developmentally Appropriate Trauma Diagnosis. Am J Orthopsychiatry, 82: 187–200,

Ford JD, Grasso, D Greene, C; Levine J; Spinazzola J; **Van der Kolk, BA** (2013) Clinical Significance of a Proposed Developmental Trauma Disorder Diagnosis: Results of an International Survey of Clinicians J Clin Psychiatry 74(8), 841–849, 2013.

We recently submitted three more empirical papers on this subject, data from a multi-site study involving over 300 children and adolescents.

F. Innovative treatments. As we became more aware of the profound neurobiological dysregulation produced by childhood trauma and saw the limited capacities of cognitive behavioral or drug treatments to produce substantial alterations in children and adults with histories of severe abuse and neglect we became intrigued with the potential of non-traditional methods to change the imprint of traumatic memories, and the pervasive physiological dysregulation and sensory integration problems.

Levin P, Lazrove S & **Van der Kolk BA** (1999): What psychological testing and neuroimaging tell us
about the treatment of PTSD by EMDR. J Anxiety Disorders. 13,159-172

Van der Kolk BA, Spinazzola J, Blaustein ME, Hopper JW, Hopper EK, Korn DL, Simpson WB. A Randomized clinical Trial of Eye Movement Desensitization and reprocessing (EMDR), Fluoxetine, and Pill Placebo in the Treatment of Post Traumatic Stress Disorder: treatment Effects and Long-term maintenance (2007). J Clin Psychiat 66 (1), 37-45.

Zucker, M., Spinazzola, J., Pollack, A. A., Pepe, L., Barry, S., Zhang, L., & **Van der Kolk, B.** (2010). Getting Teachers in on the Act: Evaluation of a Theater-and Classroom-Based Youth Violence Prevention Program. *Journal of School Violence*, *9*(2), 117-135.

Van der Kolk BA, Stone L, West J Rhodes A, Emerson D, Spinazzola J (2014): Yoga as an adjunctive treatment for posttraumatic stress disorder: a randomized controlled trial. J Clin Psychiatry 75(6):e559-65.

Gapen, M., **van der Kolk, B. A**., Hamlin, E., Hirshberg, L., Suvak, M., & Spinazzola, J. (2016). A pilot study of neurofeedback for chronic PTSD. *Applied psychophysiology and biofeedback*, *41*(3), 251-261.

van der Kolk, B. A., Hodgdon, H., Gapen, M., Musicaro, R., Suvak, M. K., Hamlin, E., & Spinazzola, J. (2016). A Randomized Controlled Study of Neurofeedback for Chronic PTSD. *PloS one*, *11*(12), e0166752.

Van der Kolk BA: The body keeps the score: brain, mind and body in the healing from trauma. Viking Press, 2014.

Over the past few years much of my efforts have gone into writing this book about what we have learned about traumatic stress, including childhood abuse and neglect, and its treatment. It has been the best selling book in psychiatry for the past year and a half, and a New York Times Science bestseller.

D. Research Support

Current Research Support

Van der Kolk (91) 7/1/14-current Role: PI (10% FTE)
Pilot study examining the impact of neurofeedback on children 6-13 with histories of severe maltreatment, Multiple private funders

Past Research Support

Affective Neuroscience Foundation
Van der Kolk (91) 1/1/11-7/1/14 Role: PI (20% FTE)
RTC on the capacity of neurofeedback on decreasing PTSD symptomatology and increase executive functioning in adults and adolescents with chronic histories of child maltreatment.

ANS Foundation Van der Kolk (91) 1/1/09-12/31/12 Role: PI (10% FTE)
Pilot study examining the impact of neurofeedback on adults and adolescents with chronic post-trauma dysreguliaton.

1R21AT003905-01A2 Van der Kolk (PI) 6/1/08-5/31/12 Role: PI (10% FTE)
Efficacy of Yoga for Treatment-Resistant PTSD, a randomized control trial of yoga versus attentional control for the treatment of chronic treatment-resistant PTSD. Outcome measures include behavioral and psychophyisological assessment.

1U79SM059314-01 Van der Kolk (Co-Director) 9/30/09-9/29/12 Role: PI (30% FTE)
Complex Trauma Treatment Network, a SAMHSA NCTSN Category II Training and Technical Assistance grant to provide intensive training and support to communities across the country on the assessment and treatment of child complex traumatic stress.

CDC 1 R49 CE000968-01 Van der Kolk (PI) 09/01/06-08/31/09 Role: PI (10% FTE)
RCT of Urban Improv-Intensive, A Youth Violence Prevention Program. Aims were to evaluate the effectiveness of a trauma-informed, improvisational theater-based tertiary prevention/intervention program in reducing engagement in and future exposure to interpersonal violence, including sexual violence, in urban middle-school youth cohorts at high risk of prior exposure to trauma and violence.

5 R01 MH58363-04 Van der Kolk (PI) 12/01/1999-12/31/2003 Role: PI; NIH/NIMH
Treatment Outcome of Fluoxetine vs. EMDR in PTSD.
The goal of this study was to evaluate the relative efficacy of a psychotherapy targeting traumatic memories with an SSRI in symptom reduction of Posttraumatic Stress Disorder and related conditions.

97-MU-FX-K012, 05-S40 Van der Kolk (PI) 12/05/2001–09/30/2005 Role: PI; OJJDP
Hamilton Fish Youth Violence Prevention Consortium Grant
Hamilton Fish Institute, George Washington University
This goal of this study was to evaluate using controlled outcome design youth violence prevention programs for high-risk urban elementary and middle-school students.