The Psychology of Adopting Medical Device Innovations in Mental Healthcare: The Case of Neurofeedback in the United States and the Netherlands

Mark Trullinger

A Dissertation Submitted to the Faculty of The Chicago School of Professional Psychology In Partial Fulfillment of the Requirements For the Degree of Doctor of Philosophy in Psychology

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Mark Trullinger

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Approved By:

Dr. Priscilla Dass-Brailsford, PhD, Chairperson Department Chair, The Chicago School of Professional Psychology

Dr. Gerrit Dielissen, PhD, Member Assistant Professor, The Chicago School of Professional Psychology

Dr. H. Edmund Pigott, PhD, Member Private Practice



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I am grateful to Dr. Snyder for permission to use his *Self-Monitoring Scale* (Snyder, 1974).

The letter of permission is included as Appendix A.



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#### Abstract

Barriers to the acceptance of a medical device innovation, electroencephalogram neurofeedback (EEG-NFB) for the treatment of ADHD in children, were investigated with a mixed-method embedded design utilizing the theoretical frameworks of Latour and Rogers. Within Latour's framework EEG–NFB is a technological innovation that is part of a larger paradigm shift occurring in medical healthcare treatment. Healthcare professionals act as gatekeepers to medical innovation within Roger's framework. Eighteen U.S. and Dutch healthcare professionals, who commonly diagnose and treat children with ADHD, participated in the study. No significant differences were present between the U.S. and Dutch healthcare professionals. The main barrier identified was awareness about EEG–NFB as a treatment for ADHD in children. Technical knowledge about how to conduct, refer patients for, and evaluate progress in EEG–NFB was another major barrier. One of the recommendations to increase adoption is to initiate marketing campaigns focused on increasing awareness among healthcare professionals. Another recommendation is affordable or free continuing education courses for healthcare professionals targeted toward how to speak to a patient about the proposed mechanism of action for EEG–NFB, find a provider to refer to, and evaluate a patient's progress during a course of EEG–NFB treatments.



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#### Chapter 1: Nature of the Study

This study examines the decision-making processes of mental health professionals as they select referrals for their child patients who suffer from ADHD. With a focus on one specific innovative medical device, electroencephalogram–neurofeedback training (EEG–NFB), this study aims to understand how and why mental health professionals sometimes resist cutting-edge treatments that could potentially benefit children with ADHD. Reasons for this resistance vary. At the clinical level, one major reason for practitioner resistance to innovation is self-monitoring because the practice of medicine tends to be conservative in accepting new medical innovations (Forman, 1981). Moreover, high self-monitors conform to the social group's thoughts rather than focus on their own thoughts and beliefs. This investigation takes place within the framework of social constructivism (Latour, 1990). Hopefully, insights into practitioners' decision-making processes will facilitate a process of change in which devices such as the EEG– NFB become more widely accepted.

#### **Purpose of the Study**

The purpose of this study was to investigate the barriers in the acceptance of a specific medical device innovation, EEG–NFB, as a treatment for ADHD in children. This study's focus was to investigate the impact of the treatment referral decision-making process of healthcare professionals who act as gatekeepers to medical innovation. Understanding these barriers may have the potential to facilitate a process in which the medical and mental health fields more readily accept innovative medical devices and treatments, both for ADHD in children and in general.



#### Background

Mental health patients have benefited from the development of new and innovative medical devices and treatments (Bergsland, Elle, & Fosse, 2014). However, the development and diffusion of medical devices and treatments into common medical practice has been markedly slower than other medical products due to innovation barriers (Bergsland et al., 2014). Despite the rapid progress in medical discoveries over the last few decades, the medical field is categorically conservative and favors the status quo (Forman, 1981).

#### **Medical Paradigms and Innovation**

The biomedical model, a paradigm of human health that examines physical well-being while ignoring subjective psychological elements, has dominated the medical field since the middle of the nineteenth century. As a result of this outlook, therapeutic endeavors have utilized a biomedical approach, relying on physical interventions such as drug therapy in the management of diseases. Although they are ubiquitous today, at one time, antibiotics were extremely innovative. Fortunately, the spirit of innovation within the medical field persists. As Rogers (2010) discussed, cancer used to be viewed as a serious ailment, and the best professionals could do was predict the number of possible years of survival. Today, it is possible to discuss a cure for a growing number of cancers (Rogers, 2010). However, innovations do not only occur in the realm of physical disease. In addition, important innovations have also been occurring with the use of medical devices as healthcare treatments (Bergsland et al., 2014).

In addition to advancements in drugs, medical innovation has also taken place within the domain of surgery (Rogers, 2010). Surgical practice now includes the use of medical devices such as lasers, robotics, and imaging technology. In fact, medical devices and the application of medical technologies into treatment tools provide some of the greatest opportunities for



innovation (Bergsland et al., 2014). This represents a shift away from the current biomedical, drug-based paradigm of medicine toward one that embraces technological advancements (Fuchs, 2010).

This paradigm shift in healthcare requires medical, social, psychological, and biological innovations to merge into a collaborative system (Fuchs & Sox, 2001). However, in the biomedical model, these components are viewed and treated as independent of each other (Fuchs & Sox, 2001). Engel's (1980) biopsychosocial model for healthcare is an early example of the healthcare paradigm shift and focuses on the interaction of biological, psychological, and social factors. The biopsychosocial model is extremely important for understanding and treating disorders such as ADHD because, unlike the biomedical model, it utilizes a holistic view that does not discount factors that may impact the patient merely because they are not physical. The biopsychosocial model is an important paradigm for mental health professionals to adopt so that they can present the largest number of treatment options to their patients. It is in its infancy, but U.S. and European medical schools have begun to teach the biopsychosocial model (Jaini & Lee, 2015).

Although the biopsychosocial model and medical device innovation are gaining acceptance in some disciplines of physical medicine, the innovation in medical devices for mental health treatment seems to be adopted more slowly and plagued by more barriers. The barriers are present because medical device innovations transition away from traditional mental healthcare practice, which relies solely on conscious interaction and conversation (American Federation of Labor and Congress of Industrial Organizations, 2014). The electroencephalogram (EEG) is an example of a medical device innovation in mental healthcare. It measures real-time



electrical activity of brain function to identify varying explanations for identical behavioral profiles within mental health disorders (Johnstone, Gunkelman, & Lunt, 2005; Kropotov, 2010).

#### **EEG–NFB for ADHD**

EEG–NFB is both an innovative mental health treatment and a medical device. EEG– NFB meets the requirements for an innovative medical device (Bergsland et al., 2014; Latour, 1990) because the EEG provides information about human beings that was previously not observable prior to the advent of EEG (Evans & Abarbanel, 1999). Further, the EEG uses sensor electrodes connected to amplifiers to record the brain's electrical activity in real time at 256 times a second or more, which makes it a medical device. EEG–NFB also continues to evolve along with advances in modern computing power, which allows exponentially more real-time quantitative understanding of EEG than ever before (Budzynski, Budzynski, Evans, & Abarbanel, 2009; Hammond, 2011) and the seamless integration of complex behavioral training paradigms (Collura, 2014). The current advancements are leading to more specific treatment protocols for specific mental health conditions (Budzynski et al., 2009; Evans & Abarbanel, 1999).

For diagnostic purposes, quantitative analysis of the EEG is commonly used to assist in diagnosing dementia with common insurance reimbursement for this purpose in the US, and one specific EEG measure is U.S. Food and Drug Administration (FDA) approved for assisting to diagnose ADHD (FDA, 2013). The quantitative EEG also has other diagnostic and treatment planning uses in mental health. They have been used to guide mental health prescribing for over twenty years, with data from many studies by the Psychiatric Electroencephalography Evaluation Registry suggesting as high as 86% accuracy at predicting the most effective medication and dosage (MYndAnalytics, 2016).



EEG–NFB is the application of behavioral training to alter the EEG quantitatively and has been used as a treatment for ADHD in children since the 1970s (Lubar & Shouse, 1976). Its usefulness as a treatment for children diagnosed with ADHD has substantial evidential support from numerous randomized controlled trials (Arns, Heinrich, & Strehl, 2014; Pigott, Bodenhamer-Davis, Davis, & Harbin, 2013; Van Doren, Arns, Heinrich, Stehl, & Loo, 2018). Over 9,000 publications are devoted to various aspects of EEG–NFB (Rogala et al., 2016), with the strongest evidence and most prevalent clinical use in the treatment of ADHD in children (Hammond, 2011; Pigott et al., 2013). A National Institutes of Health-funded randomized double-blind placebo controlled trial is well underway. It is called The International Collaborative ADHD Neurofeedback Study and is being conducted at Ohio State University, yet it is facing an evidentiary bias with insurance reimbursement (Pigott et al., 2013).

The United States and the Netherlands have the highest levels of development and research of EEG–NFB in the treatment of ADHD in children (van Dongen-Boomsma, 2014). They have the highest number of board-certified neurofeedback practitioners (Biofeedback Certification International Alliance, 2016). Moreover, the US and the Netherlands have clearly defined medical governance types (Giarelli, 2010). All of these factors make the two nations ideal for study. They are both critical cases for comparison in the adoption of EEG–NFB for the treatment of ADHD in children. The U.S. healthcare governance is a private healthcare system, which means that the markets dominated the dimensions of regulation, financing, and provision (Böhm, Schmid, Götzeb, Landwehr, & Rothgang, 2013). The Netherlands has an etatist social health insurance system with regulation being dominated by state actors, financing being dominated by society actors, and provision being dominated by private actors (Böhm et al., 2013).



Similar to the United States, the Netherlands has many insurance companies (Daley & Gubb, 2011; Schäfer et al., 2009). However, mandates exist requiring all citizens and residents to purchase health insurance to cover certain items. It should be noted that in the United States, the Affordable Care Act will be shifting to a model that mimics the system in the Netherlands (Harrah, 2014). The Affordable Care Act may yet be replaced without being fully implemented. Even so, the shifts that would be expected from the Affordable Care Act will take up to 10 years from its inception to have a significant impact (Aaron, 2015).

EEG–NFB has a significant presence in both the United States and the Netherlands even though it is not yet a standard recommendation for treating children with ADHD (Pigott et al., 2013). The evidential support contains numerous randomized control trials and meta-analyses. The U.S. Centers for Disease Control (CDC, 2015) considers EEG–NFB a possible alternative treatment in ADHD children who are unresponsive to medication. Moreover, EEG–NFB in the treatment of ADHD in children has fewer side effects than drug therapies such as stimulants or selective norepinephrine reuptake inhibitors (Pigott et al., 2013). However, only 1.5% of children with ADHD are currently receiving EEG–NFB, and only 11% receive treatment with EEG–NFB during their lifetime (Danielson, Visser, Chronis-Tuscano, & DuPaul, 2018).

The most common reason cited to deny insurance reimbursement for EEG–NFB to treat ADHD in children is a claim that the confirmatory research to prove that it is not experimental or investigational does not exist. The positive research is often downplayed because of concerns about methodological flaws in some randomized control trials (van Dongen-Boomsma, 2014). However, the standard being used to make that claim is much stricter than in medicine as a whole (Hammond, 2011; Pigott et al., 2013). In conclusion, EEG–NFB as a treatment for children with ADHD is not as well accepted in the United States and the Netherlands as it should



be, which makes it ideal for studying the barriers to medical device innovation in mental healthcare.

#### **Barriers to Medical Innovation**

The lack of acceptance of innovation in medical device technology is a problem within the healthcare systems around the world (Bergsland et al., 2014). It is partly because medical device innovation often represents a paradigm shift in treatment protocols (Walshe & Rundall, 2001). The initial cost of its adoption is a common reason for not innovating, but most often, these medical devices lead to a lower cost over the long-term by as much as 33% per procedure ("Medical Innovation," 2013). An example is lack of acceptance of EEG–NFB as a treatment for ADHD in children in the United States and the Netherlands. The cost of EEG–NFB for children with ADHD ranges from \$3,000 to \$4,500 (Pigott et al., 2013) over a few months with posted prices from a Google Internet search showing up to or slightly beyond \$6,000 from some providers. Whereas the cost of treatment with medication and psychotherapy for a person with ADHD often exceeds \$6,000 a year (Pigott et al, 2013) and the CDC (2015) website estimates the costs to be beyond \$14,000 a year on average during the first few years.

Despite the fact that EEG–NFB has a lower cost per patient over the course of a lifetime with fewer side effects than even medication because it does not involve continued treatment (Pigott et al., 2013), it is classified as underadoption within the four types of outcomes for medical innovation (Denis, Hébert, Langley, Lozeau, & Trottier, 2002). Underadoption occurs when a medical innovation is being slowly adopted despite leading evidence. Success is when leading evidence causes it to be rapidly adopted, and overadoption occurs when evidence is lagging to support the rapid adoption. Finally, prudence occurs when lagging evidence and slow adoption occurs (Denis et al., 2002).



The United States and the Netherlands are near the top in the acceptance of new assessments and interventions based on medical device innovation (Holden & Karsh, 2010), which makes their lack of rapid adoption of EEG–NFB as a treatment for ADHD in children even more baffling. In addition, both countries started transitioning toward evidence-based interventions 15 years ago (Plsek, 2003), which favors evidence over the opinion of medical practitioners. The severity of the lack of integration of neurofeedback into healthcare treatment protocols for treating children with ADHD is probably best described by Harvard Medical School professor and pediatric neurologist Duffy (2000). He wrote, "In my opinion, if any medication demonstrated such a wide spectrum of efficacy it would be universally accepted and widely used" (p. v). Some have gone further to suggest the possibility of an antineurofeedback conspiracy (Trocki, 2006). Duffy's opinion was published 17 years ago; Trocki's was published more than 10 years ago. The peer-reviewed research and evidential support for EEG–NFB as a treatment for ADHD in children has only strengthened (Van Doren et al., 2018).

The *Medical Innovation in the Changing Healthcare Marketplace: Conference Summary* highlighted three main categories of social structural barriers to medical innovation: technical, policy, and economic (Institute of Medicine and National Research Council, 2002). These barriers can be linked and discussed as a paradigm shift within Latour's (1990) article, "Technology Is Society Made Durable." Organizational literature in medical innovation contains models that highlight the impact of the researcher's and practitioner's work environment as well as structure on the development of and diffusion of medical innovation (Fennell & Warnecke, 2013). Studies on patients' impact on medical innovation have led to a discussion of these influences and whether they result from social contagion or direct patient marketing (Van den Bulte & Lilien, 2001).



Research on medical innovation processes, successes, and barriers to medical innovation has been conducted primarily on medical professionals (Fennell & Warnecke, 2013). Further, recent research has identified the decisions made by healthcare professionals as a suppressing effect in medical innovation (Ferlie, Fitzgerald, Wood, & Hawkins, 2005), meaning that medical professionals are gatekeepers for medical innovation; unfortunately, they do not contribute to the normal or expedited acceptance of medical innovations (Ferlie et al., 2005). As such, research into the decision-making process of medical professionals regarding specific medical devices is essential. Further, it is important to study medical professionals' decision-making practices especially when new devices are introduced.

## **Role of the Clinical Professional**

Understanding clinical professionals and their role in the innovation of specific medical devices requires recognition that medical professionals work systemically. As such, clinical professionals have agency or the ability to make decisions based on their own criteria but within various social structures (Barker, 2012). Some examples of social structures are professional organizations, peer groups, educational training, clinical experience, and personal experience outside of their work. These social structures have the ability to exert influence on the decisions of a medical professional (Barker, 2012). To a lesser extent, the medical professional can impact the social structure (Barker, 2012). This perspective is social constructivism (Barker, 2012).

Barker's (2012) social-constructivist model in healthcare innovation places the crux of this process on the medical professional's treatment decisions. Moreover, the innovation of medical devices is indirectly influenced by the organization's recommended practices, peer opinion, education, patient experience, and the personal experience of the mental health professional. Therefore, it is necessary to evaluate the existing influences on the decision-



making process of each individual clinical professional. Each influence can be understood as adherence to the clinician's own personal beliefs (i.e., agency, or adherence to the viewpoint of a societal group or social structure; Bergsland et al., 2014).

## **Self-Monitoring**

With the goal of understanding and influencing practitioners' willingness to accept medical innovations, evaluations of the clinical decision-making process and the agency– structure relationship in healthcare professionals must include an understanding of the potential impact and importance of self-monitoring (Epstein, Siegel, & Silberman, 2008). Self-monitoring is defined by Snyder (1987) as "the differences in the extent to which people monitor (observe, regulate, and control) the public appearances of self they display in social situations and interpersonal relationships" (p. 4). Self-monitoring is divided into two types; high self-monitors adhere more to structural influences by trying their best to do what is socially acceptable in that situation (Snyder, 1979, 1987). Low self-monitors adhere more to their agency by acting on their own beliefs and principles in a situation instead of relying on what is socially acceptable (Snyder, 1979, 1987).

In medical professionals, higher self-monitoring is viewed as a positive in clinical practice and is often encouraged (Epstein et al., 2008). A potential negative consequence of high self-monitoring medical professionals is that innovation in clinical practice could be stifled because of over adherence to the recommendations and opinions of peers and medical professional organizations. It is a potential negative because medical professional organizations are known to be slow to accept innovation and subject to the influence of political factions wanting to resist certain innovations (Bergsland et al., 2014; Forman, 1981).



Treatments using medical device innovation elicit challenges with healthcare professionals that go beyond the influences of peer networks and social structures. Other challenges include:

- the perceived relative advantage in patient care, taking into account cost effectiveness;
- the compatibility of the innovation within the healthcare professional's perceived problem and his or her existing clinical model and mind-set;
- the perceived difficulty due to the complexity or simplicity of the innovation;
- the trial ability or potential for the innovation to be tested on a small scale and modified; and
- the observability or the visibility of the innovation to other professionals in a way that makes the professional want to adopt the new procedure (Rogers, 2010).

Healthcare providers who offer services using innovative medical devices can experience particularly taxing financial strain or loss. Often, it is difficult under current reimbursement schedules for practitioners to perceive a financial advantage in adding these devices and treatments to their list of services (Bergsland et al., 2014).

#### **Impact of National Medical Governance on Medical Innovation**

The United States is considered the hub of medical innovation based on the most recent assessment (Cowen, 2006; Turner 2012). Cowen (2006) made this conclusion based on the number of Nobel prizes for medical innovation and their significance, the absolute value of money spent on medical innovation, and the money spent in relation to per capita gross domestic product. Turner (2012) made this conclusion based on the number of new medicines developed in the past decade. However, policy changes in European countries reveal an attempt to encourage more medical innovation that started in the early 1990s (Burstall, 1991). In 2010, the



European Union (EU) initiated the 10-year Europe 2020 initiative that included a program called Innovation Union to improve innovation and the adoption of innovation into the healthcare systems of EU countries (European Commission, 2019).

The major contributor to the differences in medical innovation among different countries is often derived from the type of federal healthcare governance system of each country (Giarelli, 2010). Moran (1995, 1999, 2000) has identified a system of criteria to assess a country's 27 types of healthcare governance system. Moran's criteria classify a healthcare system type according to three dimensions: (a) *financial* or control over access to healthcare and consumption, (b) *provision* or control of hospitals and doctors providing the service, and (c) *regulation* or control over medical research and innovation. Each of Moran's dimensions can be driven by one of three types of actor: (a) *state* or governmental institutions, (b) *societal* or nonprofits such as hospital or professional organizations, and (c) *private* or market driven (Powell, 2007). Therefore, it would be ideal to study the acceptance of the same medical device in countries with similar and different healthcare governance systems. This type of study would provide insight into the effects of healthcare governance types on medical device innovation.

#### **Problem Statement**

Children should have medical and mental health practitioners who are dedicated to exploring all possible treatment options and offering these options to families as appropriate. Given the current status of EEG–NFB in the United States and the Netherlands, an opportunity exists to investigate the barriers that impact the decision of medical professionals to recommend or not recommend EEG–NFB as a treatment for children with ADHD. Studying the barriers of acceptance of EEG–NFB in the treatment of ADHD in children may provide key insight into the



adoption process and challenges for innovative medical devices in the treatment of mental healthcare conditions.

#### **Theoretical Framework**

The theoretical framework for this study was Latour's (1990) social constructivist framework. Latour (1990) argued that technological advancement is inseparable from social relations, which act as the fabric that holds society together. He argued that technological advancements allow individuals to interact with the society around them in ways that they were unable to previously. Without technological advancement, societies lose power because they are losing stability, not evolving enough, or both (Latour, 1990).

#### Advantages of Innovation in Medicine

Medical device technology advancements often allow people to perceive something they were previously unable to, such as an X-ray, MRI, or EEG. When one of those advancements also changes the way individuals interact with the world around them, it would be a further advancement. Therefore, EEG–NFB is a technological, medical device advancement in two ways. First, it is an advancement of the EEG, allowing people to see brain activity in new and real-time quantitative perspectives because of advances in EEG devices and their integration with modern higher power computing. Second, the ability of individuals to interact with their EEGs and achieve behavioral training to change their brain function fundamentally alters their interaction with and perception of the world around them. EEG–NFB would meet the requirements of a technological innovation set forth by Latour (1990) and can be understood within this framework.

Understanding the diffusion of medical device innovation, such as EEG–NFB, has some unique barriers not present in other aspects of medical innovation (Bergsland et al., 2014).



Models of diffusion of medical advancements are used to identify and explain those barriers. The categories of models available to analyze medical innovations were at the societal, organizational, clinical professional, and patient levels (Fennell & Warnecke, 2013). This study examines the clinical professional level because research has shown them to be the gatekeepers for medical innovation (Ferlie et al., 2005).

#### **Rogers's Diffusion of Medical Innovation Model**

The most utilized and common model for analyzing medical innovation through the clinical professionals is that of Rogers (2010). His model was used for understanding the progression of EEG–NFB as a treatment for ADHD in children into its place in medical practice. Rogers's (2010) model consists of five elements: relative advantage, compatability, complexity, trialability, and observability. *Relative advantage*, defined by Rogers (2010), is the amount that the innovation is thought to be better than the existing option(s). *Compatibility* is how much the innovation is thought to fit within the existing practices. *Complexity* is the ease or difficulty with which the new innovation is thought to be able to be understood and implemented. *Trialability* is how much the innovation can be modified and subjected to trial. Finally, observability is the ability for clinicians to try out the innovation on a limited basis to assess acceptability and outcomes.

In addition, Rogers's (2010) model accounts for many factors that affect the clinical professional's decision making. Each of Rogers's (2010) categories contains the ability of practitioners to adhere to the societal or organizational pressures in making their decisions, which is referred to as structure, or their own beliefs about the appropriate decision, referred to as agency (Barker, 2012). A person's or clinical professional's level of adherence to structure or agency is self-monitoring (Epstein et al., 2008; Snyder, 1979, 1987). Therefore, knowing the



level of self-monitoring in a clinical professional was an essential part of understanding their acceptance of medical innovations.

#### Comparison of EEG-NFB in the United States and the Netherlands

Additionally, a country's medical governance structure is known to have an impact on medical innovation and its acceptance (Burstall, 1991; Giarelli, 2010). This study compared and contrasted findings in the United States and the Netherlands to investigate the impact of different medical governance structures on the acceptance of EEG–NFB as a treatment for children with ADHD. Moreover, these countries are considered similar cases according to Mill's (1843) five inductive methods intended to draw conclusions about causation. Similar cases are used to evaluate Mill's (1843) direct method of agreement, which is when the variable being studied is present in both cases and an examination of the properties of the cases can lead to a list of possible necessary conditions for occurrence of the variable of interest. EEG–NFB's acceptance as a treatment for children with ADHD is the variable of interest and is at the same stage of acceptance within the United States and the Netherlands.

#### **Perspective and Design**

The principal investigator for this study was a clinical practitioner of EEG–NFB, and was driven to conduct this research for two purposes. First, the researcher sought to add to our understanding of medical device innovation in mental healthcare treatment. Second, the researcher sought to gain an understanding of the barriers to acceptance of EEG–NFB as a treatment for ADHD in children. This understanding would indirectly benefit the researcher's own work on insurance reimbursement initiatives of the EEG–NFB for the International Society for Neurofeedback and Research. The principal investigator was thus of the opinion that medical device innovation is important.



This study was grounded in Latour's (1990) theoretical position regarding medical device innovation as valuable for societal progress and that ongoing paradigm shift of medical devices is a part of mental healthcare treatment. The specific framework that provided the lens for understanding the barriers in accepting medical device innovation was based on Rogers's (2010) model that focuses on medical professionals as the gatekeepers of the diffusion of medical innovation, including their individual integration with various layers of social structure and their own agency (Barker, 2012). The application of a theoretical framework as a lens to analyze a medical treatment's position within social structures is one of the examples for the need to utilize mixed-methods models (Creswell & Clark, 2011; Fetters, Curry, & Creswell, 2013).

Within this theoretical framework, any of the styles of mixed-method research are possible, and the one that best fits the question(s) should be utilized (Creswell & Clark, 2011). This study used the concurrent embedded design (Creswell & Clark, 2011). The qualitative interview will be embedded with quantitative measures in the form of a scale, vignette, selection, and ranking. The concurrent embedded design is the mixture of quantitative and qualitative data that is collected and analyzed simultaneously (Creswell & Clark, 2011).

#### **Sample and Recruitment**

A sample of 18 medical professional respondents, 10 in the United States and eight in the Netherlands, were interviewed to gain a comparative perspective on the pattern of innovation as well as barriers to adoption of EEG–NFB in the two countries. The five groups of medical professionals included psychiatrists, psychologists, neurologists, pediatricians, and primary care physicians. The data collection took place over a period of 2 to 3 months in each country, and a \$10 gift card was provided as a part of participation.



The sample was originally to be recruited via lists of members of each of the medical professionals' organizations that work near Washington, DC, and Utrecht, Netherlands. The list came from the professional websites of the representative member organizations in each country. For example, the website of the American Association of Child and Adolescent Psychiatrists (AACAP) provided the searchable list of members for identifying and selecting child psychiatrists in the US. However, this method was unable to obtain any participants. Therefore, the sampling method was altered to convenience sampling and snowballing in order to obtain enough participants.

## **Procedure and Materials**

Each research encounter involved seven sequential steps, taking less than 1 hour to complete. The first was brief restatement of the goals and objectives of the study: to understand the decision-making process of medical professionals. Each participant gave written consent at this point. Once consent was established, the audio recording was started and the interview process was initiated in sequential steps. The purpose of each step was explained briefly prior to the participant being asked to complete it.

The second step was the completion of the true–false self-monitoring questionnaire (Snyder, 1974). The third was the reading of the vignette of a 7-year-old male with ADHD by the primary investigator and the selection of a recommended treatment option by participants (Epocrates, 2016) followed by a rank ordering of the various options. The fourth step was interviewing the participant about the factors that influenced the decision of what treatments to recommend in the vignette, which was tracked by the investigator and bifurcated into structure and agency factors. The fifth step was using participatory ranking to assign a weight to the amount of influence of the factors in the decision-making process. The sixth step probed the



participant on EEG–NFB as a treatment for ADHD in children for its relationship with the most heavily weighted influential factors. In the seventh step, the respondents were thanked, provided with a debriefing form regarding their participation in the research study, and offered the gift card.

#### **Data Processing and Analysis**

The quantitative data for the study relied on hand calculations and SPSS to provide descriptive statistics and a limited number of inferential statistics tests. The analysis focused on the similarities and differences between occupational specialties and country of practice, levels of self-monitoring on the types of treatments that match the vignette of the referred child with ADHD, and categories of influential factors in the decision-making process when making a referral.

Leximancer (version 4.5) qualitative analysis software was used to identify key themes, concepts, and word choices used by the participants during the structured interviews. A Leximancer analysis captures the number of times one or more factors are mentioned, their relationship to each other, and how they are used together to identify concepts. Leximancer then produces a concept map showing the important concepts and the relative co-occurrence of important concepts. The qualitative data collected during this study provided a hierarchy map of influences on the diffusion of neurofeedback for children with ADHD into common clinical practice.

In addition to the use of Leximancer and SPSS, the integration of the quantitative and qualitative findings was possible. The qualitative and quantitative data integration followed guidelines established by Bazeley (2012) who argued that integrating distinct data sources is a critical feature of mixed-methods studies: "While different models of integration are appropriate



for different research settings and purposes, an overcautious approach to integration can generate invalid or weakened conclusions through a failure to consider all available information together"

(p. 2). Bazeley and Kemp (2011) discussed integrating different but complementary sources:

[It] best occurs at the stage where results are being composed, well before the final conclusions are made. Reporting then reflects the input of both methods throughout, and in these circumstances is best arranged by the issue or aspect of the topic being discussed, rather than the source of the data. (p. 2)

These integrated findings were used in this study to depict patterns of influence over respondents and their adoption attitudes and decisions. The findings were interpreted within the context of Rogers's (2010) model for diffusion of innovation.

#### **Research Questions and Hypotheses**

This study conducted an in-depth exploration of the barriers to acceptance of medical device innovation by examining the underadoption of EEG–NFB as a treatment for ADHD in children. To do so, it utilized mixed methods (Creswell & Clark, 2011) to assess the acceptance of EEG–NFB as a treatment for children with ADHD. The research questions were as follows: (a) In what way do various factors affect the decision-making process for recommendations the clinical provider gives for the treatment of ADHD in children, and (b) how do clinical providers' decision-making processes create barriers to medical device innovation, and how can these barriers be overcome? The mixed-method approach had research questions that are both quantitative and qualitative. The quantitative questions were as follows:

1. How many clinical practitioners recommended EEG–NFB for the child afflicted with ADHD in the vignette?



- 2. Out of those who recommended EEG–NFB as a treatment, where did EEG–NFB rank compared to other potential treatments?
- 3. What are the most common factors identified by the participants as having an impact on their decision of what treatments to recommend and which carry the most influence in the decision-making process, including a bifurcation of each factor into one of structure and one of agency?
- 4. Are structure or agency factors more influential in the clinical professionals' decision? The hypothesis is that structure factors would be ranked higher in those clinical practitioners who have high self-monitoring and agency factors would rank higher for those who have low self-monitoring.

The qualitative research questions were as follows:

- 1. What factors do the clinicians take into account when making the treatment recommendation for children with ADHD?
- 2. How is the acceptance of EEG–NFB as a treatment for children with ADHD among these clinical professionals impacted by these influential factors?

## Scope of the Study

This study was able to examine the research questions sufficiently and achieve its purpose. However, some limitations to the scope of this study do exist. The embedded design approach may have reduced the scope of the findings because it is not possible to limit all of the bias that each method may introduce into the other (Creswell & Clark, 2011). Interactive bias was a possibility because of the structured interview's potential impact on the participatory ranking of factors that influence their decision-making process. Moreover, having drawn more attention toward more minimal factors in a healthcare professional's decision-making process



may have caused these factors to be ranked higher in the participatory ranking because of priming. In addition, the need to establish trust and accuracy in the responses from participants could have resulted in bias because of a lack of acceptance of the researcher as someone with whom the participant is comfortable sharing information, though there was no assessment for whether or not this occurred. The study was limited in the Netherlands to what participants could speak comfortably in English for the interview. While the Dutch medical professionals are fluent in English, the fact that English is a second language for the majority of them may have caused those who were not comfortable with their English to choose not to participate.

The utilization of the same analytic framework for a study in two different countries could have also caused limitations in the validity of the findings because of the differences in structures, governances, and the dynamics within organizations between countries. However, research has shown that the same analytical framework and model can be utilized in the United States and the Netherlands to understand medical governance and structures (Davies, Tawfik-Shukor, & de Jonge, 2010). Furthermore, studying the impact of a country's medical governance system on the practice of psychology and the treatment of mental illness is identified as one of the tenets of the field of international psychology (Stevens & Gielen, 2012).

#### **Definition of Key Terms**

*Acceptance*. The use of innovative medical devices used synonymously with adoption. *Adoption*. The use of innovative medical devices used synonymously with acceptance.

*Agency*. The personal beliefs about the appropriate decision in a given situation; sits on a continuum with structure.

*Barrier*. Obstacle that impedes progress; refers to something intangible such as a perception rather than something tangible such as a wall.



*Electroencephalogram.* An imaging tool that uses electrodes and amplifiers to detect and record electrical brain wave activity; often uses computers to record and provide visual representation of electrical brain wave activity.

*Electroencephalogram Neurofeedback.* The application of a behavioral training paradigm to a specific and quantifiable EEG signal to correct abnormalities and/or improve psychological symptoms.

*Healthcare governance*. The social framework that exists within a country that defines the basic structure within which healthcare must operate.

*Medical innovation*. The process of both discovering and applying new techniques toward the diagnosis or treatment of people with illnesses.

*Medical device*. Any machine, implant, or other similar or related article that is tangible and has been applied toward the diagnosis or treatment of people with illness, including EEG– NFB.

*Mill's methods*. Five inductive methods that are intended to draw conclusions about causation.

*Neurofeedback.* A subcategory of biofeedback focused on brain activity; the application of behavioral training paradigms to physiological brain imaging sources in real time with the goal of correcting abnormalities or treating psychological symptoms.

Paradigm shift. The fundamental alteration of the approach, assumptions, or perception.

*Rogers's model*. Four-component model used to evaluate the rate of diffusion of innovation and explain why an idea or technology is spreading at that rate.

*Structure*. Societal, organizational, or other social groups that promulgate shared perceptions and viewpoints that impact a person's choices and decision-making process.



#### Significance of the Study

The findings contributed to the literature in several ways. The findings contributed to the research on the lack of common acceptance of EEG–NFB as a treatment for ADHD in children (Pigott et al., 2013). The literature on medical device innovation now has another model to evaluate the barriers affecting specific devices that are being underadopted (Bergsland et al., 2014; Rogers, 2010). This study also serves as a model for the investigation of causal relationships in the acceptance of other medical innovations into common healthcare practice beyond just medical devices. Further, this study contributed to the literature in the utilization of mixed-methods research, which is still in need of many more applications to verify its usefulness (Creswell & Clark, 2011). It also contributed to literature on the applicability of analytical frameworks for studying healthcare in different governance types (Davies et al., 2010).

Governments may find this study useful in policy making when trying to improve outcomes and reduce costs in the treatment of ADHD in children. In addition, the findings may be useful to many different types of organizations in making future plans. For example, organizations that represent the EEG–NFB field may begin to apply this analytical framework toward understanding the barriers causing EEG–NFB to be in the underadoption category for other conditions, such as anxiety, seizures, traumatic brain injury, and posttraumatic stress disorder (Hammond, 2011). Organizations that represent other medical device innovations may find this study useful in planning how to analyze the barriers they currently face or may face when moving toward the adoption of their innovation.

Finally, these findings could be used as a base for further research into the acceptance of EEG–NFB as an intervention for children with ADHD in other countries. In doing this research in other countries, that information could be added into the findings of this study to identify



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causal relationships in the barriers to the acceptance of EEG–NFB for the treatment of ADHD in children by using Mill's (1843) methods of causal reasoning.

#### Summary

Medical device innovation is part of a larger paradigm shift, which is moving away from the drug model and toward technology such as medical devices (Fuchs, 2010). Within medical device innovation, the emergence of EEG–NFB as a treatment for children with ADHD (Arns et al., 2014) has yet to realize its place fully in the treatment recommendation protocols in both the United States and the Netherlands (van Dongen-Boomsma, 2014), yet the level of evidence supporting the efficacy of EEG–NFB is comparable to the treatment of ADHD with other nonpharmacological treatments (Arns et al., In submission). EEG–NFB also has the advantage of saving costs over the lifetime of treatments. Moreover, EEG–NFB causes no significant side effects common in drug treatments of ADHD in children (Pigott et al., 2013). Therefore, EEG– NFB is an area ripe for investigation in order to understand what barriers exist in the adoption of medical device innovations (Bergsland et al., 2014) and the impact that these barriers have on the process.

The goal of this study is to understand the decision-making process of clinical professionals for treatment referrals of children with ADHD and identify the influencing factors. The study will utilize vignettes of children with ADHD and interviews within a mixed-methods embedded design to study the phenomenon of underadoption in medical device innovation. The study will also assess barriers that are causing underadoption and the impact of the interplay of structure and agency through clinician self-monitoring on the process to decide what treatments to recommend. Comparative analysis of EEG–NFB, an innovative medical device for the treatment of ADHD in children, will be conducted across clinical professions in the United


States and the Netherlands. The information will add to the literature in the field in various ways and be useful to the EEG–NFB organizations, medical device innovators, and governments.

The next chapter is the literature review and will provide a more in-depth review of the topics discussed in this chapter. It will cover medical innovation models and theories, specific examples of research into barriers in medical device innovation, further explanation of EEG and its development, and additional research into the development and evidentiary basis of EEG–NFB as a treatment for ADHD in children. Finally, it will integrate the comparison of these factors in the United States and the Netherlands.



## Chapter 2: Literature Review

EEG–NFB, a medical procedure using an innovative medical device, has a rich fortyplus-year history and has been used to treat over 20 health conditions, most of them mental health conditions (Hammond, 2011). Despite previous hurdles, the literature suggests that as research on the technique picks up more people are becoming aware of the treatment, and it is becoming mainstream clinical practice. The use of EEG-NFB for the treatment of ADHD in children has the most robust supporting research compared to other uses of EEG–NFB (Hammond, 2011; Pigott et al., 2013). Despite the evidential support and growing popularity, EEG–NFB in the treatment of children with ADHD remains in a state of underadoption. The United States and the Netherlands are the two leading countries for EEG-NFB research and board-certified practitioners. However, challenges still exist. For example, both countries still have low usage of EEG–NFB as a treatment for children with ADHD (Kruijt & Hjelmar, 2014; Pigott et al., 2013). Furthermore, American Academy of Neurology (AAN) classifies EEG–NFB in the treatment of ADHD as still experimental or investigational; the AAN has a weighty reputation and strong influence in the decisions of many third-party payers in the US and the Netherlands. Overall, an important theme that emerges from the literature about EEG–NFB treatment of ADHD is that the research is far ahead of clinical practice. Therefore, practitioners and professional organizations must familiarize themselves with the unequivocal evidence in favor of EEG-NFB.

## **History of EEG–NFB**

The history of EEG–NFB begins in the late 19<sup>th</sup> century. In his 1875 research, Caton noticed the fluctuations of the electrical activity in a brain track with mental activity. During the 1920s, Hans Berger measured an EEG on the human scalp and recorded it on paper to make the



first raw EEG record (Millet, 2002). He went on to discover that the beta frequency band (13–30 Hz) responded to thinking and alertness with bursts of activity, and in 1929, Berger published a paper establishing the belief that clinical disorders are reflected by abnormalities in the EEG (Millet, 2002). According to Demos (2005), Berger's assumption is the basis for many neurofeedback training protocols, which apply neurofeedback training to "regions of the brain that are known to influence cognitive and behavioral performance" (p. 16).

During the early 1900s, Carl Jung investigated physiological responses to psychological issues, though with galvanic skin response and not EEG (Puckhaber, 2006). Jung's research attempted to correlate physiological responses with psychological issues by using the galvanic skin response, which demonstrated that the mind's activity could be represented in physiological signals (Demos, 2005). However, a more important link was made between physiology and psychotherapy as Jung began to incorporate the monitoring of galvanic skin response into his psychotherapy sessions (Puckhaber, 2006).

The continued research into biological processes, such as heart rate variability, blood pressure, and hand temperature, led scientists to assume them to be controlled by the body's automatic management system and to "question the concept of voluntary control of the ANS [autonomic nervous system]" (Demos, 2005, p. 16). By 1960, Neal E. Miller utilized an operant conditioning protocol to demonstrate that participants were capable of consciously altering its functions (Olson, 1995; Robbins, 2000), thereby establishing the foundation for biofeedback with operant conditioning (Demos, 2005). The evidence for the mind–body connection was further reinforced around this time by Jon Basmajian in 1963 when he discovered the basic principles of electromyography and utilized them to demonstrate the ability to learn to control a single motor unit (Demos, 2005; Robbins, 2000).



Developers of EEG–NFB, beginning in the 1960s, have drawn on a prior body of scientific research and technology development dating back to the original discovery and measurement of the EEG (Evans & Abarbanel, 1999). They were assisted by the use of a differential amplifier to increase the volume of the activity for better measurement that was pioneered by Adrian and Matthews, while replicating Berger's initial EEG measurements (Demos, 2005). At the University of Chicago, Kamiya (1963) also tried to demonstrate individuals could consciously recognize brain waves, and he successfully demonstrated the human ability to control the alpha brain wave with the use of instrumentation. Moreover, he was responsible for the first biofeedback training loop upon which all biofeedback modalities are based, including neurofeedback. Demos (2005) described the biofeedback training loop as a three-way process: "(a) an instrument records a specific biological activity of interest; (b) a trainee is reinforced each time the desired activity occurs; then (c) voluntary control of a biological activity becomes possible" (p. 23).

As the 1960s progressed, Barry Sterman at UCLA observed a new brain wave that had a tendency to surge in cats and was associated with muscle relaxation at 14 Hz. It was discovered in the sensory motor cortex leading to the discovery of a band range from 12–15 Hz that is referred to as Sensory Motor Rhythm (SMR; Arns & Sterman, 2019). In an unrelated experiment requested by NASA into the effects of human exposure to rocket fuel (hydrazine), Wyricka and Sterman (1968) unintentionally included cats that had been trained to elevate SMR. Their study found that the cats that had received SMR EEG–NFB did not experience seizures an hour after the injection of hydrazine, while all of the other cats did.

In 1971, Sterman chose to train a sufferer of epilepsy to increase SMR along the sensory motor cortex of the brain based on the assumption that the increase in SMR in the left



hemisphere would improve the person's seizure disorder. The results of the study were a reduction in incidence of seizures after three months that was sufficient enough for the participant to obtain a driver's license (Robbins, 2000). Many more people seeking help followed in the first client's footsteps. Other researchers and clinicians such as Joel Lubar, for attention and learning, and Margaret Ayers, for brain trauma, began to apply EEG–NFB for rehabilitation and the treatment of mental health disorders (Demos, 2005).

Peniston and Kulkosky (1989) used neurofeedback in a successful treatment program with a small population of Vietnam veterans suffering from posttraumatic stress disorder. In 1991, Peniston and Kulkosky studied the effect of the same neurofeedback training program on veterans with a dual diagnosis of posttraumatic stress disorder and alcoholism, again finding it to be successful. Peniston and Kulkosky (1999) assessed the long-term outcomes of these studies and found them to be positive.

EEG–NFB techniques and devices have shown clear evidence of success with epilepsy sufferers. As late as 2002, there was still skepticism about whether NFB could reduce the incidence of seizures (Monderer, Harrison, & Haut, 2002). Within a few years, skepticism gave way to a growing body of confirming evidence (Walker & Kozlowski, 2005). Tan et al. (2009) conducted a meta-analysis of 63 studies conducted between 1970 and 2005 to determine biofeedback's impact on epilepsy sufferers who did not respond to traditional medical treatment. The studies reported an overall mean decreased seizure incidence following treatment, and 64 out of 87 patients (74%) reported fewer weekly seizures in response to EEG biofeedback.

Hammond (2003, 2005), among others, has sought to test EEG–NFB for the treatment of depression and obsessive–compulsive disorder, noting that medications and behavioral therapy may have limited effects. Sufferers of these disorders experience a different set of brain wave



abnormalities from those with epilepsy or ADHD. Preliminary evidence suggests that adjusting the EEG–NFB treatment to account for these differences can yield positive treatment outcomes. In the case of obsessive–compulsive disorder, where both medication and behavioral therapy have utterly failed, EEG–NFB may be the treatment of last resort.

The strongest evidence and most prevalent clinical use of EEG–NFB are for the treatment of ADHD in children (Hammond, 2011; Pigott et al., 2013). However, the prevalence rates for other mental disorders in children and adults that may be responsive to EEG–NFB are rising dramatically (Twenge et al., 2010). The first major study in EEG–NFB demonstrated its ability to reduce epileptic seizures (Sterman & Friar, 1972). During the next two decades, 162 NFBbased studies were published. The number increased rapidly in the subsequent decades, reaching 1,260 in the 1990s and 6,100 between 2001 and 2010. Since 2011, there have been over 9,000 publications devoted to various aspects of EEG–NFB (Rogala et al., 2016). EEG–NFB has been used to treat learning disabilities, ADHD, addiction, anger, anxiety, asthma, autism and Asperger's, autoimmune disorders, brain injury, cerebral palsy, chronic fatigue, cognitive decline, coma, criminal behavior, depression, dissociative disorders, epilepsy, fibromyalgia, headache, hypertension, obsessive–compulsive disorder, posttraumatic stress disorder, pain, Parkinson's, premenstrual syndrome, schizophrenia, sleep disorders, stroke, tinnitus, Tourette's syndrome, and other medical conditions (Hammond, 2011).

### **ADHD and EEG–NFB**

According to the CDC (2015), ADHD is a neuropsychological condition that is increasingly diagnosed in children. The American Psychiatric Association's (APA, 2013) *Diagnostic and Statistical Manual of Mental Disorders* defines ADHD as follows:



[ADHD is] a persistent pattern of inattention and/or hyperactivity–impulsivity that interferes with functioning or development, has symptoms presenting in two or more settings (e.g., at home, school, or work; with friends or relatives; in other activities), and negatively impacts directly on social, academic or occupational functioning. Several symptoms must have been present before age 12 years. (p. 38)

The *Diagnostic and Statistical Manual of Mental Disorders* (APA, 2013) states that approximately 5% of the children in the United States have ADHD and the CDC (2015) estimates that almost 11% of the children aged 4–17 have been diagnosed with ADHD at some point in time. In the Netherlands, it is estimated that 5% of children under the age of 21 are diagnosed with ADHD (Kruijt & Hjelmar, 2014).

The treatment of ADHD in children has been primarily dominated by medication and behavioral therapy. The most prevalent treatment is medication in both the United States (Danielson, Visser, Chronis-Tuscano, & DuPaul, 2018) and the Netherlands (Kruijt & Hjelmar, 2014). Medication treatments for ADHD have a high response rate. However, a nonresponse to stimulant medication is measured as 29.8–43.1% for children with ADHD (Zuvekas & Vitiello, 2012). Moreover, the long-term efficacy and outcomes of the stimulant medications for the treatment of ADHD in children have been recently questioned (Kruijt & Hjelmar, 2014; Pigott et al., 2013; Swanson et al., 2017). Treatment of ADHD in children with behavior therapy has been recommended as the primary alternative to medication, but the research supporting those recommendations has also been questioned (Pigott et al., 2013).

For years, EEG–NFB, and biofeedback as a whole, struggled for acceptance as a legitimate medical practice despite having accepted medical procedure codes since the 1978 inception of the Current Procedural Terminology at the highest level (Category I). Two decades



ago, much of the medical establishment still viewed biofeedback treatments with considerable skepticism, if not outright derision (Beyerstein, 1990). The skepticism and outright derision toward EEG–NFB as a treatment has continued through the years since 1990 and is still present and strong (Thibault & Raz, 2018). However, as the number of early adopters has expanded. Evidence from the field increasingly suggested that EEG–NFB is a viable method for treating ADHD (Arns, de Ridder, Strehl, Breteler, & Coenen, 2009; Heinrich, Gevensleben, & Strehl, 2007; Pigott et al., 2013; Van Doren et al., 2018). EEG–NFB treatment of ADHD has only recently begun to be tracked in the US, and it is still not tracked by government agencies in the Netherlands, making it difficult to compare the number of children with ADHD who have received EEG–NFB accurately.

The highest levels of recommendation for using EEG–NFB to treat ADHD come from the International Society for Neurofeedback and Research and the American Association for Applied Psychophysiology and Biofeedback. According to these societies, EEG–NFB is efficacious in the treatment of ADHD, though some disagreement still persists about the specific type or protocol to be universally applied. While Hirshberg, Chiu, and Frazier (2005) stated in the AACAP journal that EEG–NFB meets their "Clinical Guidelines," their website still does not endorse EEG–NFB for the treatment of ADHD. AACAP's website does not list an updated review of EEG-NFB in the treatment of ADHD; their last review of ADHD treatments is listed in past policies and is dated 2007 (Pliszka, 2007). However, the AACAP website does contain a flyer on medication treatment for ADHD that lists brainwave biofeedback as an unproven treatment (ADHD parents medication guide, 2019).

The American Academy of Pediatrics (AAP) has taken a different position toward EEG– NFB for ADHD; their practice guidelines discuss neurofeedback with other alternative



treatments but do not recommend them because of a need for more research (ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents, 2011). The CDC (2015) recommends EEG–NFB as an alternative only in cases where the ADHD is not responsive to medication. The professional advisory board for Children and Adults with Attention-Deficit/Hyperactivity Disorder (2019), the membership organization for education and advocacy for individuals with ADHD, states that EEG–NFB is an "Option" for the treatment of ADHD. The National Institutes of Health (2019) website does list EEG–NFB as a complementary and alternative medicine treatment option for ADHD, though they state the evidence is mixed. The American Academy of Neurology website (2019) and The American Psychological Association website (2019) do not mention neurofeedback in their ADHD guidelines.

The medical policies of insurance companies in the United States reveal much variability as well. Blue Cross Blue Shield of Michigan's medical policy determines EEG–NFB to be efficacious and pays for its use, and some state Medicaid plans do as well, such as Maryland's. Many Blue Cross Blue Shield policies and other private insurances only cover EEG–NFB for the treatment of ADHD on a case-by-case basis after a medical appeal. Even then, EEG–NFB is often considered to be a complementary and alternative treatment and is only when the plan covers those services. In the Netherlands, EEG–NFB for the treatment of ADHD was not covered by insurance plans until 2017. However, Holland also considers EEG–NFB to be a complementary and alternative treatment, and only people who purchase the higher tier of plans receive that level of coverage (HollandZorg, 2016).

While support for EEG–NFB in the treatment of ADHD has grown, studies continue to show effective outcomes from stimulant medication and behavior therapy, especially stimulant



medication. Pigott et al. (2013) and Pigott and Cannon (2014) have conducted comparative studies suggesting that results from EEG–NFB are superior to those of other treatments and less burdensome because results from the initial treatment last six months or more and do not require ongoing reinforcement. Pigott et al. (2013) have also criticized other studies for overstating the benefits from stimulant medication and behavior therapy. A meta-analysis published in the *Journal of Attention Disorders* found NFB to be more than twice as effective in treating the core symptoms of ADHD as various types of behavior therapy, with an average weighted effect size of .21 for NFB compared to effect sizes of only .09 or less for the other six treatments (Hodgson, Hutchinson, & Denson, 2014). The results of the study led the authors to conclude that five of the six commonly utilized behavioral treatments for ADHD are not efficacious.

Direct comparisons of treatment outcome from stimulant medication and EEG–NFB for ADHD have produced mixed results. Nonetheless, the research shows that EEG–NFB is certainly a viable option for treating ADHD in children. Duric, Assmus, Gundeersen, and Elgen (2012) found that both treatments, either separately or combined, yielded positive outcomes for both inattentive and hyper-compulsivity symptoms without substantial differences between them overall. However, the impact of NFB on inattentive symptoms specifically was the strongest. Meisel, Servera, Garcia-Banda, and Moreno (2013) conducted a comparative study of standardized pharmacological and NFB treatments separately among adolescents and children and found that while both treatments yielded positive outcomes for core ADHD behaviors, oppositional, pharmacological treatments yielded somewhat stronger effects. At the same time, only the NFB treatments yielded substantial gains in academic performance among the test subjects at the posttest 2-month and 6-month periods. Adolescents and youth receiving medication on an ongoing basis reported no academic gains in the posttest period. Finally, a



recent randomized control trial comparing EEG–NFB, behavioral therapy, and medication found that they were all equally effective at treating ADHD in children (Moreno-Garcia, Meneres-Sancho, Camacho-Vara de Rey, & Servera, 2017).

Despite the growing evidence indicating the benefits of EEG–NFB to treat ADHD, defenders of medication and behavior therapy have continued to criticize EEG–NFB studies as lacking in methodological controls to minimize the influence of nonspecific factors, such as therapist-patient interactions, on reported treatment effects (Logemann, Lansbergen, Van Os, Böcker, & Kenemans, 2010). Some studies have attempted to correct for these presumed therapist effects by including "sham" EEG-NFB testing. Logemann et al. (2010) found that once these factors were taken into account, the specific benefits of the EEG–NFB testing could not be demonstrated. Complaints about treatment consistency seem to be growing as EEG–NFB has gained greater acceptance (Aliño, Gadea, & Espert, 2016; Marzbani, Marateb, & Mansourian, 2016; Rogala et al., 2016). A recent meta-anlaysis by Van Doren et al. (2018) has shown EEG–NFB to have significant long-term effects beyond those that could be explained by placebo and beyond the benefits of an active sham. Moreover, a double-blind randomized placebo controlled trial is being conducted with National Institutes of Health funding at Ohio State University and the University of North Carolina (ICAN.org, 2019). Only preliminary results have been presented at conferences, and no formal conclusions have been drawn yet as they are waiting on the results of the final 1-year follow-up.

The issue of consistent treatment protocols is related to another issue: the potential side effects and threats to patient safety from EEG–NFB. It is commonplace in the ADHD treatment literature for practitioners to warn of the potential overuse of pharmacological treatments, especially for ADHD children as young as toddlers (Insel, 2014; Kruijt & Hjelmar, 2014; Pigott,



2017; Pigott et al., 2013; Storebø et al., 2015; Swanson et al., 2017). However, the American medical establishment has attempted to refute these concerns by citing Connor's (2011) conclusion:

The public's fear that ADHD is overdiagnosed and that stimulants are overprescribed is not generally supported by the current scientific research. . . . Comprehensive physician ADHD evaluation practices are essential to accomplishing evidence-based stimulant prescribing and to reduce unwanted variation in stimulant prescribing rates that should, in turn, reassure the public that management is accomplished consistently and with due expertise. (p. 4)

The same issue has arisen with EEG–NFB but not from patient consumers, in part because the practice is not a drug-based treatment and is nowhere near as widespread. Some physician opinion leaders have expressed concern about negative side effects based on improper EEG–NFB training and on the under-the-radar sale of EEG–NFB feedback equipment to lay practitioners outside of FDA regulations (Hammond & Kirk, 2007). Anecdotal evidence from social media communications suggests that consumers are worried about potential NFB side effects, including a worsening of their condition as well as concomitant problems, depression, attacks of mania, and sleep deprivation. Other scholars have sought to refute these charges without addressing issues relating to suboptimal treatment procedures (Collura, 2014). It is difficult to know the actual extent of prospective EEG–NFB side effects because to test for them formally, as some suggest is necessary using a medication model style of research, would be a violation of established research ethics (Sorger, Scharnowski, Linden, Hampson, & Young, 2019). However, this issue, along with the ambiguity of treatment outcomes, may have helped weaken the case that EEG–NFB to treat ADHD offers a distinct and quantifiable relative



advantage (Rogers, 2010) over rival approaches that the medical field continues to endorse as best practices.

### **EEG–NFB: A Medical Device Innovation**

Studies focused on medical devices specifically occupy their own expanding niche (Consoli, Mina, Nelson, & Ramlogan, 2015). This expansion reflects the growing number and types of medical device innovations that have entered the healthcare market in recent years due to advances in medical engineering technology as well as rising patient demand for alternatives to drug treatments (Bergsland et al., 2014), yet despite these facilitating factors, major barriers to medical device adoption remain.

The complexity and rigor of the regulatory process can have the effect of slowing down the diffusion and adoption of devices that have already proven themselves effective with endusers and commercially viable to produce. The FDA, or a comparative body outside the United States, regulates medical devices. The payment for services provided with medical devices by third parties, such as insurance companies, is often dependent on different criteria and regulatory processes for the coverage of any medical procedure, drug, or device. Moreover, the policy and regulatory environment surrounding medical devices has traditionally been tighter and more restrictive than those for other innovations (Foote, 1991). However, the FDA in the United States has been given a mandate to develop a specific set of criteria and guidelines for medical devices to alleviate some of these growing concerns through the 21st Century Cures Act of 2016 (FDA, 2018), which appears to have lessened the criteria to be less stringent than those required for medications.

As discussed in the first chapter, EEG–NFB meets the requirements for an innovative medical device (Bergsland et al., 2014; Latour, 1990). The EEG has provided a with a tool to



see an aspect of human beings that was previously not seen or known (Evans & Abarbanel, 1999), and modern computing power allows exponentially more real-time quantitative understanding of EEG than ever before (Budzynski et al., 2009; Hammond, 2011). Therefore, using EEG–NFB to treat ADHD offers an opportunity to test and refine medical diffusion and medical device adoption models.

# Latour's Paradigm Shifting: Technology and Society

Latour (1990) presented a theoretical framework for understanding technology paradigm shifts in society. According to Latour (1990), technological innovations move the societies or cultures that create them into a more dominating position of power in comparison to those that do not technologically innovate. A technological innovation is something nonhuman that gives the ability to observe, see, or interact with other human beings or the physical world in a way that was unavailable to prior to the technological innovation (Latour, 1990).

Latour (1990) argues that a paradigm-shifting technological innovation is best understood as a story, or narrative, because it goes through many stages and involves many factors that may change through each iteration of technology to the point where the original technology. In essence, the innovation is often still changing during the process of the paradigm shift and its adoption into society. For example, EEG–NFB has undergone a major evolution since the development of computers to read the EEG and process information (Al-Kadi, Reaz, & Ali, 2013). It went through even more with the increase in home computing power, yet through all of these changes, EEG–NFB has still not breached the paradigm shift into common acceptance in society and may change much more before it does so.

Latour (1990) identifies both human actors, such as healthcare professionals and inventors, and nonhuman actors, such as the EEG itself, as a part of the narrative of a paradigm



shifting in technological innovation. Moreover, all actors are part of a network or group of networks, which are the space in which these innovations occur. This is called the Actor-Network Theory (Latour, 1990). However, Latour (1990) explains that an ongoing paradigm shift cannot be retrospective because a retrospective analysis is a description of the actor(s) and network(s) that led to the success or failure. Therefore, to understand the ongoing paradigm shift, one needs to analyze the successes and failures of the past to predict or influence the future trajectory.

# **Rogers's Model: Assessing a Medical Innovation**

Medical innovation theory traces its roots to the work of Rogers (2010) who created the now well-established paradigm for explaining how innovations are conceived, introduced, adopted, and disseminated. Rogers's (2010) work did not specifically focus on the medical field, but he argued that the basic dynamics of the innovation process as he conceived them would apply broadly across numerous fields from economics to anthropology. In subsequent years, a host of scholars have applied and adapted the model developed by Rogers (2010) to explain the process of medical innovation, including medical device innovation, yet the basic structure of his model has remained intact.

At the heart of Rogers's (2010) model is his concept of *diffusion*. For Rogers (2010), diffusion of an innovation occurs through a five-step, sequential, decision-making process. Within organizations or practice fields, diffusion also occurs through a number of communication channels that link members of a common "social system." Rogers (2010) initially labeled the five decision-making stages as follows: awareness, interest, evaluation, trial, and adoption. Innovation and diffusion could be disrupted, suspended, or blocked at any one of these five stages. In later years, he changed the names of the diffusion stages to knowledge,



persuasion, decision, implementation, and confirmation. However, their underlying meaning and logic has remained constant.

Rogers (2010) also linked the stages of a diffusion process to the activities of five different "adopter" groups. The five adopter groups roughly corresponded to the different stages of diffusion. Innovators are the first stage of diffusion and represent less than 2.5% adoption. Early adopters account for another 13.5%, early and late majority each account for another 34%, and laggards account for the final 16%. According to Danielson et al. (2018), 1.5% of ADHD patients currently receive EEG–NFB. In addition, 11% of ADHD patients have received EEG–NFB treatment at least once in their lifetimes. In both the United States and the Netherlands, EEF-NFB to treat ADHD is solidly in the early adopters stage of Rogers's (2010) model.

Rogers (2010) was well aware that scientific evidence for the utility of any innovation was not enough to ensure that it would be adopted widely. Rogers (2010) posited that innovations proceeded through various stages and steps based on a constellation of factors, including their (a) relative advantage, (b) compatibility, (c) complexity, (d) trialability, and (e) observability. These elements include both subjective and objective factors. For example, "relative advantage" is simply whether the new innovation is perceived as better than what came before it. However, who offers and promotes that perception is often critical.

The scientific evidence may suggest that an innovation is superior to previous methods, but key opinion influencers, which Rogers (2010) saw as concentrated in the early adopter and early majority groups, need to agree with that evidence and also agree to promote the innovation to members of their common social system. The same would likely be true of "compatibility," which Rogers (2010) defined as the degree to which an innovation conformed to existing values, past experiences, and the needs of potential adopters. Beyond the early adopters, most



prospective recipients of the innovation might not be in a position to assess the value of a prospective innovation unless contacted and told about it face-to-face through established media or via some other form of influential social communications.

The three other elements—complexity, trialability, and observability—tend to be closer to the experience of the adopter. If an innovation is too difficult to use, despite being heavily promoted, it may not be adopted in practice, at least not widely. If it cannot be tested by the adopter and modified and adapted to real-life settings, it may be seen as inflexible and impractical. Finally, observability requires that actual results from the innovation be visibly demonstrated. Opinion leaders and influencers may play a role here, but the availability of documented field experience usually comes from later adopter groups.

# **Barker: Social Structure and Agency**

Since the medical professionals are the gatekeepers to the adoption of medical innovation, according to Rogers' (2010) model, it is important to understand the medical professionals within their various cultural strata (Barker, 2012). The medical professional is subjected to the information and positions supported during their education, practicum training, their association's professional stances and viewpoints, their personal social network, their own experiences, and the position of medical policies and viewpoints for the country in which they live (Barker, 2012). Each one of them has various identities, influences, and roles because of each of these structures that impact the decisions they make as medical professionals (Barker, 2012).

To grasp the psychology of their adoption of medical innovations better, it is necessary to also understand their level of adherence to their personal viewpoints, or agency, or the influences of the perspectives forwarded by their various social strata or structure (Bergsland et al., 2014).



The level of a person's adherence either to structure or agency is referred to as self-monitoring (Epstein et al., 2008; Snyder, 1979, 1987). For this reason, the participants of the study were assessed for their level of self-monitoring and the influential factors that the participants identify were bifurcated into whether or not they were a structure or agency factor with the ability to identify both. Their level of self-monitoring was used to understand better the factors that influenced their treatment recommendation decision during the vignette of the child with ADHD.

## EEG-NFB in the United States and the Netherlands: A Comparison

The United States and the Netherlands were chosen as research sites for this study because adoption of NFB is highest in these two countries despite their contrasting healthcare systems and policy environments. Additionally, both countries have experienced significant changes in their healthcare systems in the past few years. The Netherlands has mandatory universal coverage with standardized premiums charged by private insurers that are regulated by the national government (Okma, 2009). The United States has shifted to a system that combines private insurers operating competitively alongside of Medicare and Medicaid, which guarantee government-funded health coverage to vulnerable groups. The Affordable Care Act transitioned to mandatory insurance coverage and a model similar to the Netherlands (Harrah, 2014). However, neither system has been in operation long enough to arrive at a conclusive assessment of its costs and benefits.

Research on the effects of contrasting national healthcare and regulatory systems on medical device adoption has focused on the United States and some of the larger European countries, including Great Britain, France, Italy, and Germany. Since the 1990s, these countries and other members of the European Union, including the Netherlands, have agreed to common medical device adoption policies (Kramer, Xu, & Kesselheim, 2012). Devices in the United



States and the European Union are subject to classification based on their presumed health and safety risk. European Union policies appear to favor less stringent oversight, with fewer requirements for premarketing clinical studies and more rapid approval for commercial marketing (Kramer et al., 2012).

At the same time, low-to-moderate risk devices, the classification for EEG–NFB, are not necessarily handled more quickly in the European Union (Basu & Hassenplug, 2012). In part, this may be due to the fact that national insurance and medical reimbursement policies in European countries generally have a slower response time than in the United States (Basu & Hassenplug, 2012). Another factor is funding for the regulatory process, which is mainly public in the United States while largely private in Europe. Device manufacturers in Europe need only convince one member country to approve their product to receive EU-wide approval, and they can achieve this goal with less evidence that their product will function as intended or pose a risk to consumers (Basu & Hassenplug, 2012).

Understanding how these contrasting regulatory environments might affect the diffusion of NFB in the Netherlands and the United States is one of the goals of this research. However, in-depth comparative field research is required as the literature available in English on the Dutch healthcare system and on Dutch treatment of ADHD is still relatively spare. Some important preliminary clues of a comparative nature include the following:

 As late as 2007, Dutch health authorities viewed medication and behavior therapy as the only viable treatment options for ADHD. An overview of ADHD in the Netherlands published in 2010 did not even mention alternative therapies, let alone EEG–NFB (Health Council of the Netherlands, 2000).



- In the past several years, Dutch medical opinion leaders have strongly criticized the overreliance of physicians on medications like Ritalin for the treatment of ADHD, especially among children (Kruijt & Hjelmar, 2014). Studies have documented a rising prevalence and incidence in the use of ADHD medication among preschoolers, children, and adults (Hugtenberg, Heerdink, & Egberts, 2004; van den Ban et al., 2010). In 2015, a leading Dutch psychiatry organization called on the government to eliminate the use of drug therapies for youth and children with ADHD except for the most severe cases (Vriesema, 2015).
- Even the Dutch Congress has addressed the issue with legislation demanding that the Dutch government reduce the widespread use of Ritalin and expand the use of alternative therapies. Dutch opinion leaders have also cited a number of United Nations medical rights resolutions that call for all available treatment remedies to be made available to disease sufferers, regardless of cost.
- The latest official government review of ADHD treatment options contains a separate listing for alternative therapies (HollandZorg, 2016). The document also notes that all of these therapies, including EEG–NFB, have been available for medical reimbursement without restriction since 2017. This is an enormous policy change but is only available on the higher tier of insurance plans.

These medical opinion and government regulatory changes would appear to favor NFB adoption in the Netherlands in the coming years. At the same time, aspects of the Dutch healthcare system and the latest reorganization push might affect this trend less favorably. They include the following:



- The Dutch government has mandated establishing specialized ADHD clinics for the treatment of ADHD (Schmidt, 2012), which are largely run by nonprofit groups. However, hospitals that lack specialized ADHD treatment providers are increasingly setting up their own ADHD clinics to compete with nonprofit providers. This trend is not likely to speed diffusion of EEG–NFB (Schmidt, 2012).
- The central government is also transferring healthcare authority and funding to Dutch municipalities with uncertain impacts on the provision of quality care (Vermeulen, 2015). The reorganization especially targets youth care, including specialized care. Smaller local hospitals and clinics are likely to be the main providers of ADHD treatment. In theory, this trend might favor EEG–NFB adoption. However, without a strong federal mandate, NFB may not be among the options for medical device adoption or innovation at the local level.
- General physicians appear to exercise a dominant role as gatekeepers within the Dutch healthcare system, as is common practice throughout Europe, compared to the United States and other countries where specialized providers often hold sway (Loudon, 2008). It is not clear where general practitioners stand on ADHD treatments and how their influence will be affected by the ongoing healthcare reorganization. At present, a formal referral from a general physician is required to receive treatment for ADHD. Other healthcare reorganizations in Europe, such as Germany, have tended to strengthen the general physician's role (Höhne, Jedlitschka, Hobler, & Landenberger, 2009).
- However, widespread skepticism in the Netherlands doubts the scientific foundation of diagnoses for ADHD (Kruijt & Hjelmar, 2014). In addition, a growing concern



exists regarding ADHD's comorbidity with depression and other mental disorders (Kruijt & Hjelmar, 2014). These concerns have fostered further concerns about potential overdiagnosis or misdiagnosis of ADHD and overuse of medication to treat it (Kruijt & Hjelmar, 2014). The foundation Nederlands Comité voor de Rechten van de Mens reports a lack of strength in the evidence base for alternative therapies in the treatment of ADHD children, primarily citing low clinical usage of them in the Netherlands (Kruijt & Hjelmar, 2014).

The issue of general physician resistance to alternative therapies for ADHD in the Netherlands is discussed in an ADHD policy report produced by independent evaluators for the Nederlands Comité voor de Rechten van de Mens (Kruijt & Hjelmar, 2014). The report found that between 3–5% of Dutch children suffer from ADHD of whom approximately 130,000 are medicated or approximately 4.5% of the age group between 4 and 18 years of age. The majority of them are treated with psychostimulants with Ritalin being the most popular. The authors noted a lack of research evidence that psychostimulants had improved the behavioral conditions of ADHD sufferers; at the same time, there was clear evidence of negative side effects. Despite these shortfalls, the authors also noted a profound reluctance on the part of medical doctors to contemplate the use of alternative therapies. According to the Nederlands Comité voor de Rechten van de Mens, the cause of the reluctance is that "alternative therapies lack attention because of problematic research budgets, as well as the limited dissemination of knowledge about the existence of such alternative therapies and treatments" (Kruijt & Hjelmar, 2014, p. 14).

In the United States, general physicians exercise far less control over the mental health patient referral process. However, the shortage of psychiatrists at a time of expanding mental healthcare, and increased medical reimbursement options, has led to a greater reliance on nurse



practitioners to make mental health diagnoses and referrals under the authority of a trained physician (Radnofsky, 2015). The APA, in a series of reports, has described this new model as a collaborative between primary care providers and mental healthcare specialists:

Integrated mental health providers take on more consultative and team-based roles and focus on helping primary care providers treat mental health disorders, leveraging their skills and expertise to reach more patients in need. In addition, integrated care encounters are typically briefer and more problem-focused than traditional specialty mental health encounters. (APA–APM, 2016, p. 10)

In theory, this expanded care system might allow for greater diffusion of EEG–NFB.

The views of physician opinion leaders about the dangers relating to overmedication of ADHD children can affect diffusion of EEG–NFB (Rogers, 2010). American doctors have regularly tried to allay the public's concerns about this issue and have staunchly defended the use of psychostimulants such as Ritalin (Connor, 2011; Goldman, Genel, Bezman, & Slanetz, 1998). Since the late 1990s, drug prescription treatments for ADHD have increased substantially (Schwarz & Cohen, 2013). However, in the past 5 years, some sectors of the medical establishment have limited unrestricted prescriptions of Ritalin and other medications for preschoolers. In 2012, the American Association of Pediatrics instituted new guidelines that restricted drug treatments for ADHD to moderate-to-severe cases and only after parental behavioral treatments had failed (Smith, 2012). Still, these new guidelines appear to fall far short of the wider diagnosis and treatment restrictions that many doctors and mental health specialists in the Netherlands are seeking to institute for ADHD.



# **EEG–NFB** as Placebo

In recent years, many sham-controlled trials found EEG–NFB is not an effective treatment for ADHD in children, concluding that the benefits of NFB can be chalked up to placebo effects. Moreover, these studies have often been included and given more weight in reviews of the literature by organizations such as AAP, AAN, and third-party payers because they are randomized and double-blinded. Pigott, Cannon, and Trullinger (2018) dissected these six often-cited, sham-controlled studies and found that the authors of the studies each make some variation on the claim that subjects trained to self-modulate using the EEG and those in the EEG–NFB condition were unable to self-modulate above the control group. Therefore, since little difference exists between experimental and control groups, any benefits apparently enjoyed by patients using EEG–NFB are mere sham (i.e., placebo) effect.

However, the aforementioned reviews by third-party payers and medical professional organizations, which claim to have examined the literature on EEG–NFB as a treatment for ADHD in children, and those six sham-controlled studies themselves did not pick up on a significant methodological flaw in the independent variable of the active EEG–NFB condition. Pigott et al. (2018) determined that the findings of these six sham-controlled trials are invalid because the actual techniques used in these studies do not allow subjects to learn to self-modulate and because they are antithetical to behavioral conditioning. This error caused these researchers and clinicians to concluded a false no-effect, meaning they falsely concluded that there was no effect from EEG–NFB. They go on to point out a series of studies that demonstrate that the effects are not due to placebo, which were often ignored or downplayed in the position of medical professional organizations, third-party payers, other literature reviews, and meta-analyses focused on evaluating the validity of EEG–NFB as a treatment for ADHD in children.



Moreover, a recent meta-analysis highlighted the comparable effectiveness of EEG–NFB beyond active sham or placebo and close to that of stimulant medication at 2- to12-month follow-up (Van Doren et al., 2018).

Van Doren et al.'s (2018) recent broad meta-analysis vindicated EEG–NFB by proposing its effects are not likely due to placebo and appear to be as effective as stimulant medication, which is the most commonly accepted and used treatment for ADHD. One of the authors of this meta-analysis is Dr. Sandra Loo of the University of California, Los Angeles's Brain Research Institute. She has reversed her previous position that EEG–NFB is not effective in treating ADHD (Loo & Barkley, 2005). She is now declaring support for the treatment: "Neurofeedback (NF) has gained increasing interest in the treatment of attention-deficit/hyperactivity disorder (ADHD). Given learning principles underlie NF, lasting clinical treatment effects may be expected" (Van Doren et al., 2018, p. 293).

### Conclusion

These preliminary research observations point to a pressing need for in-depth, qualitative field research with Dutch and North American medical professionals and opinion leaders about the current status of ADHD and EEG–NFB adoption. With recent health regulatory and policy changes, and the ongoing structural reorganization of healthcare administration, the timing of this study was critical for examining influences on EEG–NFB diffusion in the Netherlands. The Netherlands will also provide an important research counterpoint to the United States, clarifying certain aspects of the model articulated by Rogers and later scholars.

While EEG–NFB's evidence base becomes increasingly consistent, it may take some time for practice to catch up with research. Without reduced treatment and hardware costs, improved protocols, greater physician support, and a stronger medical reimbursement



commitment, the current EEG–NFB underadoption rate is likely to continue. In some cases, government influence may actually speed up diffusion if opinion leaders have demonstrated the overwhelming need for a device.



# Chapter 3: Research Design and Method

### **Chapter Overview**

This chapter describes the research design and methods used in this study. To investigate the barriers to acceptance of EEG–NFB, the study utilized an embedded mixed-methods design, including a self-monitoring questionnaire, a vignette, and an interview. The five most common clinical professional categories responsible for diagnosing and providing treatment recommendations are the targeted population because they are the gatekeepers of medical innovation (Ferlie et al., 2005). These clinical professionals were psychologists, psychiatrists, pediatric neurologists, pediatricians, and primary care physicians. In studying the acceptance of EEG–NFB as a treatment for children with ADHD, the United States and the Netherlands were identified as two critical case countries with different medical governance types (Burstall, 1991; Giarelli, 2010; Moran, 1995, 1999, 2000) and, therefore, can be compared.

The sample size of this study was 18 medical professional respondents, 10 in the United States and eight in the Netherlands. These participants were interviewed to gain a comparative perspective on the pattern of innovation as well as barriers to adoption of EEG–NFB in the two countries. A mixed-methods research design captured the quantitative and qualitative dimensions of respondent attitudes toward ADHD treatment options, including their selection and ranking of EEG–NFB in relation to drug and behavioral therapies and the underlying influences shaping their reaction to medical innovations, generally, and to EEG–NFB, in particular.

#### **Research Questions/Hypotheses**

The primary issue addressed in this study is why, despite strong positive evidence for EEG–NFB, adoption rates of EEG–NFB in the treatment of ADHD in children remain low. The



main research questions guided an investigation into the structure and agency factors that shape medical adoption receptivity by five main groups of medical professionals in two different critical case countries, each with a different relationship to ADHD treatment. Agency factors relate to the personality characteristics of these professionals, for example, their degree of aversion to challenging accepted medical methods as well as their embeddedness in networks of like-minded professionals and their exposure to opinion leaders on preferred ADHD treatment options. Structure factors relate to broader influences on these same professionals, including institutional limitations on their medical decision-making autonomy and budget and insurance reimbursement constraints on their individual adoption and treatment options. For example, a high self-monitor and a more constrained institutional environment is a structure factor, and an example of an agency factor is a professional who decides individually to adopt an innovation regardless of whether or not it is encouraged by the structure but because the professional wants the innovation.

The quantitative questions were intended to gauge the level and ranking of medical professional support for EEG–NFB as an ADHD treatment option in relation to other options and the highest-ranking structure and agency factors influencing their treatment recommendations. The hypothesis was that most medical professionals would rank medication treatment higher than EEG–NFB regardless of their perception of the evidence base for EEG–NFB. Furthermore, those with a higher level of self-monitoring will be more influenced by structure factors and would be less likely than those more influenced by agency factors to recommend EEG–NFB as a treatment option and vice versa for those with a lower level of self-monitoring.

The qualitative questions were intended to clarify respondent survey answers to the quantitative questions. Respondents were probed about their professional training background



and prior exposure to EEG–NFB, past experience recommending or implementing EEG–NFB as a treatment option, current relationship to other ADHD treatment professionals, receptivity to learning about medical innovations, and the characteristics of their work environment that influence medical device adoption. The anticipation was that differences in personality and professional specialty, past and ongoing exposure to EEG–NFB, and constraints and opportunities afforded by work environments all play a role in shaping individual receptivity to adopting EEG–NFB as an ADHD treatment option.

Based on the research questions, the investigation concluded with a hierarchy map (Rogers, 2010) of understanding the barriers leading to the underadoption of EEG–NFB in relation to each other, the impact of medical specialty, and the impact of country of practice. The map set the stage for future research investigations that explore these associations with larger and more statistically representative samples of ADHD-related medical professional groups and further comparative investigations across countries to lead to a structural network analysis (Lorenz, 2009).

### **Research Design**

This study utilized a concurrent embedded mixed-methods research design that allowed for the collection and integration of quantitative and qualitative data (Bazeley, 2010; Creswell & Clark, 2011). The quantitative data collected revealed the participants' levels of self-monitoring, the number of practitioners in the total sample who recommend EEG–NFB as a treatment, their ranking of EEG–NFB in relation to other treatments, the number of structure and agency factors deemed to influence their assessment, and their ranking of these same factors. These numbers resulted in the generation of primarily descriptive statistics that gave a numerical sense of the weight of EEG–NFB in practitioner-recommended treatment options for ADHD and the weight



of the different factors in shaping their recommendation. Inferential statistics were used to analyze the relationship between self-monitoring and the impact of structure and agency factors on the decision-making process.

A mixed-methods quantitative/qualitative research design was selected for its logistical and methodological advantages over a stand-alone quantitative or a qualitative research design. A stand-alone quantitative design might have involved a large random sample survey of medical professionals using a standardized questionnaire. The potential advantage of this approach would have been the ability to generalize about attitudes regarding EEG–NFB in the sample toward the total universe of medical professionals. However, to be time efficient, administering a survey of this kind would have required the use of online or random-digit telephone dialing methods, the costs of which can be prohibitive. Survey administration of this kind, unless conducted online, would also have made it more difficult for the respondent to review the vignette in detail. In general, face-to-face interviewing allowed for a more intimate interview process to establish the trust that can enhance survey validity and decrease the potential for social desirability bias (Green & Crosnick, 1999).

A qualitative methods-only research design was also rejected for this study. As a rule, a qualitative study sacrifices breadth for depth. Fewer respondents would have been interviewed. Furthermore, the study would preclude the ability to gauge the degree of statistical reliability or representativeness of this smaller sample. A qualitative approach would not have allowed the study to gauge which professional specialties tend to be most receptive to EEG–NFB or to make other important preliminary quantitative determinations as to the rank order of EEG–NFB as a treatment option and the mix of structure and agency factors that shape adoption perspectives.



Numerous studies have pointed to the advantages of a mixed-methods research design, generally (Creswell & Clark, 2011), and for health research, specifically (Morgan, 1998). The study's mix of qualitative and quantitative methods allowed for two different modes of data collection to amplify and reinforce each other's results. The quantitative data discriminated clear patterns in the results; the qualitative inquiry explored the causes and reasons for this pattern. On balance, a mixed-methods design offered the prospect of an expanded breadth and depth of explanation. For this kind of an investigation, a mixed-methods design is superior to a quantitative-only or qualitative-only research design.

One quantitative instrument was a questionnaire exploring ADHD treatment options. Respondents read a one-paragraph vignette that described a 7-year-old boy with ADHD symptoms. Then they selected or suggested their own options to treat the child from the vignette. Respondents were offered a menu of survey options and asked to rank which they would consider applying as treatment for the boy's condition. They could also add in other treatments that they would consider if they were not on the list. A second quantitative instrument was a 25-item, true–false questionnaire that asked participants about their views toward structure and agency factors in determining their approach to treatment options. Another quantitative instrument was the list of influential factors generated during the interview process. These were weight ranked with participatory ranking. On the basis of the responses to these instruments, descriptive statistics provided an understanding of what responses were given by the participants. The qualitative portion of the study was a semi-structured interview to gain more in-depth analysis of the motivations and influences that shaped respondent treatment recommendations.



# **Population and Sample**

The population of this study consisted of five groups of medical professionals that diagnose or treat ADHD patients, including psychiatrists, psychologists, neurologists, pediatricians, and primary care physicians. The sample was obtained via convenience sampling and snowballing after the initial plan discussed in Chapter 1 was not yielding any participants. There were a total of 18 participants, 10 from the US and eight from the Netherlands. Participants were obtained based on their qualifications as one of the medical professionals identified earlier in the paragraph and their availability and willingness to complete the survey process. In addition, respondents demonstrated experience with patients under the age of 18 and with ADHD treatment options by having assessed or treated someone under 18 with ADHD in the past year. It was not necessary that all respondents have past experience with EEG–NFB.

# Procedures

Convenience sampling was utilized for obtaining participants for the study. Some of those participants also shared the information about the study with others they knew. Therefore, snowball sampling was also used to obtain participants. The initial convenience sample consisted of medical professionals in the five specialties of interest known by the primary investigator.

The data collection consisted of quantitative measures collected concurrently and embedded at various points during the qualitative interview. Therefore, the data collection occurred in a series of steps, which took a maximum of one hour to complete:

 The participant was given an overview of the goals and objectives, interview, and survey process, and written consent was obtained to participate in the study and allow it to be recorded via iPad.



- The participant completed a 25-item, true–false, self-monitoring questionnaire that queried respondents about their views toward structure and agency factors in determining their decision-making process (Snyder, 1974).
- 3. A one-paragraph vignette that described a 7-year-old boy with ADHD symptoms that is commonly used for medical training was administered to the participant (Epocrates, 2016). The participants first selected which treatments from the list they would recommend for the child in the vignette and any others that they would recommend that were not included in the list of options given to them. The participants were then asked to rank their selected treatment recommendations as first, second, third, and so on for treatment for the boy's condition.
- 4. The participants were asked how they decided which treatments the child with ADHD should be referred for and specifically what they took into consideration when making the decision during the vignette. Some examples of identified factors were their knowledge about the treatments they recommended, their understanding of the research supporting the treatments, their professional organization's recommendations, success they have had with that treatment being used with other patients, personal experience with those treatments, organizational structures that encourage certain treatments over others, and other possibilities. Each identified factor was probed further to determine whether or not these factors are adherence to structure, agency, or both. The factors identified by the participant were kept track of by the interviewer, and any that were novel were put on an index card by the primary investigator at that time.



- 5. Predesigned and customized index cards were placed on the table in front of the participant in random order. In addition, the participants were provided with each of the identified influential factors in the participant's decision-making process. The participant was given 10 coffee beans and asked to place them next to the factors that had the most influence in their decision about what treatments to refer the child for in the vignette. The participant was informed that they could place all of the coffee beans on one influencer or split them up but that the strongest influencer should have the most coffee beans next to it, the second strongest should have the second most coffee beans, and so forth. However, each coffee bean must be placed during the process and there should be none left over. This participatory ranking method generated a weighted rank for the impact of the influencers.
- 6. The participant was asked to speak about EEG–NFB and its use in treating ADHD in children. The participant was asked to discuss it in relation to their highest ranked influencer, then second highest, then third and so on until the maximum time was reached for the study or there was nothing further that the participant was willing to share on the topic.
- 7. The participant was provided a debriefing sheet and thanked for his or her participation in the study. The basic terms of the informed consent were also restated. The participants were informed that after the conclusion of the PhD defense, the participants were able to view the dissertation research study through its publication in Proquest and encouraged to share their comments and reflections.



### Validity

Survey validity is a fundamental problem that arises in all qualitative research (Lincoln & Guba, 1985). Despite the difficulty of applying the same rigorous standards of validity from quantitative to qualitative research, this investigation ensured the trustworthiness and credibility of the findings with a number of techniques acknowledged in this type of applied research (Noble & Smith, 2015). First, the same structured interview format, with the same sequence of questions, was used for all participants to ensure a broad uniformity in the survey process. Second, the recording of participants' responses ensured that they are documented word for word. Third, all of the interviews were transcribed in typewritten form.

## Instrumentation

The study used three instruments:

- A one-paragraph vignette that described the ADHD conditions of a 7-year-old boy. After the reading of the vignette, there was a questionnaire asking respondents to identify and rank their recommended treatments for the described condition.
- A 25-item, true–false, self-monitoring questionnaire that measured respondent attitudes toward social acceptance and individual autonomy and their propensity for independent thought and action in their personal and professional life.
- A semi-structured interview to gain more in-depth analysis of the motivations and influences that shape respondent treatment recommendations and personality characteristics.

The vignette is a standard tool used in medical training to prepare clinicians to treat ADHD (Epocrates, 2016). It offered a clear description of a 7-year-old boy with the characteristic symptoms of hyperactivity and impulsivity that define the disorder. The use of a



7-year-old boy allows for consideration of all available treatment options. Younger children, below the age of 6, may or may not be prescribed drug stimulant therapy and/or treated with EEG–NFB. While the vignette is not widely employed in ADHD research, it provides an effective common standard for assessing treatment options without introducing selection bias.

The 25-item, self-monitoring questionnaire was first developed by Snyder (1974), ostensibly to distinguish basic personality types as either highly reactive to the opinions of others or more inner-directed (Snyder, Berschedi, & Glick, 1985). Numerous other scholars have applied the model and the results to determine the likelihood that consumers will try a new product or remain brand loyal (Ha, 1998) or whether employees will share new knowledge or rely on received opinion (Ho, Hsu, & Oh, 2009). In the context of this study, the self-monitoring questionnaire assessed the propensity of medical professionals to share new evidence about ADHD treatment options, especially EEG–NFB (Epstein et al., 2008; Snyder, 1979, 1987). Hypothetically, the medical professionals who demonstrate a greater affinity for established norms and choices would also be more likely to recommend existing drug stimulant and behavioral therapies over an innovation like EEG–NFB.

The structured interview format was adapted from qualitative instruments used in other studies that have assessed the role of physicians in medical innovation (Zeuner, Frosch, Kuzemchak, & Politi, 2015). Participants were asked about their backgrounds as medical professionals, their training in ADHD, their affiliations and membership in physician networks, their past and present medical employment settings, their experience with medical adoption, and their knowledge and beliefs about EEG–NFB. For those with EEG–NFB experience, details about their adoption experience were probed.


### **Data Analysis**

This study used SPSS to provide descriptive statistics and correlations. The tests for difference of means were Tukey-Duckworth tests (Tukey, 1959) that are hand calculated. These statistics sought to describe the participants and their responses. They also assessed for associations and differences among the participants on some responses to understand the adoption of medical innovation and specific ADHD treatment options with children, including EEG–NFB. These statistics were used to evaluate the research questions and hypotheses about structure and agency factors and country in which the participant practices.

Leximancer qualitative analysis software was used to identify key themes, concepts, and word choices used by respondents during the structured interviews. In recent years, Leximancer has been validated as a powerful qualitative research tool (Smith & Humphreys, 2006). According to Watson, Smith, and Watter (2005), Leximancer's concept map "shows the importance of concepts and the relative co-occurrence of these concept" (p. 1234). The concept maps are useful for initial levels of investigation as well as uncovering textual relationships that may not have been as apparent initially (Watson et al., 2005). Leximancer allowed close attention to be paid to the characterization of the adoption and current status of EEG–NFB as a treatment for ADHD in children. A Leximancer analysis works by capturing the number of times one or more factors are mentioned and their relationship to each other, amplifying other parts of the survey analysis.

With the assistance of Leximancer, some conclusions with the integration of the quantitative and qualitative findings were possible. Data integration followed guidelines established by Bazeley (2012), who argued that integrating distinct data sources is a "critical feature" of mixed-methods studies, noting, "While different models of integration are



appropriate for different research settings and purposes, an overcautious approach to integration can generate invalid or weakened conclusions through a failure to consider all available information together" (p. 2). The optimal integration of different but complementary sources occurs during the composition of results and conclusions, which ensures that their focus is on the topic rather than the data source (Bazeley & Kemp, 2011).

The interviews were taped and held in an encrypted format. They were kept confidential and transcribed by a research interview transcription service where any identifying information was removed. Then the text data was entered into the Leximancer system for analysis and findings. Answers to the two questionnaires were entered into SPSS and stored on a laptop. No names were used as descriptors; instead, the code name of each respondent was substituted. After the completion of the study and the defense of the dissertation, the recorded interviews and the notes from the interviews will be retained for 5 years prior to their destruction.

#### Assumptions

The study assumed a number of characteristics about the respondents. First, the participants were committed fundamentally to the need for an evidence base for ADHD treatment options, even if they have different interpretations of what that evidence suggests. Second, the respondents have kept abreast of the latest research on ADHD treatment options, read medical journals on ADHD, or have ongoing contact with other medical professionals who are opinion leaders in the field. Third, they were not constrained by private commercial self-interest. For example, the respondents were not receiving special incentives or pay from major drug companies or from EEG–NFB manufacturers to push their products as treatment options for ADHD in such a way that might skew their independent medical judgment. Assumptions were also made about the basic reliability of the information being provided by respondents who cited



incidents or facts about their ADHD treatment experience that cannot be verified independently. However, this is an inherent limitation of every self-reported survey or interview; this study was hardly unique in this regard. Respondents were encouraged at the outset to be as frank and truthful as possible.

#### Delimitations

The final sample included a disproportionate number of respondents that are completely unfamiliar with EEG–NFB. This suggests that a level of underadoption would have to be factored into the interview probing of these respondents. The study was limited to two designated research sites in two large cities and surrounding areas in two contrasting countries. The choice of the research sites was purposive in nature based on budget and time constraints. Washington, DC was the location of the university campus for the primary investigator. Utrecht, Netherlands is where research support and collaboration was possible. These choices invariably introduced a measure of selection bias. Medical professionals who work with ADHD patients in large metropolitan areas, specifically these two cities, may not be representative of medical professionals in either country, especially in more isolated rural areas. For example, some regions of the United States may feature a large number of ADHD treatment professionals who have adopted EEG–NFB. Differing views of EEG–NFB adoption may have been provided were the field research based in different geographical areas of the United States. The same is likely true of other geographical areas in the Netherlands.

The two countries were chosen because of their strong research and practice histories with EEG–NFB, particularly in the treatment of ADHD in children, making them critical cases for comparison. The specific cities of Washington, DC, and Utrecht, Netherlands, were chosen because they are the universities supporting the research. Therefore, drawing inferences from



the data collected at these two sites about trends in the United States and the Netherlands at large is risky (Banerjee & Chaudhury, 2010). Despite the sample size and diversity of medical professionals involved, study results still point to important comparative differences in EEG– NFB adoption rates between the two countries, especially when accompanied by broad differences in magnitude in the quantitative results. However, statistics for subsample comparisons may have limited reliability.

In the strictest sense, this study compared adoption trends in two different cities that may not fully represent the broader trend among medical professionals in the United States and the Netherlands. The qualitative interviews helped offset this limitation by including self-reporting by respondents in each country about their knowledge of trends elsewhere. Through their physician associations and professional networks, and through interactions with medical opinion leaders, respondents were likely to have substantial information about adoption trends by medical professionals in other cities.

### **Ethical Assurances**

All reasonable and possible measures were taken to protect and guarantee the confidentiality of all survey respondents. Only the researcher knows the actual names and occupational specialties of interview participants. The researcher maintains a master list that links each name to a code number. Without the master list, it is impossible to link these sheets to any participant's identity. The list is being maintained on a password-protected file on his laptop computer. No one else has access to the same computer, and the file will not be transmitted by email or stored on a separate drive other than the hard drive. The laptop computer is also stored in a secure location at all times.



Prior to the administration of the interview and questionnaires, participants were provided with an informed consent document for their signatures. The document established the project's commitment to guaranteeing the confidentiality of all participants and set out the means by which confidentiality will be maintained. It stipulated that the process is impartial and no penalties, including the threat of disclosure, will be imposed for any of the views and opinions expressed by participants. In addition, the document clarified that the participant was not required to answer any question with which he or she might be uncomfortable and was free to withdraw from the survey at any time for any reason, without explanation, by simply communicating that decision to the primary investigator.

A slight risk exists that the survey process could have inadvertently triggered negative reactions from respondents about their diagnosis and treatment of ADHD patients or about the topic of ADHD and its diagnosis and treatment generally. Some respondents might have also felt uncomfortable with the list of treatment options, the 25 items on the true–false questionnaire, or the types of questions being posed and probed during the structured interviews. This investigation touches on the possibility of adopting a new medical device and procedure more widely, and some medical professionals already have strong views about how to diagnose and treat ADHD that do not include EEG–NFB. At all times a spirit of scholarly objectivity and nonjudgment was conveyed toward all participant viewpoints, which were based on their professional experience and medical expertise.

The Chicago School of Professional Psychology Institutional Review Board (IRB) and Utrecht University reviewed the protocols of the survey process. Contact information for the IRB was provided to the participants to allow them to verify that all of the research protocols



were being observed and to alert the IRB to any violations that may have occurred or any other concerns that may have arisen.

#### Summary

This dissertation intended to explain why, despite a growing evidence base for its use as a treatment option for ADHD, EEG–NFB remains underadopted. In doing so, it also identified some main factors that appear to explain the variation in EEG–NFB adoption rates in two leading countries for its adoption—the United States and the Netherlands. The study employed a mixed-methods research design to collect quantitative and qualitative data from a sample of medical professionals in each country and across the five main occupational specialties that diagnose or treat ADHD. Validated instruments and an interview were used to collect the survey data: a vignette with an accompanying short-answer questionnaire, a 25-item, true–false questionnaire, and a semi-structured interview.

Participants were queried about the personal, professional, and structural influences that shape their ADHD treatment preferences as well as their attitudes toward medical innovation and adoption of EEG–NFB as a treatment option. Patterns of variation in the survey results were identified and relationships between variables tested statistically using SPSS or hand calculations. A concept map was created to depict graphically how influences of various types combine to shape respondent EEG–NFB adoption attitudes and decisions. All data collection methods were collected and are maintained in a way to protect the confidentiality of participants in accordance with approved IRB ethical research requirements. The next chapter presents the results of the study.



## Chapter 4: Results

This chapter discusses the results of the transformative mixed-methods research (Creswell & Clark, 2011) used to understand and evaluate the decision-making process of mental health professionals when recommending treatments for ADHD. Also included is a comparison of data collected from the United States and the Netherlands. The study targeted mental health professionals who most commonly treat ADHD: primary care physicians, psychiatrists, psychologists, neurologists, and pediatricians. All 18 participants—10 from the United States and 8 from the Netherlands—completed a semi-structured interview that contained quantitative instruments such as a vignette and a self-monitoring scale. The transcript of the interview, specifically the final questions regarding EEG–NFB for the treatment of ADHD, was the source for the qualitative data. Findings revealed that the majority of the practitioners are intermediate self-monitors with the low self-monitoring group occupying a close second. In addition, most practitioners responded to the vignette by recommending diet and exercise. Study results also showed that research agency and knowledge agency were the strongest influences on the practitioners' decision-making process.

## **Data Collection Settings**

The interviews were collected over a period of 2.5 months, February to May 2018. Participants were recruited via convenience sampling and snowballing. U.S. participants were interviewed between February 23 and March 27, 2018. All were practitioners licensed in 2018 in Maryland and based within 100 miles of Washington, DC. Permission to collect data in the Netherlands was obtained through Utrecht University, and Dutch practitioners were interviewed between April 17 and May 8, 2018 at their clinical offices.



## **Demographics**

The ten U.S. interviewees included three primary care physicians, three psychologists, two psychiatrists, and two neurologists. The Dutch interviewees consisted of six psychologists, one primary care physician, and one pediatrician. All participants were familiar with EEG–NFB. All of the participants can be considered *highly aware* of EEG–NFB, with 50% practicing neurofeedback themselves, 28% referring clients for EEG–NFB, and 22% who have heard of EEG–NFB but do not practice it or refer clients for it.

## **Quantitative Data**

The quantitative data included three items: (a) responses to the self-monitoring scale, (b) the selection and ranking of treatments from the vignette, and (c) the identification and weighting of the influencing information.

- a. The primary researcher administered the self-monitoring scale (Snyder, 1974) by reading statements to the participant who answered "true" or "false." The sum of all 25 questions generated the self-monitoring scale variable score called "SelfMonitor."
- b. The vignette of a child with ADHD (Epocrates, 2016) was read by the primary investigator and generated two data categories: the frequency of recommended alternative treatments and the ranking of these treatments by the practitioners according to which they would recommend first, second, third, and so forth. The mean score for each treatment represents the ranking it received in comparison to the other treatments, with a lower score meaning the treatment was more strongly recommended than other treatment options.
- c. Interviewees were asked probing questions about what factors affected their treatment recommendations for the purpose of identifying whether their recommendations were



due to structure, agency, or both. How much weight structure factors had versus agency factors was calculated by subtracting the sum of the agency weights from the sum of the structure weights. The resulting variable, called "StructureAgencyWeight," consisted of a single score with a higher number signifying more influence by structure factors and a lower number signifying more influence by agency factors.

The comparison between the U.S. and Dutch samples was conducted using the Tukey-Duckworth test for differences between the two samples (Tukey, 1959). This is a nonparametric conservative test. This study used the revised and extended tables with a critical value for an alpha level of .10 for significance (Gans, 1981). Depending on what was being compared, different lines of the table were used as per the instructions.

Self-monitoring scale. The results of the self-monitoring scale are presented in three sections and summarized in Table 1. Overall, seven of the participants scored as low self-monitors (scores from 0 to 8), eight as intermediate (scores from 9 to 14), and three as high self-monitors (scores from 15 to 25). The overall group had a mean of M = 9.22, SD = 4.89. Thus, the mean for all participants combined would be an intermediate score, according to the norms (Ickes & Barnes, 1977), though at the bottom end of the intermediate range, which has a minimum cutoff of 9.

Applying the same norms and analysis to the U.S. participants yielded two low selfmonitors, six intermediate self-monitors, and two high self-monitors. The mean was M = 9.60, SD = 4.43, which places the U.S. contingent in the intermediate self-monitor category with slightly more confidence than for the overall group due to the higher mean and smaller standard deviation. The Dutch contingent had five low self-monitors, two intermediate self-monitors, and



one high self-monitor. The mean was M = 8.75, SD = 5.70, which places the group in the intermediate self-monitor category but barely so (see Table 1).

### Table 1

Self-Monitoring Frequencies, Means, and Standard Deviations

			Normative Frequency			
	М	SD	Low	Mid	High	
Full Sample	9.22	4.89	7	8	3	
United States	9.60	4.43	2	6	2	
Netherlands	8.75	5.70	5	2	1	

M=Mean; SD=Standard Deviation

**Vignette responses.** The results of the treatment recommendations yielded by the vignette of a child with ADHD were also analyzed in three groupings: overall, the US, and the Netherlands. Two variables are reported for each and the findings are summarized in Table 2: the frequency of each of the recommended options and the mean and standard deviation for the rank of each treatment option. A lower score on the mean identified treatments that are more highly recommended, and vice versa.

*Overall findings.* For the entire group of 18 participants, the most recommended treatment options with over 14 participants selecting them in descending order were diet, exercise, stimulant medication, EEG–NFB, behavior therapy, and cognitive behavior therapy. All these options were on the list available to every participant with none being add-ons by the participants. The most highly recommended treatments in descending order were EEG–NFB, behavior therapy, and stimulant medication.

The moderately recommended treatments, selected in descending order by between nine and five of the participants were selective norepinephrine reuptake inhibitor, family therapy, school-based intervention, sleep hygiene, and supplements. The selective norepinephrine reuptake inhibitor was the only option that appeared on the list of predetermined treatment



options with the rest added by the interviewees. The most highly recommended of these treatments from highest to lowest were sleep hygiene, school-based intervention, family therapy, supplements, and selective norepinephrine reuptake inhibitor.

The least recommended treatment, with less than three participants selecting them, was hypnotherapy. Alpha agonists, sensory integration toolkit, and probiotics were the next lowest. Passive infrared spectrography NFB, heart rate variability feedback, mood stabilizers, buproprion, tricyclic, occupational therapy, yoga/martial arts, meditation, relaxation training, psychodrama, group therapy, and homeopathy were each selected by only one participant. Finally, selective serotonin reuptake inhibitor was the only treatment that did not receive a recommendation even though it was on the predetermined list offered to each of the participants. The participants added all of the other treatments in this group. Since the number of participants recommending these treatments is low, the means and standard deviations, when possible, are only reported in Table 2.

*Findings from participants in United States.* The most recommended treatment options by the ten U.S. participants were diet, stimulant medication, and behavior therapy, with all participants recommending each of them. Nine participants recommended EEG–NFB and exercise. Eight recommended cognitive behavior therapy. The most highly recommended of these treatments in descending order were behavior therapy, EEG–NFB, stimulant medication, cognitive behavior therapy, diet, and exercise.

Among the moderately recommended treatments, five participants recommended selective norepinephrine reuptake inhibitor, four recommended family therapy and school-based intervention, and three recommended sleep hygiene and supplements. The most highly recommended in descending order were sleep hygiene, school-based intervention, family



therapy, supplements, and selective norepinephrine reuptake inhibitor. The remaining recommendations were low and can be found in Table 2.

*Findings from participants in Netherlands.* The most recommended treatment options by the eight Dutch participants were diet and exercise, by all eight. Seven recommended EEG–NFB and stimulant medication. Six recommended cognitive behavior therapy. The most highly recommended in descending order were EEG–NFB, exercise, cognitive behavior therapy, diet, and stimulant medication.

The moderately recommended treatments were behavior therapy and family therapy by five participants, a selective reuptake inhibitor by four, and sleep hygiene and hypnotherapy by three. The most highly recommended of these treatments in descending order were sleep hygiene, behavior therapy, family therapy, selective norepinephrine reuptake inhibitor, and hypnotherapy. The remaining recommendations were low and can be found in Table 2.

**Influencing factors.** The factors that most influenced the vignette treatment recommendations of all 18 participants from most common to least were research agency, knowledge agency, research structure, professional success agency, individual circumstances agency, employer recommendations structure, and knowledge structure.



# Table 2

	TOTAL			US			DUTCH		
	М	SD	F	М	SD	F	М	SD	F
Stimulants	5.65	3.76	17	4.70	2.54	10	7.00	4.93	7
CBT	5.43	3.41	14	5.38	2.67	8	5.50	4.51	6
BT	3.67	2.53	15	3.40	2.41	10	4.20	2.95	5
Hypnosis	10.67	3.21	3	_	_	_	10.67	3.21	3
SNRI	8.33	3.35	9	7.40	2.30	5	9.50	4.44	4
EEG–NFB	3.31	1.82	16	3.56	1.24	9	3.00	2.45	7
Diet	5.00	2.74	18	5.60	3.41	10	4.25	1.49	8
Exercise	5.35	1.94	17	6.22	1.64	9	4.38	1.85	8
Supplements	6.00	3.24	5	6.33	4.51	3	5.50	0.71	2
PIR-NFB	5.00	_	1	5.00	-	1	_	_	_
MS	9.00	_	1	9.00	_	1	_	_	_
SA	3.17	2.04	6	2.25	0.96	4	5.00	2.83	2
FT	5.00	3.39	9	3.50	2.52	4	6.20	3.77	5
AA	5.50	0.71	2	5.50	0.71	2	_	_	_
Buproprion	11.00	_	1	11.00	-	1	_	_	_
SH	1.50	1.23	6	1.00	0.00	3	2.00	1.73	3
Trycyclic	10.00	—	1	10.00	_	1	_	_	_
ОТ	9.00	_	1	9.00	-	1	_	_	-
ST	11.50	6.36	2	7.00	_	1	16.00	_	1
Y&MA	8.00	_	1	8.00	-	1	_	_	_
Meditation	5.00	_	1	5.00	-	1	_	_	_
RT	6.00	_	1	_	-	_	6.00	_	1
PD	9.00	_	1	_	-	_	9.00	_	1
GT	11.00	_	1	_	-	_	11.00	_	1
Priobiotic	3.00	1.41	2	_	-	_	3.00	1.41	2
HRV-BFB	7.00	_	1	_	-	_	7.00	_	1
РТ	11.00	-	1	-	-	_	11.00	-	1
CFN	5.00	_	1	_	_	_	5.00	_	1
ILS	12.00	_	1	_	_	_	12.00	_	1
Homeopathy	13.00	_	1	_	_	_	13.00	_	1

Vignette Treatment Frequency, Rank Mean, and Rank Standard Deviation

Note. M=Mean, SD=Standard Deviation, F=Frequency, CBT=Cognitive Behavior Therapy, BT=Behavior Therapy, SNRI=Selective Serotonin Reuptake Inhibitor, PIR-NFB=Passive InfraRed Neurofeedback, MS=Mood Stabilizer, SA=School Accomodations, FT=Family Therapy, AA=Alpha Agonist, SH=Sleep Hygiene, OT=Occupational Therapy, ST=Sensory Toolkit, Y&MA=Yoga and Martial Arts, RT=Relaxation Training, PD=PsychoDrama, GT=Group Therapy, HRV-BFB=Heart Rate Variability Biofeedback, PT=Play Therapy, CFN=Functional Neurology Chiropractice, ILS=Integrated Listening Systems.



For the U.S. participants, the most identified in descending order were research agency, research structure, professional success agency, personal experience agency, employer organization recommendations structure, and knowledge agency. For the Dutch participants, the most identified in descending order were individual circumstances agency, knowledge agency, research agency, and knowledge structure. The full results are in Table 3.

For the total sample of 18 participants, the most weighted factors in descending order were individual circumstances agency, research agency, employer organization recommendations structure, knowledge agency, knowledge structure, professional success agency, and research structure. The factors that had the most influence on the ten U.S. participants in descending order were research agency, knowledge agency, professional success agency, personal experience agency, employer organization recommendations structure, and research structure. For the Dutch participants, the most influential factors in descending order were individual circumstances agency, research agency, knowledge structure, and knowledge agency. The full results are in Table 3.

Inferential statistics. The inferential quantitative analysis was conducted in two ways. First, the Tukey-Duckworth statistical test was used to compare the U.S. and Dutch samples. This test was used because the size for each of the samples is between 4 and 80, and there was no ratio between the two samples acceptable for comparison. Tukey-Duckworth tests the null hypothesis of no differences in the distributions of the two samples and is used when sample sizes are small.

The second inferential statistic was a Spearman correlation. Each of the dependent variables was a ranked score, making the Spearman correlation the most appropriate correlation test. It was conducted to assess the impact of personal self-monitoring on the clinical decision-



making process. The assessed correlations were between self-monitor score, structure agency structure agency weight score, vignette EEG–NFB rank, vignette stimulant rank, and vignette behavior therapy rank.

# Table 3

Influencing Factors: Frequency, Rank Mean, and Rank Standard Deviation

	TOTAL			US			DUTCH		
	М	SD	F	М	SD	F	М	SD	F
Structure									
KN	1.30	1.06	10	1.00	0.92	4	1.50	1.05	6
RE	0.79	1.12	14	0.56	0.73	9	1.20	1.64	5
PO	0.17	0.41	6	0.17	0.41	6	_	_	_
PS	1.11	1.45	9	1.60	1.82	5	0.50	0.58	4
PE	0.00	0.00	6	0.00	0.00	5	0.00	_	1
ER	1.45	2.02	11	0.75	1.75	8	3.33	1.53	3
IR	0.00	0.00	2	0.00	_	1	0.00	_	1
PC	1.00	1.00	7	0.75	0.96	4	1.33	1.16	3
IC	0.13	0.35	8	0.00	0.00	4	0.25	0.50	4
Agency									
KN	1.33	1.11	15	1.38	0.92	8	1.29	1.38	7
RE	1.59	1.12	17	1.40	0.70	10	1.86	1.58	7
РО	0.75	0.71	8	0.86	0.69	7	0.00	_	1
PS	1.14	0.86	14	1.22	0.67	9	1.00	1.23	5
PE	1.00	0.50	9	1.13	0.35	8	0.00	_	1
ER	0.43	0.54	7	0.40	0.55	5	0.50	0.71	2
IR	0.50	0.71	2	1.00	_	1	0.00	_	1
PC	1.00	0.71	9	1.40	0.55	5	0.50	0.58	4
IC	2.14	1.51	14	2.00	1.27	6	2.25	1.75	8

Note. M=Mean, SD=Standard Deviation, F=Frequency, KN=Knowledge, RE=Research, PO=Professional Organization recommendations, PS=Professional Success, PE=Personal Experience, ER=Employer Recommendations, IR=Insurance Reimbursement, PC=Patient Choice, IC=Individual Circumstances.



**Comparison of U.S. and Dutch findings.** *The t* values for the Tukey-Duckworth test are presented in Table 4. The distribution of self-monitoring scores was not significantly different between the U.S. and Dutch samples, meaning that the self-monitoring was similar. A similarity also exists between the U.S. and Dutch samples in the rankings for EEG–NFB and all other testable treatment rankings for the vignette. Finally, the two samples are similar in the sum of weights assigned to structure and agency influencing factors. The U.S. and Dutch samples appear to be similar, or at least not significantly different, in every testable quantitative factor examined in this study.

Table 4

	Т
Self-Monitor	1.5
S-A Weight	4.5
Vignette	
EEG–NFB	2.5
Stimulants	3.0
CBT	1.5
BT	1.5
SNRI	2.5
Diet	5.0
Exercise	5.5
FT	3.5

U.S.-Dutch Comparison Tukey-Duckworth Tests

Note. Alpha=.10 for significance. *EEG–NFB=EEG neurofeedback, CBT=Cognitive Behavior Therapy, BT=Behavior Therapy, SNRI=Selective Serotonin Reuptake Inhibitor, FT=Family Therapy.* 

# Self-monitoring and decision-making. The impact of personal self-monitoring on

professional decision making was assessed with Spearman correlations. The correlations were

conducted to assess if self-monitoring affects a series of other variables:

StructureAgencyWeight, Stimulant Medication, EEG-NFB, behavior therapy, and SNRI. The

significance of the correlations was adjusted with a Bonferroni correction because multiple



correlations were conducted. None of these correlations were significant, meaning that personal self-monitoring did not have a significant impact on the professional decision making in this sample. The correlation results are presented in Table 5.

## Table 5

	Self-Monitor	S-A Weight	Stimulants	EEG–NFB	BT	SNRI
Self-Monitor	_					
S-A Weight	-0.28	_				
Stimulants	0.13	0.31	_			
EEG-NFB	-0.08	-0.06	-0.28	_		
BT	-0.15	0.22	-0.06	-0.10	_	
SNRI	-0.44	0.67	0.83*	-0.03	-0.08	_

*Correlations: Bivariate Spearman Statistic for Self-Monitoring with Vignette Decision and Structure–Agency Influencing Factors* 

Note. \*Marks significance at Alpha  $\leq$  .05 after Bonferroni correction. *S*–*A Weight=StructureAgencyWeight*, *EEG–NFB=EEG Neurofeedback*, *BT=Behavior Therapy*, *SNRI=Selective Serotonin Reuptake Inhibitor* 

# **Qualitative Analysis**

The qualitative data consist of the participants' responses to the final questions of each interview, which pertained specifically to EEG–NFB. The interviews were initially transcribed into Temi (Version 2018), an automated transcription service. The primary investigator then went over the transcript of each interview word for word while listening to a recording of the interview to correct any errors. Before uploading the data into Leximancer, the transcripts were divided into multiple levels to generate more specific analytical comparisons. The first layer divided the transcripts among the eight influencing factors: professional organization recommendation, employer recommendation, personal experience, knowledge, patient choice, research, professional success, and individual circumstances. The second layer further divided the transcripts between the agency and structure aspects of each influencing factor. The third



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layer of separation was between the U.S. and Dutch samples. The fourth and final layer was separation of the interviews according to medical or professional specialty: psychologist, neurologist, primary care, psychiatrist, and pediatrician.

The layered data was uploaded into Leximancer for word content analysis and to extract common themes. A custom concept map was created in Leximancer by manually setting all parameters of the analysis in three multistep stages that manually identified compound concepts and adjusted the parameters for the concept coding and project output. Three different settings were used to generate three different concept maps that illustrate and summarize the qualitative content analysis of the interview questions about EEG–NFB.

**Primary concept map.** As illustrated in Figure 1, and as expected, *neurofeedback* is the most central concept in this analysis, since it is the most present concept in the interviews. The next largest concepts are: *effective*, *research*, *people*, *patients*, *treatment* and *ADHD*. These terms were almost always referenced in context with each other, suggesting a strong degree of dependence and interaction.

Five concepts that were independent and directly connected to *neurofeedback* are *important* connected through *ADHD*, *understand* connected through *research*, *problem* connected through *effective* and *ADHD*, *change* connected through *effective*, and *use* connected through *practice* and *knowledge*. The *understand* concept overlapped the *research* concept with *neurofeedback*. The *problem* concept also contained *need* and *brain*, which were outside the sphere of *neurofeedback*.

*Brain* and *need* were connected to *effective*, which is inside the *neurofeedback* concept, and *problem* was connected through *ADHD*, which is also inside *neurofeedback*. The *change* concept also included *feel*, but only *change* was directly connected to *effective* within



*neurofeedback*. Finally, the *use* concept also contained *practice* and *knowledge*, which were directly connected to and overlapped with *neurofeedback*. The conclusion is that these five concepts were often invoked in connection to concepts usually used with *neurofeedback*, but not always.



# Figure 1. Primary concept map.

Two independent concepts were indirectly connected to *neurofeedback*. One was *time*, which also contained *certain*, *school*, and *better*. The *time* concept was connected to *change* through *better* before passing from *change* into *neurofeedback* through the *effective* concept. The other independent concept was *people*, which also contained *sense*, *try*, *experience*, and *feel*.



There were two indirect connections for the *people* concept to *neurofeedback*. One connected *people* to *change* through the overlapping concept of *feel*, and then from *change* into *neurofeedback* through the *effective* concept. The other connected the *try* concept within *people* to the *use* concept that connected to *practice*, which, in turn, overlapped with *neurofeedback*. This means that these two concepts were referenced in context with terms that were often mentioned in context with *neurofeedback*, but they were rarely if at all mentioned with *neurofeedback* without their connecting concepts also being present.

**Structure and agency comparison map.** A concept map was constructed in order to look more deeply into the presence of structure and agency factors in the decision-making process of the healthcare professionals that were interviewed regarding EEG–NFB as a treatment for children with ADHD. Although the inferential quantitative analysis did not show any significant differences between structure and agency in this regard, underuse of medical treatments has been linked to these factors. Therefore, better understanding of their interplay in the adoption of EEG–NFB is warranted. Figure 2 is the visualization of this concept map, with structure and agency placed at opposite ends. A concept that is nearer the center of the map indicates a stronger presence of both factors. Correspondingly, distance from the center in either direction reflects the differential importance of each of the two factors.

The largest concept in the map is *neurofeedback*, the primary concern of this study, and it is centrally located. It is directly connected to structure but not to agency. Instead, agency connected first to the *effective* concept through the *patients* subconcept inside *effective*, then through the *effective* subconcept inside effective to the *neurofeedback* subconcept inside the *neurofeedback* concept. Structure took the exact opposite path of connectivity from *neurofeedback*, connecting the *neurofeedback* subconcept to the *effective* subconcept and the



*patients* subconcept. This shows a continuum of the same concepts connecting *neurofeedback* to structure and agency from exactly opposite paths. All other concepts are contained in paths that do not provide any eventual linkage between *neurofeedback* and structure or agency. This offers a distinct and clear understanding of the differential impact of structure and agency in this interviewee sample, even if they are not quantitatively significant.



Figure 2. Concept map for structure and agency.

*Structure.* Structure connected through independent paths to three concepts, two that connected uniquely to structure and one that was shared with agency. The shared concept was



connected through different and independent side paths to both structure and agency. The shared concept was *people* and the unique concepts were *knowledge* and *school*.

School was its own concept, with only school as a subconcept connected directly to structure. Similarly, *knowledge* was directly connected to *structure* through the *knowledge* and *level* subconcepts. The *knowledge* subconcept connected on out to the subconcept of *understand*. *Understand* was shared equally by the themes of *knowledge* and *neurofeedback*. The *people* theme, shared with agency, was indirectly connected to structure. Its connective path was from structure to the theme of *neurofeedback* through the concept *neurofeedback* and then to the concepts of *try* and *brain*, which are a part of the *people* theme.

*Agency.* Agency was uniquely connected to the themes *important*, *research*, and *change*. The *important* theme was connected directly through the *important* concept. The *research* theme was connected directly to agency through the *research* concept, which connected onward to the *ADHD* concept. Finally, the *change* theme was connected directly to agency through the *feel* concept and from there to the *change* concept.

Agency was also connected to the joint theme *people*, as discussed earlier. The connection to *people* came indirectly from agency to the concept of *patients* inside the *effective* theme, then to the *effective* concept, also within the *effective* theme. Finally, it connected to the *people* concept inside the *people* theme. From there, agency's connects went in two different directions: One path led from the *people* concept to the *time* concept and the other led from the *people* concept to the *experience* concept.

**U.S. and Dutch comparison map.** The final concept map was generated to explore the status of EEG–NFB as a treatment for children with ADHD with a focus on the similarities and differences between the U.S. and Dutch interview participants. The two samples showed no



significant differences in the quantitative analysis, as discussed in the results section already presented. However, further inquiry was important to understand and conceptualize appropriately how the under adoption of this treatment may present in each country. Figure 3 is a visualization of the content analysis from the interviews with the U.S. and Dutch samples placed at opposite ends.

Joint themes and concepts. The central themes of this analysis, *neurofeedback* and *research*, were the only direct concept link between the U.S. and Dutch samples passed through these two themes. The U.S. sample passed through the *research* theme first and then the *neurofeedback* theme, while the Dutch sample went in the opposite direction. The one direct concept link between the two formed a continuum, and the path went through exactly the same concepts in opposite directions. This link, starting from the U.S. sample, connected first to the *research* concept inside the *research* theme, then to the *effective* concept also inside the *research* theme, and then to the *neurofeedback* concept inside the *neurofeedback* theme before finishing by connecting into the Dutch sample. This meant that the U.S. sample only connected to *neurofeedback* indirectly through *research* and that the Dutch sample only connected to *research* indirectly through *neurofeedback*.

US. The U.S. sample connected to one theme that was not connected to by the Dutch sample. That theme was *people*, and there were seven concepts connected through six paths. The concepts that had a direct connection to the US were *experience*, *school*, *sense*, *feel*, *knowledge*, and *people*. The *people* concept connected out to the final concept contained in the *people* theme, which was *time*.





Figure 3. U.S. and Dutch comparison map.

**Dutch.** The Dutch sample also connected to one theme to which the U.S. sample did not connect. The theme was *problem*, and it contained three concepts and two paths. *Important* was the only concept in its path connecting to the Dutch sample. The *problem* concept was directly connected to the Dutch sample. Then it connected out to the *ADHD* concept, which means that *ADHD* was indirectly connected to the Dutch sample only through the *problem* concept.



## Summary

The major findings of this study indicate that most practitioners may be intermediate selfmonitors, and most may not recommend EEG–NFB before other treatment options. The sample in this study included practitioners who had heard of neurofeedback and knew someone who successfully practiced it, or practitioners who regularly referred patients for neurofeedback treatment or are neurofeedback practitioners. The quantitative analysis revealed no significant differences between the U.S. and Dutch sample, suggesting homogeneity and no significant influence of personal self-monitoring on the decision-making process of the participants. None of the correlations were found to be significant. Consequently, a qualitative content analysis of the interviews with the entire sample was conducted to explore the current status of the adoption of EEG–NFB as a treatment for ADHD in children. In addition, content analysis was also conducted to explore the similarities and differences further between structure and agency influencers on the U.S. and Dutch samples.

The results of the content analysis yielded the primary, central role played by theme of neurofeedback. Other themes were also identified that came up when talking about neurofeedback, both directly and indirectly. Closely connected concepts were revealed, such as *understand*, *change*, *use*, *problem*, and *important*. The first concept map helped provide a deeper understanding of this sample's viewpoint of the status of neurofeedback in participants' decision-making process. These themes were also further examined to understand what practitioners really meant when using them.

The last two concept maps focused on the similarities and differences between the U.S. and Dutch samples with structure and agency as the influencing factors. The comparison revealed a direct connecting path through the neurofeedback and effective themes, with structure



being more connected to *knowledge* and *school*, while agency was more connected to *patients* and *research*. A direct path was also revealed in both the U.S. and Dutch samples that connected through the neurofeedback and research themes, with the U.S. sample having an independently connected theme of *people* and the Dutch sample having an independently connected theme of *ADHD*. In addition, all of the themes for both of these maps were examined further to understand the meaning and type of context they were used in.

The next chapter discusses the significance of the quantitative descriptive and nonsignificant inferential statistics. It also discusses the importance of what the primary concept map revealed about the status of EEG–NFB as a treatment for ADHD in children among the factors that most influenced the decision-making process of these medical professionals. The next chapter is also attentive to the interplay between structure and agency highlighted in the second concept map and the interplay between the U.S. and Dutch samples highlighted in the third concept map. The quantitative and qualitative findings will be integrated to provide an overall conclusion about the current status of the adoption of EEG–NFB as a treatment for ADHD in children for this sample of medical professionals. Finally, the recommendations and final conclusions that can be drawn from the findings of this study are discussed.



## Chapter 5: Discussion

This chapter describes the findings of this study to the established literature, particularly Rogers's (2010) model for the diffusion of innovation and Latour's (1990) *Technology is society made durable*. One major component of this literature is the need for, and potential benefit of improving awareness about, EEG–NFB as a treatment for ADHD in children. The findings of this study support that observation and demonstrate the value of increasing awareness of EEG–NFB in the treatment of ADHD in children among healthcare professionals, the gatekeepers of adoption of medical innovations. Moreover, the similarity between the US and the Netherlands is striking and amplifies these findings because it suggests that problems may have international universality. Recent developments in the validity research for the efficacy of EEG–NFB as a treatment for ADHD in children can lead to increasing the rate of adoption and of EEG–NFB becoming a viable first-line treatment for ADHD in children.

## Interpretation

The main finding of this study is that the underadoption of EEG–NFB as a treatment for ADHD in children appears to be due to a reduced awareness rather than a lack of acceptance. Therefore, the goal of increasing EEG–NFB adoption is a priority, though other problems will need to be solved, as well. The sample for this study was made up entirely of providers who were familiar, to some degree, with neurofeedback. Although their level of knowledge varied, the participants were all at least aware of the technique and its application to ADHD. This makes the group a good sample for understanding adoption and acceptance of EEG–NFB as a treatment for ADHD in children.

Another important finding is the striking similarity between the U.S. and Dutch samples. The U.S. healthcare system is currently in flux, which also must be taken into account: It is



becoming somewhat less of a research hub while making strides toward becoming more functional for the majority of its citizens. Despite low medical scores due to factors ranging from lack of access to healthcare to poor self-care practices and an aging population, the United States is still, for the moment, considered the hub of medical innovation (Cowen, 2006). The percentage of money being contributed to global medical innovation by the United States is gradually being reduced. However, in part due to the European policy changes that have been made to encourage more medical innovation (Burstall, 1991; European Commission, 2019), many U.S. and European countries are becoming more aligned.

The U.S. and Dutch practitioners in this study seemed to be on the same level of resistance to certain medical innovations perhaps because of the result of intercontinental communications, Internet-based trades of information, and traditional conferences that cross practices and attitudes (Greenhalgh et al., 2017). The difference in system history, however, does not seem to affect the way that practitioners in the two countries currently think and interact with the various technologies available for ADHD treatment. Therefore, both samples were treated as a single sample as a way to gauge professionals' overall attitude regarding different techniques and technologies.

#### Awareness as a Barrier

The lag in awareness of EEG–NFB as a treatment for ADHD in children is crucial in understanding the process of adoption of innovations. This study suggests that this delay in awareness may explain a large portion of the underadoption of EEG–NFB for treating ADHD in children or at least provide an opportunity to increase awareness. Awareness, and how to increase it, is not a simple concept when considering medical treatments for disorders. Treatment effectiveness has the greatest influence on healthcare professionals' adoption process



of innovation. Fortunately, recent developments are significantly shifting toward support for the efficacy of EEG–NFB in treating ADHD in children. Moreover, this shift is coming at an opportune time and could be an effective conduit for increasing awareness of EEG–NFB among healthcare professionals. Scientific literature will be a crucial factor to the adoption curve (Rogers, 2010).

The US practitioners' responses show that they judge treatments largely on research findings, and the Dutch are not far behind. Therefore, the research findings appear poised to determine whether practitioners adopt EEG–NFB as a treatment for ADHD in children. However, it is contingent upon each individual practitioner's exposure to literature and its ability correctly and convincingly to identify EEG–NFB as an effective therapy or not. The failure of practitioners to keep abreast of the latest literature can, in part, explain the lack of widespread use of EEG–NFB in the treatment of ADHD in children.

# Structure and Agency: Clinicians' Interaction with Rogers's Innovation Curve

In general, overall quantitative results of this study can be structured together as a similar understanding by combining the U.S and Dutch samples in both their vignette and the factors that influenced their decision-making process. However, structure and agency in the US model versus the Dutch model have some interesting similarities and differences. The concept map for structure and agency showed knowledge being closely linked to structure rather than to agency, which is somewhat troubling when trying to push for greater adoption of EEG–NFB. It implies that the participants may think of knowledge as belonging to the structure of the profession itself, as opposed to being related to their own personal agency, or to that of individuals in general. These results may shed some light via Rogers's (2010) model on why many practitioners, though they know about and approve of NFB, are slow to adopt it.



The participants linked *important* to agency; they did not link *knowledge*, *sense*, or *understand*. Those three terms of knowing were all clustered close to structure with knowledge itself nestled deepest on the structure end of the map. The association with knowledge concepts to structure and not to agency may explain why many practitioners are late majority or laggard adopters. An association of knowledge with the structure of the profession may imply an ethos by the healthcare professionals that focuses on shifting one's practice and one's perception of what knowledge is with the superstructure of the profession rather than helping to shift the superstructure of the profession through one's own agency. However, it is interestingly mitigated by research, which is more closely related both to structure and agency and, in fact, leads more toward agency. Therefore, healthcare professionals see these concepts in this order may show that they perceive the current state of understanding, or lack thereof, in the superstructure of the profession as a barrier to more widespread acceptance of EEG–NFB as a treatment for ADHD in children.

These findings indicate that practitioners accept the idea of change if it is carefully fit into the superstructure of the profession, but they see research as being less of an institutionally stable process than knowledge, and knowledge as less the property of individuals with agency. Therefore, the development of new practices must be slowly built into the social structure of the profession, which is approached via the agency of the researcher and the process of research.

#### **Research Developments**

AAN, for example, promotes the notion that Theta-Beta Ratio and frontal EEG beta power tests are not a reliable indicator of the presence of ADHD. This may lead clinicians to the conclusion that ADHD diagnoses cannot be tracked via EEG; therefore, symptoms cannot be tracked, either (Nuwer, Buchhalter, & Shepard, 2016). This conclusion might lead to the



misleading idea that EEG–NFB is a less than solid proposition if one is to assume that the actual change of a specific EEG signal thought to explain the symptoms of ADHD is necessary for establishing the validity of EEG–NFB as a treatment for ADHD. Such an idea is reflected in the continued position of the AAN against the use of EEG–NFB in ADHD treatment (Nuwer et al., 2016).

However, this measuring stick has been called into question (Pigott et al., 2013). Many medication treatments for psychiatric diagnoses do not actually work by the proposed mechanism of a chemical imbalance, such as SSRI's for depression (Montcrieff, 2007). However, that has not impeded their acceptance because it is based on the correlation of symptom change with the proposed effect of the medication. Therefore, the correct requirement for the efficacy of EEG–NFB as a treatment for ADHD is identified by Loo and Barkley (2005) as the ability "to demonstrate that EEG changes are responsible for treatment effects, reporting of actual EEG changes and correlation with treatment outcome must be shown" (p. 72). This means it is necessary to demonstrate that the relationship between the EEG changes and the symptom change is correlative, not causative, as is implied in the position of the AAN, AAP, and numerous third-party payers.

#### **Shifting Position of Key Influencers**

A few key influences in the field of ADHD and EEG–NFB have recently re-evaluated their position on the efficacy of EEG–NFB as a treatment for ADHD in children, which is sign of a major shift that usually leads to an increased pace of adoption according to Rogers's model. One key player in the field whose work is extremely influential is Dr. Sandra Loo of the Brain Research Institute at the University of California, Los Angeles. Loo with Barkley (2005) argued against the efficacy of EEG–NFB for the treatment of ADHD and was foundational in



establishing the requirements for EEG–NFB to be considered efficacious. In 2005, Loo and Barkley wrote an overview of the history of EEG in hyperactivity, noting that EEG was one of the first methods used to study the condition in a quantitative way, showing excess slow wave activity and generally describing EEG as an effective way of describing brain activity in children with ADHD. Their findings remained ambivalent as to whether EEG and NFB had positive agency as a therapeutic device (Loo, 2004). They seemed to understand that EEG's main function was as a descriptor or research tool rather than a therapeutic tool.

A transitional period took place in 2012, when Loo and Makeig (2012) authored a paper promoting the clinical utility of EEG as a diagnostic tool in a clinical setting, adding that EEG could also lead to effective EEG-NFB approaches alongside the precise diagnostic measures. At this time, it appeared Loo had shifted positions. She began to see evidence pointing toward EEG not just as a research or diagnostic tool but also as guiding neurofeedback in a therapeutically significant way. More recently, she was an author on a meta-analysis that concluded efficacy for EEG–NFB in the treatment of ADHD (Van Doren et al., 2018).

Another key influence in EEG–NFB as a treatment for ADHD is Eugene Arnold, a professor of pediatrics and researcher of treatments for ADHD at Ohio State University. He is a respected researcher in the field of ADHD and has even been a member of the AAP subcommittee on ADHD. His previous research into EEG–NFB as a treatment for ADHD in children did not have positive findings (Arnold et al., 2013; Lofthouse, Arnold, & Hurt, 2012), and the AAP does not currently recommend EEG–NFB as a treatment for ADHD in children. It is not clear yet whether or not EEG–NFB will be superior to the active sham or what the final conclusions will be after the final follow-up. During a recent conference presentation, Arnold (2018) stated that all of the treatment conditions saw significant improvement in their ADHD



symptoms. The final findings of this study and his opinion will carry significant weight with the AAP in revising their recommended treatments for ADHD.

Neuwer, who has been a coauthor on the AAN position papers on quantative EEG in psychiatric diagnosis and EEG–NFB as a treatment, is another key influencer. Neuwer stated during personal correspondence on May 18, 2018, that he is open to a re-evaluation of the literature and a possible shift in his position regarding EEG–NFB as an effective treatment in ADHD because of some of the new literature coming out showing EEG–NFB can be effective when it is done in certain ways and according to certain standards. Moreover, his position has not been as adamantly opposed to EEG–NFB as often characterized. Rather, his skepticism is due to a lack of standards in the field, which has caused confusion when interpreting the literature. However, the recent literature from Loo (Van Doren et al, 2019), whom Neuwer says he considers a high quality researcher, is quite influential in his viewpoint of the efficacy of EEG–NFB in the treatment of ADHD.

As Loo, Arnold, and Neuwer are leading scholars in the area, it is expected that practitioners in the field will follow their lead. However, many practitioners are occupied with practicing what they already know rather than learning and applying a new specialty, another factor that slows their progression along Rogers's (2010) adoption curve or prevents them from improving their class of adopter. In addition, as the present study's concept map shows, the practitioners' association of knowledge with structure rather than agency may affect the degree to which they look to new literature for ideas to adopt. Some practitioners may be waiting for the structure paradigm to shift and are perfectly willing to shift along with it. The paradox is obvious: If no one will shift paradigm, then there will be no paradigm shift with which they can move along. The ill effects of the introduction of incorrect ideas to the system as they are



difficult to eradicate once entrenched, but appeals to authority can be used for good as well as for incorrect information. Therefore, the number of early adopters of EEG–NFB as a treatment for ADHD in children needs to be increased, and publicizing these key influencers' change of mind or reconsideration of their position may aid in that paradigm shift.

#### The Paradigm Shift: Latour's Framework

In light of Latour's (1990) contention that technology is society made durable, it appears that the social infrastructure is failing to advance the more cautious adopters along Rogers' acceptance curve, resulting in a failure to adapt new "durable" innovations such as EEG–NFB in the treatment of ADHD in children quickly. Innovators and researchers willing to accept EEG have not ceased to develop the related physical technology, and behavior modification has not ceased to progress in its clinical applications for the treatment of psychiatric disorders, even specifically for treating ADHD. EEG–NFB, which is merely the application of behavior modification to the EEG, has passed through multiple iterations of development, equipment, and administration, yet over the 40-plus year history of the treatment, researchers and practitioners who are willing to do the research and understand the practice of EEG–NFB have not let the technology terminate (Arns & Sterman, 2019). In other words, the physical pieces of the puzzle—the EEG technology and behavior modification techniques—have been created, but the social fabric is not incorporating them at their fullest capacity.

Per Latour's (1990) framework, the human actors (i.e., clinicians) must interact with new nonhuman actors (i.e., EEG and behavior modification techniques) in order to integrate the innovation. In the case of EEG–NFB for the treatment of ADHD in children, the clinicians hesitate to adopt this treatment into their practices, likely due to their emotional investment in the social structure element. This social structure element is an actor, which is not human and yet is



comprised of humans. The social contract is the network (i.e., link) between Latour's (1990) idea of society made concrete in the form of applying behavior modification techniques to the EEG and the practitioner's own volition in accepting the innovation. As is even admitted by Thibault (Thibault & Raz, 2017), quantitative EEG brain mapping has been used to visualize symptoms of ADHD, making the disorder as a whole more tangible to patients, practitioners, and the public. In Latour's work, this aligns with society and by making concrete the research that presents ADHD as a "real" disorder with possibilities for improvement and remission (Donald, Cannon, Thatcher, Koberda & Gunkelman, 2014). This idea can be used to try to increase the adoption of EEG–NFB as a treatment for ADHD in children by increasing social and structural signals.

One clearly identifiable example of a failure by the social infrastructure to incorporate EEG–NFB adequately as a treatment for ADHD in children is with third-party insurance reimbursement. Since the first manual in 1978, EEG–NFB has had an American Medical Association Current Procedural Terminology code, and it has been revised once. However, prejudice exists against paying for EEG–NFB as a treatment for ADHD in children by insurance companies, even though in the long-term EEG–NFB is less expensive than constant medication (Pigott et al., 2013). Coverage does exist, in both the US and the Netherlands, when it is recommended or prescribed as a treatment for ADHD in children, though insurance coverage is not universal in either country. In the Netherlands, participants revealed that much of the reimbursement comes from the municipalities that cover children and can have different coverage policies in different cities/regions. Moreover, insurance providers in the Netherlands offer coverage in higher-level plans (HollandZorg, 2016).



In the US, insurance coverage for EEG–NFB as a treatment for ADHD in children is a mixed picture. Some regional Blue Cross Blue Shield private insurance plans offer coverage for EEG–NFB as a treatment for ADHD in children, with other private insurance companies having covered the treatment only rarely on a case-by-case situation through a formal appeals process. On the national level, Medicare and Tricare have a specific exclusion for EEG–NFB as a treatment for any condition. However, Medicaid plans that are managed by the individual states sometimes offer coverage. Just a few years ago, Maryland approved coverage of EEG–NFB as a treatment for ADHD in children. The trend is clearly moving, though very slowly, toward more coverage for EEG–NFB as a treatment for ADHD in children in both the US and the Netherlands.

## **U.S. and Dutch Professionals Strikingly Similar**

The results of the vignette and self-monitoring segment of the study led to the conclusion that the U.S. and Dutch samples were considered similar enough to use as a single sample in a single concept map in the content analysis. In this concept map, the word *ADHD* was surprisingly nonpredominant. It was, in fact, somewhat peripheral, connected directly only to the concepts *understand*, *important*, and *problem*. Most of the concepts often mentioned were functional and opaque with low meaning. For example, the concept *important* was closely associated with ADHD and not associated with anything else. It is not surprising that ADHD is connected to *important* in the minds of people dedicated to treating it, which gives little insight into the practitioners' thought processes.

More interestingly, *time* was an important concept, implying that researchers in both countries were concerned with timely results or were prepared to be patient with the time it took to get them. Time was only associated directly with *better*, and through that to *certain* and


*change*; *feel* and *better* were only associated via *change*. *Better* was just as closely associated with *school* as it was to *feel*, tentatively implying that behavior or performance might have been a more pressing concern for practitioners than the child's subjective experience with therapeutic benefits.

The concept map comparing the U.S. to Dutch results showed another interesting nuance. Research and neurofeedback were related both to the U.S. and the Dutch practitioners' thinking; however, the Dutch mentioned ADHD concepts and *problem* more often, while US practitioners were overwhelmingly focused on the concept *people*. The front-of-mind status of *people* in the US practitioners at first seems paradoxical but can be explained. Moreover, the structure, the overarching healthcare systems, in the two countries appears to be converging.

#### **Converging Systems**

In recent years, after the Affordable Care Act was passed, the U.S. healthcare system has moved more in line with the European and other global models. The Affordable Care Act is closely connected to the Dutch healthcare system model. In fact, the US reforms were largely based on the Dutch system. Less well known is the fact that, in 2006, certain US practices were introduced to the Dutch system, notably the American Consumer Assessment of Health Plan Surveys was introduced into the Dutch system for evaluating practitioners and programs (Delnoij et al., 2006). Therefore, the Dutch and U.S. practices can be expected to converge. However, the similarities between the two countries' vocabulary constellations reveal a similar perception of EEG–NFB as a treatment and the important information providers need in order to decide on a treatment.

One striking finding among the responses came in the area of factors that influenced the practitioners' decision making. The emphasis on the concept *people* by the U.S. participants



implies that personal circumstances are more important to U.S. practitioners than to the Dutch, but that is not the case. Moreover, this is one area where the U.S. and Dutch practitioners differed significantly. The reasons why this has occurred can shed a light on the changing medical practice within the US and possibly on how practitioners think about new practices and devices.

The conclusions, quantifiable data, and vocabulary between the U.S. and Dutch healthcare professionals were similar, yet even if they came to similar conclusions, the information the two groups prioritized in reaching them was widely divergent. Therefore, U.S. and Dutch participants identified different reasons and factors that influence the decision-making process about which treatments to recommend for ADHD in children. For both groups of practitioners, research agency was one of the top three factors influencing choice of treatment. However, for Dutch practitioners, the order of the top three factors that influenced treatment choice shows that research agency is a lower priority than in the US, particularly when compared to individual circumstances.

Meanwhile, individual circumstances for the U.S. healthcare professionals were not even in the top six factors that affected choice of treatment, yet it was the top influence on the Dutch healthcare professionals. The U.S. professionals were focused on study results first, general knowledge second, and then their own success with treating past patients. The Dutch were more likely to assess a particular patient's situation. The US participants were condition focused while the Dutch were patient focused. It is interesting that the Dutch chose individual circumstances over research, indicating a greater tendency on the part of Dutch practitioners to consider the finer details of the situation over and above cutting-edge research or the authority of the literature.



The difference in criteria may be a lingering effect from the still, or at least recently, heavily commodified healthcare system in the United States. U.S. practitioners more often mention the concept *people* compared to the Dutch practitioners. Therefore, it might be that while the U.S. practitioners believe themselves to be more symptom or condition focused while their thoughts were more people focused. However, the reasons might be more structural. As a recent study shows, patient trust of physicians worldwide is on the decline (Huang, Pu, Chou, & Huang, 2018). Moreover, the same study concludes that this loss of trust is not occurring as steeply or as quickly in systems that are decommodified. Compared to the United States, Europe is still not as commodified. The weaker mistrust among patients in decommodified systems may be due, in part, to decommodified practitioners' habits of paying greater attention to individual patient circumstances and a concentration on personal interviews (Huang et al., 2018).

The lack of attention paid to individual circumstances is not necessarily the fault of U.S. individual practitioners but rather of incentives within the system. In more commodified systems, patients distrust physicians' possible financial conflicts of interest (Huang et al., 2018). In addition, when systems are commodified and costs increase, administrators look for cost-cutting measures. These cost-cutting measures are beyond the physicians' control and lead to patient distrust (Huang et al., 2018). Many of these measures include shorter consultation times as administrators try to process more patients in less time. In more commodified systems such as the US, due to these short consultation times and the requirement to process more patients more quickly, healthcare practitioners may develop certain habits. For example, they may rely more heavily on overall research consensus when considering best practices for particular conditions instead of tailoring care to individual patients. In other words, they "play the odds," hoping that



most of their cases will respond to treatments that are statistically likely to work, regardless of individual patient circumstances.

The concept map, paradoxically, shows that the U.S. doctors were far more likely than Dutch doctors to express concepts in terms of people. Therefore, the focus on research results does not necessarily imply that U.S. healthcare professionals dehumanize their patients. In fact, the Dutch concern with circumstances, as opposed to individual temperament, DNA conditions, and other factors, may indicate that the Dutch were, in fact, more concerned with infrastructure and sociological factors. The infrastructure and sociological factors are circumstances in which the individual happens to be, generated by society not the patient. Therefore, the U.S. professionals most often associate patients' problems to patient choices or individual differences. The Dutch professionals most often associate the problems to issues in society and the circumstances of patients' experience.

It is unclear whether reliance on research in the US is a philosophical choice or a necessity due to short visit times. Even if it may be considered less dignified for the patients to be treated for their disorder rather than for their individual circumstances, if the treatment works it is not necessarily bad. If the two different influences lead practitioners to the same answers, as it did in this study, then they are neither therapeutically good nor bad. This conclusion brings to mind the quality of the state of the science in ADHD research. If research were faulty, or if local populations are too different from research sample populations, meaning perhaps that the research population was not diverse enough to generalize to the entire population, then one would expect these habits to lead the two sets of practitioners to different conclusions (Thompson et al., 2017). Surprisingly, the practitioners indicated similar therapeutic decisions and preferences. The parallel suggests a convergence between research data and reality,



although problem areas in ADHD research regarding NFB still exist regarding specificity. These findings could also indicate that treatment efficacy transcends patient circumstances, beyond simply having the ADHD diagnosis.

#### Recommendations

Conventional treatments for ADHD in children are unable to resolve the symptoms fully in over one-third of cases, meaning more rapid adoption of newly proven treatments are essential (Lofthouse et al., 2012). Moreover, awareness-raising campaigns must be tailored to the psychology of practitioners and particularly aimed at the early majority of adopters who tend to produce the needed critical mass to push new practices toward acceptance (Gallo & Barlow, 2012). Creating initiatives targeted toward practitioners who value their agency in their treatment decisions and focus on knowledge and research should be one of the steps taken to increase the adoption of EEG–NFB as a treatment for ADHD in children.

Increasing awareness among healthcare professionals in the US and the Netherlands regarding EEG–NFB as a treatment for ADHD in children is one way to combat underadoption. Moreover, increasing knowledge about how to administer EEG–NFB appropriately is important for structural change in the healthcare professional organizations and by third-party payers such as insurance companies is another. These two appear to be both the crux of the underadoption of EEG–NFB as a treatment for ADHD and the weakness in the resistance to the appropriate adoption of EEG–NFB as a frontline treatment. Therefore, optimism should abound regarding the future adoption of EEG–NFB as a treatment for ADHD in children even in the lack of awareness by healthcare professionals and a lack of knowledge by their professional organizations and third-party payers because both of these can be addressed in a relatively simple and straightforward manner.



Providing people, in general, and healthcare professionals, in particular, with new information is easier than attempting to correct misconceptions (Gardner, 2006). If practitioners are unaware or only vaguely aware of a treatment as opposed to being entrenched in an established viewpoint against it, then education will be a less difficult process with a better outlook. If the recent research on the efficacy of EEG–NFB as a treatment for ADHD (Van Doren et al., 2018; Pigott et al., 2018) can be broadcasted and highlighted when raising the awareness about EEG–NFB, then it will likely be able to establish this perspective as the first thought in the mind of these healthcare professionals about this topic.

Once healthcare professionals are aware of EEG–NFB's effectiveness as a treatment for ADHD in children, they should be provided with training to ease its implementation. For the healthcare providers who are not going to learn to do EEG–NFB themselves, training should focus on providing them with a robust referral system, talking points for explaining the treatment to their patients, and training on how to evaluate the treatment progress. If a positive perspective toward EEG–NFB as a treatment for ADHD in children is established and sufficient training on its implementation is provided, it will be hard to deter the momentum toward EEG–NFB as a treatment for ADHD in children, 2006). Establishing a strong base of acceptance could lead to increased adoption.

After EEG–NFB as a treatment for ADHD in children moves through the early and mass adoption phases, laggards will still resist adopting the treatment. As Rogers (2010) states, one cannot force those who would be laggards to adopt early. However, to create the perception that research has moved through knowledge into the structure, or is quickly on its way to doing so, may help laggards feel as though the group has embraced the new information (Rogers, 2010). Since the research supporting EEG–NFB as a treatment for ADHD in children already exists, the



next step is for society and relevant substructures such as the healthcare professional organizations and educational training programs to adapt and incorporate this change. To achieve such a change, outdated information must be replaced by more recent research that shows the efficacy of EEG–NFB as an ADHD treatment.

In Rogers's paradigm, many so-called laggards may be found among those who would be psychologically equipped to take up new practices were they aware of them or their efficacy. Once graduated from school, beyond the necessity to keep whatever certification or practicing rights they have, the laggards are either unable or not willing to develop professionally to adopt and incorporate new treatments (Rogers, 2010). Some strategies for improving adoption could, therefore, focus on making it easier for practitioners to encounter, learn, and absorb the new information regarding EEG–NFB. It may be through designing CEU training focused on how to evaluate the literature appropriately, explaining the treatment to patients when making a referral, and learning to evaluate the effectiveness of the treatment and its progress for the referred patient. Currently, most CEU training is geared toward teaching the healthcare professional to become a practitioner. Finally, since CEU trainings are usually mandatory for healthcare professionals to maintain their license and generally cost money, laggards may be more interested in attending these trainings if they were incentivized through subsidies to cover the cost of the CEUs.

Correcting the poor knowledge regarding EEG–NFB as treatment for ADHD in children at the structural level in healthcare provider associations and third-party payers is a structure problem, and addressing it is not as straightforward. Large structural healthcare professional organizations and insurance literature reviews have accepted and incorporated faulty research discrediting EEG–NFB into their reviews and positions due to a lack of technical knowledge



about the intervention itself. Using the recent efficacy research, the organizations of providers for EEG–NFB such as the International Society for Neurofeedback and Research, Association for Applied Psychophysiology and Biofeedback, and the Biofeedback Certification International Alliance should do everything necessary to challenge these reviews and positions as a concerted effort to bring about structure change. In the US, this can be achieved through utilizing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and in the Netherlands with the Joint-Statement on Mental health for the EU Health Policy Platform on Mental Health and Policy that encourages parity across the EU (Joint-Statement, 2016).

#### Implications

About 10,000 children in the US are currently receiving EEG–NFB treatment for ADHD, out of approximately 6 million ADHD patients, according to advocates (Michaels, 2018). Within Rogers's (2010) model, the field appears to be early in acceptance according to these numbers, as 10,000 out of 6 million is not near critical mass. The 1.5% currently receiving treatment with EEG–NFB and 11% who have received EEG–NFB at some point for their ADHD (Danielson et al., 2018) make sense because EEG–NFB is a durable treatment. Preliminary research as well as follow-up research have shown lasting benefits to EEG–NFB treatments (Van Doren et al., 2018). Therefore, the next efforts should target how to increase the adoption and usage of EEG–NFB as a treatment for ADHD in children.

The connections between structure and knowledge that practitioners make around ADHD show how easy it is to delay the adoption of an innovative treatment. One way the structure has slowed the adoption of EEG–NFB as a treatment for ADHD in children is that healthcare provider associations, such as AAP, APA, AACAP, and AAN, do not include EEG–NFB as a treatment option for ADHD. Moreover, those positions still continue to cite research that was



clearly not even evaluating actual EEG–NFB (Pigott et al., 2018). Therefore, as practitioners associate structure and knowledge so closely, research that is rubber-stamped by a structural body of these professional organizations is going to carry a great deal of weight. The association of knowledge with structure means that misinformation coming from these structural forces, the healthcare provider organizations, must be combated by addressing the knowledge gaps in these professional organizations.

Although EEG–NFB treatment for ADHD in children appears to be at the early adoption phase, and those who try it with a patient are likely to recommend it in the future, the current adoption rate suggests a real lack of awareness. Awareness seems to make a difference in recommendation, so this issue appears to explain a large portion of the underadoption of EEG– NFB with ADHD. If, as the concept map shows, practitioners link knowledge to structure, then awareness depends not just on practitioners coming across a mention of the EEG–NFB technique; it needs to stick in their minds. Merely exposing the healthcare professional to EEG– NFB or the literature supporting its use for treating ADHD in children may not be enough awareness to increase its adoption. The challenge, when trying to remedy underadoption of EEG–NFB as a treatment for ADHD in children, is devising a strategy to increase awareness in a way that will increase its adoption by healthcare practitioners.

Knowledge, in this study, refers to the technical ability of healthcare providers to administer EEG–NFB treatments for children with ADHD effectively and impacts the adoption rate. As Thibault, Veissière, Olson, and Raz (2018) have inadvertently shown through their faulty research and Pigott et al. (2018) have pointed out, practitioners who do not perform the techniques optimally do no better than a placebo effect, albeit a strong one. Therefore, healthcare professionals must also be educated on how to make sure that EEG–NFB is actually



occurring when evaluating the research literature, professional organization recommendations, and outcomes with their patients to move EEG–NFB as a treatment for ADHD in children out of underadoption. Otherwise, healthcare professionals who may consider referring children with ADHD for EEG–NFB may still be hesitant. Even if the healthcare practitioners are aware of EEG–NFB, the lack of knowledge could be enough for it to remain underadopted for treating ADHD in children.

#### Conclusion

The underadoption of EEG–NFB as a treatment for ADHD in children in the US and the Netherlands was examined by this study in order to understand the barriers to adoption of innovative medical device treatments in mental healthcare. The focus was the role of healthcare professionals, as the gatekeepers of medical innovation, and their decision-making process when making treatment referrals. The responses in this study indicated that similar types of information influence the adoption of EEG–NFB as a treatment in healthcare professionals in the US and the Netherlands. The factors that most influence their decisions are the healthcare professionals' assessment of the research on the innovative treatment and their own knowledge of how to administer a session of EEG–NFB.

The recommendation for addressing barriers, and correcting the underadoption of EEG– NFB as a treatment for ADHD in children in the US and the Netherlands involves multiple simultaneous foci. Focusing on raising awareness of EEG–NFB as a treatment for ADHD in children and focusing on the recent shift in efficacy research and the viewpoints of those who were positioned against the field is a way forward for increasing awareness. Improving the knowledge of how to administer, refer for, and evaluate progress in EEG–NFB is another focus, which should be targeted with CEU trainings and eventually incorporated into the training



programs for healthcare professionals who diagnose and treat ADHD in children. Finally, focus should be on some aspects of societal structure, such as government and third-party insurance payers and the healthcare professional organizations that write recommendations and guidelines for treating ADHD in children.

Finally, this study used a mixed-method research design incorporating a semi-structured interview embedded with a self-monitoring scale, vignette, and participatory ranking that explored how healthcare professionals make treatment recommendations for children with ADHD. It was derived from Latour's (1990) paradigm shifting in technology theory and Rogers's (2010) model for the diffusion of innovation, focusing on these healthcare professionals as gatekeepers. This study established the usefulness of this new mixed-methods research design for identifying and understanding barriers to the adoption of innovation. In the future, investigations into the gatekeepers in the diffusion of innovations, particularly when those innovations are technology based, can consider using this model to increase understanding of gatekeepers' decision-making process.



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# Appendix A: Self-Monitoring Scale Permission Letter

From: Mark Snyder <msnyder@umn.edu>
Sent: Monday, October 9, 2017 12:43 PM
To: Mark Trullinger - Student
Subject: Re: Requesting permission to use "Self Monitoring Scale"

Dear Mark Trullinger,

Thank you for writing to me about your doctoral research at the Chicago School of Professional Psychology.

Your dissertation study strikes me as interesting and important, and you have my permission to use the Self-Monitoring Scale in to examine differences in reliance on personal beliefs versus social groups in decisions about medical device adoption.

I wish you well with your research, and look forward to learning about your findings.

Best wishes,

Mark Snyder

Mark Snyder McKnight Presidential Chair in Psychology Director, Center for the Study of the Individual and Society University of Minnesota 75 East River Road Minneapolis, MN 55455 (612) 625-1507 (voice) (612) 626-2079 (fax) <u>msnyder@umn.edu</u> (e-mail)



# Appendix B: Recruitment Script

### (Conducted via telephone)

Hello, my name is Mark Trullinger.

I am a student at The Chicago School of Professional Psychology. I am conducting a research study on decision making by health care professionals. I am conducting this research as part of my studies in the International Psychology Department. I will collect information such as your professional field of practice, your personal reactions to a number of situations, your clinical decision making process, and your knowledge of a specific treatment for ADHD.

You were identified as a potential participant from the directory of your professional association in the United States or the Netherlands. If you meet the inclusion criteria and agree to participate, I will set up an appointment to interview you at your office. The interview will take no more than 60 minutes to complete and will be audio recorded. After the completion of the interview all participants will be given \$10 dollar gift card.

Are you willing to answer a question to see if you qualify for participation?

Do you Speak English?

### If the response is "No."

Thank you for your time. Your do not qualify for participation in this study.

### If the response is "Yes."

Are you over 25 years old?

### If the response is "No."

Thank you for your time. Your do not qualify for participation in this study.

### If the response is "Yes."

Do you have any experience assessing or treating children under the age of 18 with Attention

Deficit Hyperactivity Disorder (ADHD)? Experience is defined as currently treating someone

under 18 with ADHD or having assessed or treated someone under 18 with ADHD within the

past year.

# If the response is "No."



Thank you for your time. Your do not qualify for participation in this study.

# If the response is "Yes."

Would you like to participate in this study?

# If the response is "No."

Thank you for your time. Your do not qualify for participation in this study.

If the response is "Yes. When is a good day and time between \_(Date)\_\_\_\_\_ and

\_\_(Date)\_\_\_\_\_ to set up the interview. Remember, it will take no more than 1 hour.

I will provide you with a reminder call 2-3 days in advance on this number. If you change your

mind you can reach me at 443-810-9483. Thank you.



### Appendix C: Recruitment Addendum Approval

14-Feb-2018 IRB # :IRB-17-09-0034 Principal Investigator: Trullinger, Mark Faculty Advisor : Dass-Brailsford, Priscilla Addendum # (dated 07-Feb-2018)

The Chicago School IRB has reviewed and approved the changes submitted to the above referenced study. These changes include utilizing convenience sampling and the PI using his personal contacts in each of the professional fields to seek out participants. Also, the screened participants will inform other individuals about the study, and they will contact the PI if they are interested. This will also lead to the possibility of connecting these potential participants through their email instead of just phone.


### Appendix D: Informed Consent

**Study Title:** The Psychology of Adoption of Medical Device Innovation in Mental Healthcare: A comparison of the United States and the Netherlands

### Investigators: Mark Trullinger

You are being asked to participate in a research study. This study is being conducted as a part of the dissertation requirements for International Psychology. Please take your time to read the information below and feel free to ask any questions before signing this document.

**Purpose:** This research study is being conducted on innovation and the decision-making process of health care professionals. The goal of this study is to identify and further investigate the factors that influence health care professionals' decision on treatments to recommend for a child with ADHD. It explores both similarities and differences in the selection of recommended treatments and influential factors across five medical specialties that commonly diagnose and/or treat ADHD in children. It also examines whether or not there are similarities and/or differences between the U.S. and the Netherlands. Additionally, the study will try to decipher the impact of adherence to, or how faithfully a person follows, the beliefs of social and organizational structures and one's personal beliefs on the professionals' decision making process.

**Procedures:** The study will take a maximum of 60 minutes. You are currently in the first step, which is the informed consent. After this, the interview will be audio recorded. Then, you will be read some statements from a survey and you will be asked to respond whether each statement about yourself is "true" or "false." Next, you will be read a common clinical vignette and a list of possible treatments that you could recommend. You will be asked to identify treatments you would consider recommending for person from the common clinical vignette. Then, index cards will be placed in front of you with the treatments you consider recommending and you will be asked to rank them from the highest recommendation to the lowest. Next, you will be asked about your decision making process when selecting and ranking treatments to recommend from for the person in the vignette. Next, your responses will be classified into categories, you will be informed of each category for your responses, and they will be written on index cards. Then, the index cards with the categories and some coffee beans will be placed in front of you. You will be asked to place coffee beans next to the index cards containing the categories that had the most influence on your decision of treatments to recommend and how they were ranked for the person from the vignette. Next, you will be engaged in a discussion about one treatment option for the person from the common vignette. Finally, the debriefing will take place and you will be provided with the compensation.

**Compensation:** You will receive a \$10 (USD) gift card after the completion of the interview and debriefing. If you choose to withdraw prior to the completion of the interview and debriefing, you will not receive the gift card.

**Risks to Participation:** There is a potential risk for a breach of confidentiality if the recorded interview or its transcript is made available to the public or if the consent forms are made public because it contains your name. The risks will be minimized by using a pseudo-name during the



interview. A pseudo-name is a fictitious name that you will use in place of your real name during the interview. The recorded interview will be kept on a password protected computer, except for when it is uploaded to a firewall and password protected cloud location for transcription. The transcript will be kept on a password protected computer and the consent forms will be kept in a locked bag at all times.

**Benefits to Participants:** There are no direct benefits to participating in the study. Indirect benefits could be that you could learn new information about treatments for ADHD. The field of medicine, particularly mental health related, may potentially benefit from this study because it could improve the understanding of the process of the adoption of medical device innovations in the treatment of mental health conditions.

Alternatives to Participation: Participation in this study is voluntary. You may withdraw from study participation at any time without any penalty.

**Confidentiality:** During this study, information will be collected about you for the purpose of this research. This includes information such as your name, telephone number and address for communication purposes only. Your confidentiality will be maintained by your selection of a pseudo- name and the recording of the interview and its transcription will be kept behind a firewall in a password protected location at all times. After 5 years, the data will be permanently deleted from the computer and/or cloud storage space. The audio recordings of the interview will be deleted after their transcription. Any paper documents collected during the study will be kept in a locked bag or briefcase. They will only be accessed during data entry. After 5 years, these documents will be shredded.

Your research records may be reviewed by federal agencies whose responsibility is to protect human subjects participating in research, including the Office of Human Research Protections (OHRP) and by representatives from The Chicago School of Professional Psychology Institutional Review Board, a committee that oversees research.

**Questions/Concerns:** If you have questions related to the procedures described in this document please contact the Principal Investigator Mark Trullinger at mxt5415@ego.thechicagoschool.edu or his dissertation chair Dr. Priscilla Dass-Brailsford at <u>pbrailsford@thechicagoschool.edu</u>

If you have questions concerning your rights in this research study you may contact the Institutional Review Board (IRB), which is concerned with the protection of subjects in research project. You may reach the IRB office Monday-Friday by calling 312.467.2343 or writing: Institutional Review Board, The Chicago School of Professional Psychology, 325 N. Wells, Chicago, Illinois, 60654.

### **Participant:**

I have read the above information and have received satisfactory answers to my questions. I understand the research project and the procedures involved have been explained to me. I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I



do not want to be part of this research project. I will receive a copy of this consent form for my records.

Name of Participant (print)

Signature of Participant

Date: \_\_\_\_\_

Name of the Person Obtaining Consent (print)

Signature of the Person Obtaining Consent

Date:



The statements below concern your personal reactions to a number of situations. No two statements are exactly alike, so consider each statement carefully before answering. If a statement is true or mostly true as applied to you, respond with "True" as your answer. If a statement is false or not usually true as applied to you, respond with False as your answer. It is important that you answer as frankly and as honestly as you can.

1. I find it hard to imitate the behavior of other people.

2. My behavior is usually an expression of my true inner feelings, attitudes, and beliefs.

3. At parties and social gatherings, I do not attempt to do or say things that others will like.

4. I can only argue for ideas I already believe.

5. I can make impromptu speeches even on topics about which I have almost no information.

6. I guess I put on a show to impress or entertain people.

7. When I am uncertain how to act in a social situation, I look to the behavior of others for cues.

8. I would probably make a good actor.

9. I rarely need the advice of my friends to choose movies, books, or music.

10. I sometimes appear to others to be experiencing deeper emotions than I actually am.

11. I laugh more when I watch a comedy with others than when alone.

12. In a group of people I am rarely the center of attention.

13. In different situations and with different people, I often act like very different persons.

14. I am not particularly good at making other people like me. 15. Even if I am not enjoying myself, I often pretend to be having a good time. 16. I'm not always the person I appear to be.

17. I would not change my opinions (or the way I do things) in order to please someone else or win their favor.

18. I have considered being an entertainer.

19. In order to get along and be liked, I tend to be what people expect me to be rather than anything else.

20. I have never been good at games like charades or improvisational acting.

21. I have trouble changing my behavior to suit different people and different situations.

22. At a party, I let others keep the jokes and stories going.

23. I feel a bit awkward in company and do not show up quite so well as I should.

24. I can look anyone in the eye and tell a lie with a straight face (if for a right end).

25. I may deceive people by being friendly when I really dislike them.

#### **Responses Scoring Section for PI:**





### Appendix F: Common Vignette: Attention Deficit-Hyperactivity Disorder

A 7-year-old boy is brought to the physician's office because of academic difficulty at school and behavior problems that first came to attention in preschool when the teacher was concerned about impulsive aggression. His mother reports that at home he runs around all day, needs multiple requests to pick up his toys, and can only sit still for a few seconds before "growing bored". A teacher's note states that he cuts in line, distracts his classmates, and loses his homework assignments but appears bright and is able to finish his work when he is given individual supervision. His mother is concerned because other children are teasing him for being stupid. However, she reports that he is a sweet and motivated boy who does not talk back to teachers or adults and does not bully anybody. In the office, he is jumping up and down in the chair despite multiple requests by his mother to sit still. She notes that his 15-year-old brother was also hyperactive when he was younger and has persistent academic problems.

Which of the following treatments would you consider prescribing for this child? Respond with "Yes" or "No". If there is something you would consider prescribing for this child that is not in the list, you will be given the opportunity to add it after this list.

- 1. Stimulant Medication
- 2. Cognitive Behavioral Therapy (CBT)
- 3. Selective Serotonin Reuptake Inhibitor Medication (SSRI)
- 4. Behavior Therapy
- 5. Hypnotherapy
- 6. Selective Norepinephrine Reuptake Inhibitor (SNRI)
- 7. EEG Neurofeedback
- 8. Diet
- 9. Exercise

Are there any other treatments you would consider prescribing for this child?

10. \_\_\_\_\_ 11. \_\_\_\_\_ 12. \_\_\_\_\_ 13. \_\_\_\_

Here are all of the treatments you would consider prescribing for this child on index cards, please rank them in order in which you would recommend these treatments from first to last.

#### **Responses:**

1	2	3	4	5	6	7	8	9
10	11	12	_13					



Appendix G: Identification and Ranking of Influencing Factors

What were you thinking about and what did you take into consideration when making the decision of what treatments you would consider prescribing and the order you would recommend them for the child with ADHD from the vignette?

The researcher will mark which of the following are identified by the participant and record whether it is an agency factor, structure factor, or both on an index cards for each. Some likely possibilities will be placed on index cards prior to the interview, as blank spaces to indicate other factors that the participant may identify.

1. Knowledge about the treatments they prescribe/recommended.

a. Structure b. Agency

- 2. The research supporting the treatments.
  - a. Structure b. Agency
- 3. The participant's professional organization's recommendations.

a. Structure b. Agency

- 4. Success they have had or heard about with that treatment being used with other patients. a. Structure b. Agency
- 5. Personal experience with those treatments.

a. Structure b. Agency

- 6. Organizational structures that encourage certain treatments over others.
  - a. Structure b. Agency

7.\_\_\_\_\_a. Structure b. Agency

## a. Structure b. Agency

Here are all of factors that you identified that you took into consideration when making the decision of what treatments and in what order you would consider recommending them for the child with ADHD from the vignette. They are on the index cards I have placed in front of you. Please use these 10 coffee beans to place coffee beans next to the factor or factors that had the most influence on your decision. You can place all of the coffee beans on one factor or an equal number of coffee beans on each factor or split them up in whichever way possible; but that the strongest influencer should have the most coffee beans next to it and the second strongest should have the second most coffee beans next to it and so forth. However, each coffee bean must be placed during the process and there should be none left over.

### Factor Ranking: recorded by the PI speaking them out loud from highest to lowest after the participant has completed the ranking



### Appendix H: Discussion EEG-NFB as a Treatment for ADHD in Children

Please tell me what you know about EEG Neurofeedback as a treatment for ADHD in children.

# (If nothing, then the PI will proceed to the debrief and do not complete the rest of the items on this page)

Please tell me about EEG Neurofeedback as a treatment for ADHD in children in the context of <insert highest ranked influential factor>.

Please tell me about EEG Neurofeedback as a treatment for ADHD in children in the context of <insert second highest ranked influential factor>.

Please tell me about EEG Neurofeedback as a treatment for ADHD in children in the context of <insert third highest ranked influential factor>.

Please tell me about EEG Neurofeedback as a treatment for ADHD in children in the context of <insert fourth highest ranked influential factor>.

(The interviews will proceed until all of the factors that had at least one coffee bean next to it in the ranking process have been discussed or there are only 5 minutes remaining in the one-hour time limit.)



### Appendix I: Debrief Form

Thank you for your participation in this study. As a reminder, the information you provided today will be used by me for the purpose of this study. Your confidentiality will be kept by your selection of a pseudo-name. The recording of the interview and its transcription will be kept in a password-protected file in a locked location at all times.

If you have any questions, please feel free to ask them now. If you have any questions later, you may contact me at:

Mark Trullinger 13941 Alderton Road Silver Spring, MD, 20906 443.810.9483 mxt5415@ego.thechicagoschool.edu

The PI will give the \$10 gift card to the participant at this point.

