CHAPTER 46

Alternative Treatments

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Alternative treatments are therapies used to replace or supplement conventional remedies for a disorder or problem. These treatments include various forms of complementary and alternative medicine (CAM) such as special diets or megavitamins offered by healthcare providers, and alternative allied health (AAH) services such as sensorimotor interventions delivered by occupational therapists, speech-language pathologists, or other practitioners.

Alternative treatments are commonly used in an effort to improve the social, cognitive, and behavioral deficits associated with autism spectrum disorders (ASD). Surveys conducted in the United States indicate that 52% to 74% of families initiate alternative treatments as part of the therapeutic regimens for their children with ASD (Hanson et al., 2007; Wong & Smith, 2006). Surveys of other Westernized countries such as Canada, Turkey, and Australia reveal similar patterns of CAM and AAH use (Angley, Semple, Hewton, Paterson, & McKinnon, 2007; Şenel, 2010; Singh & Ernst, 2008). Parents of children with ASD in other parts of the world have turned to alternative treatments as well. Many forms of CAM and AAH (such as acupuncture) have roots in traditional Chinese medicine (TCM) and appear to be especially popular in Asian countries such as Korea, China, and Taiwan (Lee, Kim, & Ernst, 2011; Shyu, Tsai, & Tsai, 2010; Wong, 2009). Given the widespread adoption of alternative treatments around the world, it is essential to be knowledgeable about the kinds of treatments that are available, their evidence base, strategies for testing their safety and effectiveness, and approaches for parents and professionals to work together to monitor the treatments in practice settings. Accordingly, this chapter discusses these issues as they relate to selected examples of influential alternative treatments.

ALTERNATIVE TREATMENTS FOR AUTISM

CAM Interventions

CAM interventions are frequently offered for hypothesized gastrointestinal disorders, neurotransmitter

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imbalances, immunodeficiencies, oxidative stress, or toxic environmental exposures. Some interventions are intended to address more than one of these concerns or are recommended for different reasons by different providers. Moreover, some organizations such as the Autism Research Institute (Edelson, 2012) recommend combining multiple interventions. The following are examples of CAM interventions, organized by their proposed mechanism of action.

CAM for Gastrointestinal Disorders

Gluten-Free/Casein-Free Diet

Special diets are a popular CAM treatment. Some investigators suggest that the distinctive eating habits and problem behaviors associated with ASD result from gastrointestinal disorders (discussed by Buie et al., 2010; Seiverling et al., 2011). One hypothesis is that individuals with ASD have trouble breaking down and absorbing gluten (a protein found in wheat) and casein (a protein found in dairy products), leading to physical discomfort and a leaky gut (Whiteley, Rodgers, Savery, & Shattock, 1999). This leaky gut is believed to allow for the release of gluten- and casein-based peptides into the central nervous system where they bind to opioid receptors (Horvath, Papadimitriou, Rabsztyzn, Drachenberg, & Tildon, 1999; Reichelt, Knivsberg, Lind, & Nødland, 1991; Reichelt & Landmark, 1995). As evidence for the leaky gut hypothesis, some reports have described abnormal levels of peptides from gluten and casein in the urine and cerebrospinal fluid in individuals with ASD (Whiteley et al., 1999). The resulting change in brain chemistry is thought to interfere with neural development, cognitive functioning, attention, and learning, all of which are impaired in children with autism (Knivsberg, Reichelt, Nødland, & Høien, 1995).

Thus far, research has not demonstrated a reliable association between ASD and a leaky gut or any other gastrointestinal disorder (Buie et al., 2010). Although some investigators find that children with ASD have an abundance of endogenous opioids and leaky guts (Reichelt, Knivsberg, Nødland, & Lind, 1994), others fail to replicate these findings (Williams & Marshall, 1992). Moreover, although uncontrolled studies have indicated that the gluten-free, casein-free (GfCf) diet might improve cognitive performance, problem behavior, social communication, or motor skills, two randomized clinical trials (RCTs) yielded much less favorable results (Elder et al., 2006; Knivsberg, Reichelt, Høien, & Nødland, 2002). In an RCT of 20 children with ASD (10 of whom were placed on the GfCf diet for 1 year), Knivsberg and colleagues found significant improvements on one of their outcome measures (reduction in autistic traits), but did not show clear changes on any other outcome measure. In a crossover study with 13 children who were placed on the GfCf diet for 6 weeks and a placebo diet for 6 weeks, Elder et al. (2006) did not detect changes on any outcome measure. Overall, studies of the diet have not produced sufficient evidence to establish whether the diet has a positive effect on core symptoms of ASD or other behavior (Millward, Ferriter, Calver, & Connell-Jones, 2008; Mulloy et al., 2010).

Secretin

Secretin is a gastrointestinal hormone conventionally administered intravenously to treat peptic ulcers or evaluate pancreatic functioning. Animal studies indicate that secretin is present outside of the gut and may cross the blood–brain barrier, affecting neurological functioning (e.g., Charlton, Miller, Crawley, Handelmann, & O'Donohue, 1983). Intravenous injection of secretin gained popularity as a treatment for ASD based on a report of three cases in which this treatment was said to be associated with social, cognitive, and communicative gains (Horvath et al., 1998). Subsequently, however, multiple RCTs involving hundreds of individuals with ASD all failed to document any improvements from secretin (Krishnaswami, McPheeters, & Veenstra-VanderWeele, 2011; Williams, Wray, & Wheeler, 2012). Thus, reviewers have concluded "there is clear evidence that secretin lacks benefit" (Krishnawswami et al., 2011, p. e1322).

CAM for Neurotransmitter Imbalances

Vitamin Therapies and Nutritional Supplements

Supporters of vitamin therapies and nutritional supplements assert that the abnormal behaviors associated with autism are caused by a genetic or medical condition leading to an imbalance or deficiency in certain vitamins or nutrients (Rimland, 1987). One popular vitamin therapy is a combination of vitamin B6 and magnesium (Nye & Brice, 2005). Other commonly used supplements include vitamin D, vitamin C, folic acid (folate), and omega-3 fatty acids. All of these nutrients have been shown to promote neurodevelopment, enhance the function of various enzymes in the body, and maintain nerve and muscle cells (Levy & Hyman, 2005). However, most individuals with ASD do not appear to have deficiencies in these nutrients (Hyman et al., in press).

Few studies have tested the efficacy of vitamin therapies for reducing problem behavior or enhancing cognitive or social skills in individuals with ASD. Early studies providing support for a B6-Mg treatment regimen had methodological flaws such as the absence of random assignment to treatment and control groups, unclear dosing procedures, and small sample sizes (Nye & Brice, 2005). Three more recent studies employed an RCT design in which participants were randomly assigned to receive either B6 and magnesium or placebo (pills without active nutrients) and assessments of outcome were double-blind (i.e., neither the participants nor the evaluators were aware of whether the participants were receiving the vitamin therapy or placebo). These placebo-controlled, double-blind RCTs, involving a total of 33 children with ASD, did not show reliable gains from B6 and magnesium (Findling et al., 1997; Kuriyama et al., 2002; Tolbert, Haigler, Waits, & Dennis, 1993). Although using methodologically strong designs, these studies had other limitations, notably a low number of participants across a large age range and widely varying lengths of treatment, making it difficult to gauge the efficacy of B6 and magnesium for ASD (Nye & Brice, 2005).

Studies examining the effects of folic acid (e.g., James et al., 2004) and vitamin C (e.g., Dolske, Spollen, McKay, Lancashire, & Tolbert, 1983; Tolbert et al., 1993) exhibit similar limitations. Likewise, trials of omega-3 fatty acids have also failed to demonstrate a positive effect on behavior (James, Montgomery, & Williams, 2011). Overall, vitamin therapies and nutritional supplements are underresearched, but the available evidence suggests that these therapies may be ineffective.

CAM for Immunodeficiencies

An example of CAM for immunodeficiencies is intravenous immunoglobulin (IVIg) therapy. Originally used to treat antibody deficiencies or autoimmune diseases (Dwyer, 1992), IVIg has been recommended by some providers who believe ASD is caused by a dysfunction in the immune system (Gupta, Aggarwal, & Heads, 1996).

Gupta and colleagues (1996) administered IVIg to 10 children with ASD over 6 months and reported improvements in communication and a reduction in autistic symptoms. However, later studies failed to replicate these results (DelGiudice-Asch, Simon, Schmeidler, Cunningham-Rundles, & Hollander, 1999; Plioplys, 1998). Thus, the available evidence indicates that IVIg is not an efficacious treatment for deficits associated with ASD.

CAM for Oxidative Stress

Perhaps the most prominent form of CAM for oxidative stress is hyperbaric oxygen therapy (HBOT), which involves having an individual inhale 100% oxygen in a chamber under high pressure. This procedure increases the oxygen content in plasma and body tissues, which may reduce inflammation and oxidative stress (Gill & Bell, 2004; Lin, Wan, Wu, Tung, & Wu, 2005). Some researchers posit that inflammation in the brain and gastrointestional system, resulting from immune dysregulation and oxidative stress, contributes to the cognitive deficits and behavioral challenges characteristic of ASD. These researchers propose that HBOT may reverse such abnormalities (Rossignol & Rossignol, 2006).

Research on HBOT as a treatment for cognitive and behavioral deficits associated with ASD is inconclusive. Many studies that describe benefits from HBOT rely on unvalidated and imprecise outcome measures, lack control groups, and use varying doses of HBOT (Bent, Bertoglio, Ashwood, Nemeth, & Hendren, 2012; Rossignol & Rossignol, 2006; Rossignol, Rossignol, James, Melnyk, & Mumper, 2007). Two RCTs have yielded mixed findings. Rossignol and colleagues (2009) conducted a double-blind, placebo-controlled RCT of 62 children with ASD and reported reductions in ASD symptoms as measured by clinician ratings but did not detect changes on a parent rating scale. The other RCT found no evidence of improvement on any measure (Jepson et al., 2010). Thus there is limited and conflicting evidence on whether or not HBOT is efficacious (Ghanizadeh, 2012).

CAM for Detoxification: Chelation

The use of chelation as a treatment for symptoms of ASD is grounded in the hypothesis that autism is caused by excessive exposure to mercury or other heavy metals. Chelation is a medical procedure in which an agent that binds to metal ions is administered to remove metals from the blood. The chelating agent is administered intravenously, orally, rectally, or intramuscularly.

No RCTs to date have examined the efficacy of chelation at improving the cognitive and behavioral symptoms of ASD. However, research has not corroborated the idea that exposure to heavy metals causes ASD (Shannon, Levy, & Sandler, 2001). In addition, although the chelating agents often used to treat children with ASD have been shown to effectively remove metals from the body, they do not cross the blood–brain barrier in order to reverse any neurological damage that may have occurred as a result of metal poisoning (Levy & Hyman, 2005). Also, the side effects associated with chelation therapy are dangerous and potentially fatal without proper monitoring (Brown, Willis, Omalu, & Leiker, 2006; Kane, 2006). In 2008, the National Institute of Mental Health canceled plans to conduct a clinical trial of chelation for children with ASD due to these dangerous side effects; a spokesperson stated that, without any scientific rationale for a potential benefit, the risk was too high (Mitka, 2008). Because chelation is implausible and hazardous, organizations such as the U.S. Food and Drug Administration (FDA; 2010) have warned against the use of this treatment.

CAM for Multiple Purposes

Acupuncture

Acupuncture is a form of CAM that involves inserting needles, electric currents, heat, pressure, ultrasound, or lasers into the skin at particular sites for therapeutic purposes (Ernst, 2005). It is commonly used to treat a variety of maladies including headaches, allergies, lower back pain, and fibromyalgia (Ernst, Pittler, Wider, & Boddy, 2007), as well as mental health concerns such as anxiety and depression (Druss & Rosenheck, 2000; Unützer et al., 2000). About a quarter of the physicians in the United States and United Kingdom endorse acupuncture as an effective means of relieving physical discomfort (Berman, Singh, Hartnoll, Singh, & Reilley, 1998; White, Resch, & Ernst, 1997).

The prevalence of acupuncture as treatment for autism varies from about 1% in the United States (Hanson et al., 2007) to as high as 43% in Chinese societies such as Hong Kong (Wong, 2009). Proponents of acupuncture as an intervention for ASD describe success in improving comprehension, cognition, and social skills (reviewed by Cheuk, Wong, & Chen, 2011). However, most studies on acupuncture for children with ASD have had substantial methodological weaknesses, especially a failure to keep participants or evaluators (or both) blind to whether the participants were receiving genuine acupuncture or a placebo (sham acupuncture; Lee, Choi, Shin, & Ernst, 2012). Two placebo-controlled RCTs showed positive effects of acupuncture on adaptive behavior but used different outcome measures (parent report vs. standardized measures), acupuncture sites, and type of stimulation to acupuncture points (Wong & Chen, 2010; Wong & Sun, 2010). A review by the Cochrane collaboration concluded, “Current evidence does not support the

use of acupuncture for treatment of ASD" (Cheuk et al., 2011, p. 2). Another systematic review called for more research to "overcome the limitations of current investigations" (Lee et al., 2012, p. 1682).

Nonvaccination and Immunization

It has been speculated that the measles-mumps-rubella (MMR) or diphtheria-tetanus-pertussis (DTaP) vaccines given to all infants cause ASD (Wakefield et al., 1998). Coulter (1990) asserted that these vaccines trigger infections and maladaptive immune responses, causing brain damage leading to the onset of ASD. Based on findings from a small study, Wakefield and colleagues (1998) soon supplanted this theory by proposing that the MMR vaccine causes inflammation in the intestines and other parts of the gastrointestinal system, preventing the absorption of essential vitamins and minerals. This new hypothesis became enormously popular, leading to many studies examining the conjectured link between inflammation, the MMR vaccine, and autism. However, these studies consistently found no such link (Demicheli, Jefferson, Rivetti, & Price, 2012; DeStefano, Bhasin, Thompson, Yeargin-Allsopp, & Boyle, 2004; Fombonne & Chakrabarti, 2001; Madsen et. al., 2002; Wilson, Mills, Ross, McGowan, & Jadad, 2003), and the original 1998 article was retracted after investigators uncovered evidence of scientific misconduct (Editors of The Lancet, 2010; Murch et al., 2004).

Another popular theory is that exposure to mercury from vaccines places susceptible infants at risk for ASD (Bernard, Enayasti, Redwood, Rogers, & Binstock, 2000). In 1999, the FDA discovered that infants could be exposed to thimerosal, a preservative that contains 50% ethylmercury by weight, from several different vaccines (though not the MMR vaccine, which has never contained thimerosal). The American Academy of Pediatrics and Public Health Service consequently called for the removal of this substance from all vaccines given to infants (Centers for Disease Control and Prevention, 1999). To many families, this recommendation lent credence to the idea that vaccines were harming children and might be associated with ASD (discussed by Gerber & Offit, 2009). However, there was never any evidence of adverse effects from thimerosal in vaccines (Gerber & Offit, 2009; Institute of Medicine, 2004; Pichichero, Cernichiari, Lopreiato, & Treanor, 2002) or a connection between mercury exposure from thimerosal or other sources and ASD (Nelson & Bauman, 2003). Many subsequent studies showed no relationship between thimerosal exposure and ASD and no reduction in the prevalence of ASD following the removal of thimerosal from vaccines (Gerber & Offit, 2009).

Although speculation about links between vaccines and ASD has been shown to be false, concern about this issue remains widespread among the general public (Bazzano, Zeldin, Schuster, Barrett, & Lehrer, 2012). Furthermore, nonvaccination as a means of preventing ASD appears to have been a factor in outbreaks of vaccine-preventable diseases such as measles and pertussis (Omer, Salmon, Orenstein, deHart, & Halsey, 2009). For this reason, organizations such as the American Academy of Pediatrics, American College of Family Physicians, and American Medical Association strongly recommend vaccination (Every Child by Two, n.d.).

AAH INTERVENTIONS

Currently, AAH interventions are most commonly administered for hypothesized difficulties in perceiving or integrating sensory information or in controlling motor movements made in response to such information. However, some AAH interventions are directed toward hypothesized problems with forming attachments to caregivers.

Auditory Integration Training

Auditory Integration Training (AIT) is a type of sensory motor therapy aimed at alleviating hypersensitivity to sound in children with ASD. It is grounded in the view that children with ASD

display behavior problems such as avoiding social interaction because environmental sounds and the voices of other people are bothersome to them (Berard, 1993).

The Tomatis and Berard Methods are the most influential forms of AIT (reviewed by Sinha, Silove, Hayen, & Williams, 2011). Both methods begin with an audiogram to determine the frequencies at which the child's hearing is particularly sensitive. If the individual qualifies for AIT, the treatment program involves exposing the patient to music that is acoustically altered such that the specific threshold frequencies most sensitive to the recipient are filtered out. In the Tomatis method, children also may speak into a microphone as their own filtered speech is played back. This method typically involves 60–90 hours of intervention in sessions lasting 1 to 3 hours. The Berard Method involves a total of 10 hours of intervention over a 2-week period.

A systematic review identified six small RCTs of AIT and found that these studies either did not demonstrate any benefit from AIT or used measures of questionable validity (Sinha et al., 2011). Given these findings, the reviewers concluded that "there is no evidence to support the use of auditory integration therapy at this time" (Sinha et al., 2011, p. 2).

Sensory Integrative Therapy

Sensory integrative therapy (SIT) aims to overcome sensory dysfunction in children with ASD through activities that stimulate vestibular or proprioceptive senses such as swinging, riding a scooter board, or brushing the child's body (Schaaf, 2011). Customarily, occupational therapists administer SIT one to three times a week during 30–60 minute sessions. The application of a "sensory diet" is a related clinical practice in which practitioners develop individualized plans to provide ongoing sensory input to a child with ASD (Schaaf, 2011). The sensory diet might include a schedule for having children engage in activities such as playing gross motor games, wearing weighted vests or wrist bands, or putting on a body sock. SIT and sensory diets can be implemented in the classroom, at home, or in a variety of other settings (e.g., horseback or a pool) by aides, paraprofessionals, or parents (Bundy & Murray, 2002; Case-Smith & Miller, 1999; Lawton-Shirley, 2002).

Practitioners assert that SIT improves processing of sensory information, which lays a foundation for developing more complex cognitive processes such as language and reading (Baranek, 2002). However, research on SIT has been limited by the absence of standardized, replicable procedures for delivering and evaluating the intervention. For example, studies on weighted vests do not describe how to determine the weight of the vest, schedule for wearing vests, or time frame for measuring outcomes (Stephenson & Carter, 2008). Moreover, many studies evaluate an individual procedure such as the use of weighted vests in isolation, with the result that conclusions about SIT as a whole cannot be made (Schaaf, 2011). One preliminary RCT of 37 children with ASD, age 6–12 years, did show a reduction in autistic mannerisms following 18 sessions of a theory-driven SIT that incorporated a variety of sensory integration techniques (Pfeiffer, Koenig, Kinnealey, Sheppard, & Henderson, 2011). However, this study did not include well-established outcome measures or a manual that would enable independent investigators to replicate the intervention. A meta-analysis by Lang and colleagues (2012) found that most studies on SIT have not documented significant improvements and the few that do have had substantial methodological shortcomings. Thus, SIT is currently unsupported by scientific evidence.

Facilitated Communication

Facilitated Communication (FC) derives from the idea that individuals with ASD possess the same level of linguistic competence as their typically developing peers but cannot express it in the same manner (Biklen, 1990, 1992a, 1992b). Using FC, a trained facilitator physically supports the individual while he or she types out a message on a keyboard or letterboard, thereby revealing the individual's hidden capacity for

communicative language (discussed by Mulick, Jacobson, & Kobe, 1993). Proponents contend that FC allows nonverbal individuals to express themselves and showcase their advanced cognitive skills (Biklen, Morton, Gold, Berrigan, & Swaminathan, 1992).

The view that individuals with ASD need a facilitator to communicate is contradicted by research showing that such individuals rarely have severe motor problems and often can learn to type independently (Mostert, 2001). Furthermore, many studies demonstrate that FC is not an effective intervention (Mostert, 2001). These studies indicate that the facilitator controls the individual's selection of letters or phrases. For example, individuals give inaccurate responses when the facilitator is unaware of the content of the message or question being posed (Calculator & Hatch, 1995). Moreover, individuals appear unable to exhibit the same skills when paired with a different or naive facilitator (Myles & Simpson, 1994; Myles, Simpson, & Smith, 1996). In addition, they show no increase in academic, social, or cognitive skills outside of FC (Myles & Simpson, 1994; Myles, Simpson, & Smith, 1996). Accordingly, many professional organizations discourage the use of FC (e.g., American Academy of Pediatrics, 1998; American Psychological Association, 1994).

Music Therapy

Music Therapy is based on the theory that music promotes social engagement and communicative behaviors in children with ASD because many of these children have a keen interest in and aptitude for music (Alvin & Warwick, 1992; Blackstock, 1978; Heaton, 2005; Heaton, Hermelin, & Ping, 1998; Heaton, Hudry, Ludlow, & Hill, 2008; Simpson & Keen, 2011). Music therapists use percussion instruments, tuned instruments, or their own voices to respond to any vocalizations made by the child and create a familiar environment that encourages social interaction and self-expression. Sessions usually occur two to three times per week in the school or home and last 30–60 minutes (American Music Therapy Association, 2006).

Some studies show that children with ASD who receive music therapy demonstrate greater increases in communication and social skills than children in control groups (Simpson & Keen, 2011). However, these studies include small numbers of participants (e.g., Buday, 1995; Simpson & Keen, 2010) and use many different forms of music therapy, ranging from highly structured sessions to open-ended improvisation (Simpson & Keen, 2011). Also, few studies have examined whether children maintain their gains in music therapy after the therapy ends and generalize these gains to new settings (Simpson & Keen, 2011). Overall, as stated in one systematic review, the research is "of limited applicability to clinical practice" (Gold, Wigram, & Elefant, 2006).

Fast ForWord®

Fast ForWord® is a commercially available computer software package that aims to improve literacy and spoken language in children with ASD by helping them process speech sounds more rapidly (Scientific Learning Corporation, 1999; Tallal et al., 1996). The package consists of a variety of computer games for children between the ages of 4 and 14 years. During the games, the computer emits speech sounds that are acoustically altered to account for impairments in auditory processing. These alterations are gradually reduced as the child progresses (Tallal et al., 1996).

Although Fast ForWard® has been used by over 570,000 children in 3,700 schools across the United States (What Works Clearinghouse, 2007), the empirical literature does not provide strong support for the efficacy of this intervention (Strong, Torgerson, Torgerson, & Hylme, 2011). A review by What Works Clearinghouse (2007) found five RCTs examining FastForWord, none of which investigated its specific effect on children with ASD. Although some of these studies yielded positive results, their relevance to children with ASD is unclear. Strong and colleagues (2011) conducted a similar review and concluded that methodologically strong studies do not show that Fast ForWord® effectively improves literacy or vocabulary.

Son-Rise

Son-Rise is a home-based intervention designed to improving the social, cognitive, and communicative skills of children with ASD. Barry and Samahria Kaufman, parents of a child with autism, designed this therapy, in which parents are encouraged to play with their child daily and establish a warm, interactive relationship by following the child's lead and reinforcing eye contact. Proponents of this program believe that such a relationship teaches children with ASD to enjoy social interaction and communication. Parents who are interested in implementing Son-Rise in their homes are invited to attend a 5-day workshop sponsored by the Autism Treatment Center of America. Although Son-Rise has been a popular intervention for children with ASD since the 1970s, no empirical research has been conducted on the efficacy of this treatment to date.

CHALLENGES IN STUDYING ALTERNATIVE TREATMENTS

Usually, as reflected in the preceding section, alternative treatments are evaluated in essentially the same way as conventional treatments (e.g., Levy & Hyman, 2005). Reviewers give the greatest credence to studies that recruit a large sample of participants, randomly assign these participants to treatment or control groups, and use well-established outcome measures. Double-blind, placebo-controlled designs are especially sought after because they offer the most protection against threats to the validity of a study such as biased reporting by providers or participants who are aware that they are receiving the active treatment. When such designs are not feasible, as occurs when the treatment requires participants to engage knowingly in therapeutic procedures, outcome data can be collected by examiners who are blind to participants' treatment status. To ensure that the intervention was delivered as intended and can be replicated by other providers, it is required that providers adhere to standardized treatment protocols and documentation.

Although controlled studies are the most reliable source of evidence on the safety and efficacy of an alternative treatment, the risks of such studies may outweigh the benefits for some interventions (Atwood, 2003). Many alternative treatments have a low probability of success because the treatments target problems that individuals with ASD do not have, such as leaky guts, toxicity from heavy metals, or severe motor problems. Other treatments rely on biologically implausible mechanisms of action, such as attempts to correct neurological damage by injecting substances that do not cross the blood–brain barrier. A few of these treatments (e.g., chelation) have potentially serious side effects. Possible ways to mitigate these problems are to conduct especially close safety monitoring and to restrict enrollment to individuals who are already receiving the treatment or have resolved to do so (e.g., Hyman & Levy, 2000). Nevertheless, as illustrated by the decision to cancel a proposed study of chelation (Mitka, 2008), some treatments may be too implausible or risky to justify randomized studies.

Researchers such as Offit (2011) worry that, even when ethical, studies of alternative treatments may be futile because providers and consumers will just ignore the results. Indeed providers often continue to offer alternative treatments despite negative research findings and warnings to desist from regulatory agencies such as the FDA. Further, although insurers routinely decline to cover such treatments, many consumers are willing to pay for them out of their own pockets (Fønnebø et al., 2007; Offit, 2011).

Experience with alternative treatments for individuals with ASD suggests that the impact of research may depend in part on how conclusive the findings are. As reviewed in the preceding section, studies of many alternative treatments (e.g., dietary and nutritional therapies, AIT) yield preliminary but not definitive evidence that the treatments are ineffective. Such studies have had no discernible influence on the popularity of these treatments (Smith & Wick, 2008). In contrast, secretin and FC appeared to fall out of favor in the wake of studies that clearly debunked them (Smith & Wick, 2008).

Still, the impact of research may be limited regardless of how clear-cut the findings are. For example, about a decade after being shown to be ineffective, FC attracted renewed attention fostered by several entertaining films depicting individuals with ASD who took part in this intervention (cf. Smith & Wick, 2008). As another example, studies that confirmed the safety of vaccines reassured primary care providers, bolstered recommendations to vaccinate all children, and helped defeat class-action lawsuits alleging damage from vaccines (Offit, 2011), yet public concern about vaccines remains widespread (Bazzano et al., 2012). Thus, although studies of alternative treatments can influence practice, researchers need to have modest expectations about the extent of this influence.

Another issue in studying alternative treatments is that these treatments tend to be developed outside of research settings by providers who work independently of one another. For this reason, generally accepted guidelines may not exist for determining the dose and duration of treatment or measuring outcome (Fønnebø et al., 2007; Mason, Tovey, & Long, 2002). Moreover, alternative treatments are often delivered in the context of a multifaceted, holistic system of care (Mason et al., 2002). For example, CAM providers may recommend many vitamin therapies, dietary interventions, and exercises simultaneously as part of a comprehensive lifestyle change. Acupuncturists may recommend herbal treatments along with acupuncture. Occupational therapists may prescribe a large collection of sensory activities. Thus, it can be difficult to pinpoint the "active ingredient(s)" in the overall treatment plan.

Because alternative treatments are often unstandardized and complex, studies on such treatments are vulnerable to criticism that the treatments were delivered incorrectly or incompletely, or were assessed with inappropriate measures (as discussed, for example, in the review of the GfCf diet by Mulloy et al., 2010). One possible solution, recommended by Fønnebø et al. (2007), is to conduct pragmatic trials, which evaluate a treatment as it is delivered in clinical practice (Roland & Torgerson, 1998). Another is to conduct studies with single-subject experimental designs (SSEDs), also called *n*-of-1 randomized trials (Sung & Feldman, 2006). In these studies, each individual serves as his or her own control, allowing for a highly individualized evaluation of a treatment. More generally, in order to design studies that properly evaluate alternative treatments, researchers need to understand not only what the key components of the treatment are but also how the treatment varies across providers and is integrated with other approaches (Fønnebø et al., 2007; Mason et al., 2002).

THE APPEAL OF ALTERNATIVE TREATMENTS

Despite the challenges of evaluating alternative treatments, it is apparent that most or all are currently unproven or disproven. Nevertheless, families still use them for their children with ASD. One reason for the appeal of alternative and complementary treatments is probably that they raise hopes by promising a "cure" (an outcome not yet achievable with conventional treatments for ASD) or at least an improvement in well-being. Because parents understandably want a solution to the difficulties they see their child facing, they may feel they cannot pass up a chance to overcome these problems with a novel treatment (Levy & Hyman, 2005). They may also perceive alternative treatments as filling in gaps left by conventional treatments. Many alternative treatments target features of ASD that can be highly stressful for individuals with ASD and their caregivers, yet remain poorly understand and hard to treat, such as feeding difficulties or unusual responses to sensory stimuli. Thus, alternative treatments may appear to be a useful adjunct to conventional treatments.

Another appealing aspect of alternative treatments is that parents may feel a sense of empowerment when they actively choose interventions given to their children (Hanson et al., 2007). Parents who embrace alternative treatments are able to do something for their child without waiting

for services or a doctor's authorization. Moreover, although researchers usually advise consulting with the child's pediatrician before initiating alternative treatments (especially CAM interventions, which may pose health risks), parents may feel they can implement many alternative treatments on their own (e.g., giving vitamin supplements, placing their children on diets, or refusing vaccinations). This sense of control may be especially attractive because conventional, specialized educational or healthcare services are often quite difficult to access (Montes, Halterman, & Magyar, 2009).

ADDRESSING ALTERNATIVE TREATMENTS IN PRACTICE

Given the popularity of alternative treatments for individuals with ASD, practitioners can expect to encounter many individuals who are receiving these treatments or whose families are considering them. To coordinate care and help families make informed decisions, open communication between practitioners and families is a priority (Gupta, 2010). Practitioners can promote communication by asking direct, nonjudgmental questions about treatments that families have tried or are interested in, and by empathizing with families who are fervently searching for remedies to help their children (Committee on Children With Disabilities, 2001).

Open discussion of alternative treatments creates an opportunity for practitioners to review what is known and unknown from relevant research and to offer recommendations. In the authors' judgment, practitioners have a responsibility to counsel against treatments that have been refuted in controlled scientific studies (e.g., FC, secretin, and nonvaccination) or are dangerous (e.g., chelation). For individuals on specialized diets or vitamin therapies, practitioners may advise strategies such as consultation with a nutritionist in order to minimize the risk of going below the recommended daily allowance or above the tolerable upper limit for consumption of particular nutrients. For individuals receiving other interventions, practitioners may guide families on the full range of benefits and risks to consider, including the direct effects of the treatment and indirect effects such as the time and expense for the individual and family, as well as potential tradeoffs (e.g., having to miss school in order to undergo an alternative treatment).

Because of the variety of alternative treatments available, practitioners may not always be familiar with a particular treatment or stay up-to-date on research findings. In this situation, practitioners can present themselves as open-minded but judicious in forming an impression about the treatment. For example, they can show interest in learning about the treatment and describe criteria they would use to gauge whether or not the treatment appears promising. Table 46.1 lists online resources that are available to practitioners and families seeking more information about specific alternative treatments.

Conflicts occasionally arise when practitioners and families hold firm but divergent opinions about an alternative treatment. Many of these conflicts can be resolved by simply "agreeing to disagree," with the mutual understanding that practitioners are likely to have valuable information to impart but that families ultimately decide what treatments to seek for their children (Gupta, 2010). However, some differences of opinion are more difficult to reconcile. For example, practitioners tend to be quite concerned about nonvaccination

TABLE 46.1 Some Online Resources for Information on Alternative Treatments

Agency for Healthcare Research and Quality, Therapies for Children with Autism Spectrum Disorders: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=651
Association for Science in Autism Treatment: http://www.asatonline.org/treatment/treatments_desc
Interactive Autism Network: http://www.iancommunity.org/cs/therapies_treatments/
Maine Administrators of Services for Children with Disabilities, Autism Task Force Report: http://www.madsec.org/publications/autismtaskforcereport/tabid/81/default.aspx
National Autism Center, National Standards Project: http://www.nationalautismcenter.org/nsp/
ResearchAutism: http://www.researchautism.net/pages/welcome/home.ikml

because it places a child at risk for preventable, potentially serious illness and can contribute to population-wide outbreaks (Omer et al., 2009). In contrast, some proponents of alternative treatments believe that healthcare providers are conspiring to cover up information about harm from vaccines in order to protect their own reputations and the profits of pharmaceutical companies (Kennedy, 2005). Such clashing views can jeopardize the working alliance between a practitioner and family, but a possible solution is to reach a compromise such as delaying vaccines or delivering single vaccines instead of combinations (Gupta, 2010).

Practitioners may be asked to assist families' efforts to obtain alternative treatments in such ways as writing prescriptions, ordering tests that are unvalidated or that are analyzed at uncertified laboratories, or sending letters to schools to advocate for the incorporation of the treatments into the child's individual education plan. At times, saying "no" may be the only ethical recourse. However, practitioners can propose other options that may be satisfactory such as referrals for further evaluation of the problem that the alternative treatment is intended to address.

Moving beyond discussions of individual treatments, practitioners are sometimes in a position to guide families on how to assess whether or not a treatment is worth undertaking or continuing. Families can learn to spot red flags that cast doubt on a treatment (Finn, Bothe, & Bramlett, 2005). Examples include reliance on anecdotal evidence and testimonials as evidence for the treatment, outcome claims that go beyond the data, studies published on the Internet or in the popular media instead of peer-refereed journals, use of grandiose terms such as *cure* or *miracle*, and vague language such as *natural* or *purifying*. Families also can be given strategies for carefully assessing their children's response to treatment. For example, Hyman and Levy (2000) suggested the following approach: First, make only one treatment change at a time and hold other treatments constant. Second, identify specific target behaviors to be addressed by the treatment, and use objective measures to obtain a baseline of this behavior prior to treatment. Finally, monitor ongoing changes in the target behavior with objective measures obtained by raters who are blind to the treatment (e.g., a teacher who is unaware of changes in vitamin consumption rate).

Going a step further, practitioners can recommend conducting single-case experiments (Smith, Mruzek, & Mozingo, 2005). Such experiments are often feasible in settings such as schools where practitioners have regular contact with individuals with ASD, allowing for frequent observations of the individuals' behavior. Perhaps the most useful type of single-case experiment is the multielement design (also called alternating treatment design) because it yields quick results. The design involves implementing a treatment on alternate days or in alternate sessions. During the other days or sessions, a baseline is in effect (i.e., no intervention is provided), or another treatment is provided. Chok, Reed, Kennedy, and Bird (2010) used this design to evaluate prism lenses worn by a 15-year-old boy with ASD. The family reported that the purpose of the lenses was to improve the boy's accuracy in completing visual-spatial tasks. Chok and colleagues compared the boy's performance with or without lenses during four activities: catching a ball, sorting money, walking on a balance beam, and shooting hoops. Figure 46.1 shows the data on catching a ball when the boy wore the glasses (ambient lenses condition), as compared to when he wore placebo glasses or did not wear glasses at all (control condition). The data reveal that the boy caught the ball more often when he left the lenses off or wore the placebo glasses than when he was wearing the prism glasses. Several other studies have incorporated a multielement design to test whether sensory interventions (e.g., wearing a weighted vest, swinging, or brushing) increase attention to academic tasks or reduce the rate of problem behavior (Lang et al., 2012). The findings indicated that sensory interventions had little or no effect on attention or problem behavior displayed by the study participants. Kerrin, Murdock, Sharpton, and Jones (1998) tested FC with a multielement design comparing children's rate of correct responding when the facilitator was able to see the correct answer versus when the correct

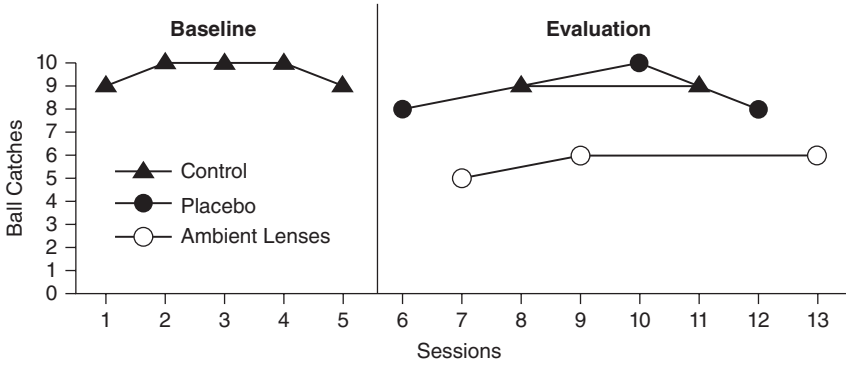

Figure 46.1 A multielement evaluation of ball catching during sessions in control, placebo lenses, and ambient lenses conditions.

Source: Reprinted from Chok, Reed, Kennedy, and Bird (2010). Copyright © 2010 by the Association for Behavior Analysis International. Reprinted with permission.

answer was concealed from the facilitator. Both children with ASD responded more accurately when the facilitator could see the answer than when the facilitator could not see, implying that the facilitator was controlling the children's responses.

A limitation of the alternating treatment design is that it is suitable only when treatment effects are discernable within a single day or session. Thus, if an intervention is said to require multiple days or weeks to change the target behavior, other designs must be considered. A useful option is the reversal design, in which a baseline phase is followed by a treatment phase, followed by a return to the baseline phase, and so on. Each phase lasts several sessions, days, or weeks. Using a reversal design, Irvin (2006) found that the GfCf diet had no detectable

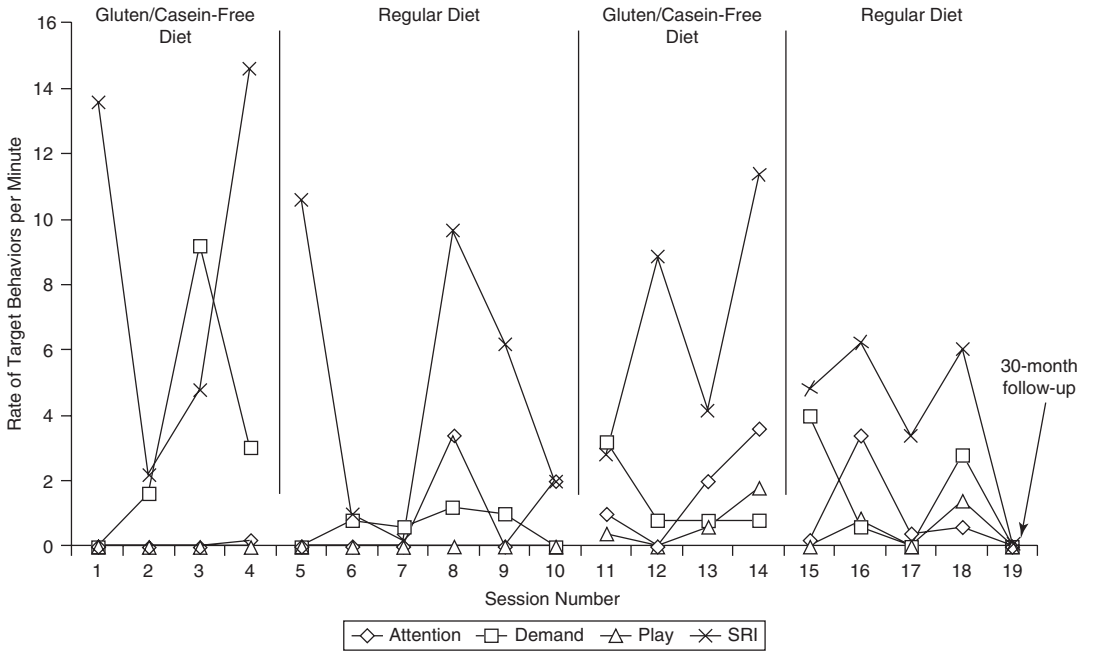

Figure 46.2 Occurrence of target behaviors within analog conditions across diet phases.

Source: Reprinted from Irvin (2006). Copyright © 2006 by John Wiley & Sons. Reprinted with permission.

effect on the rate of problem behavior displayed by a 12-year-old with autism (see Figure 46.2).

Another single-case methodology is the multiple baseline design. In this approach, practitioners run two or more baseline phases that are of varying lengths and then apply treatment to one baseline at a time. For example, three individuals could be in a baseline phase and then begin treatment at different times (a procedure called multiple baseline across participants). Lerman et al. (2008) performed a study with a multiple baseline design across three children with ASD, age 6–7 years old, to examine whether HBOT increased attention to academic tasks or reduced problem behavior. As shown in Figure 46.3, no changes with HBOT were observed for any of the children.

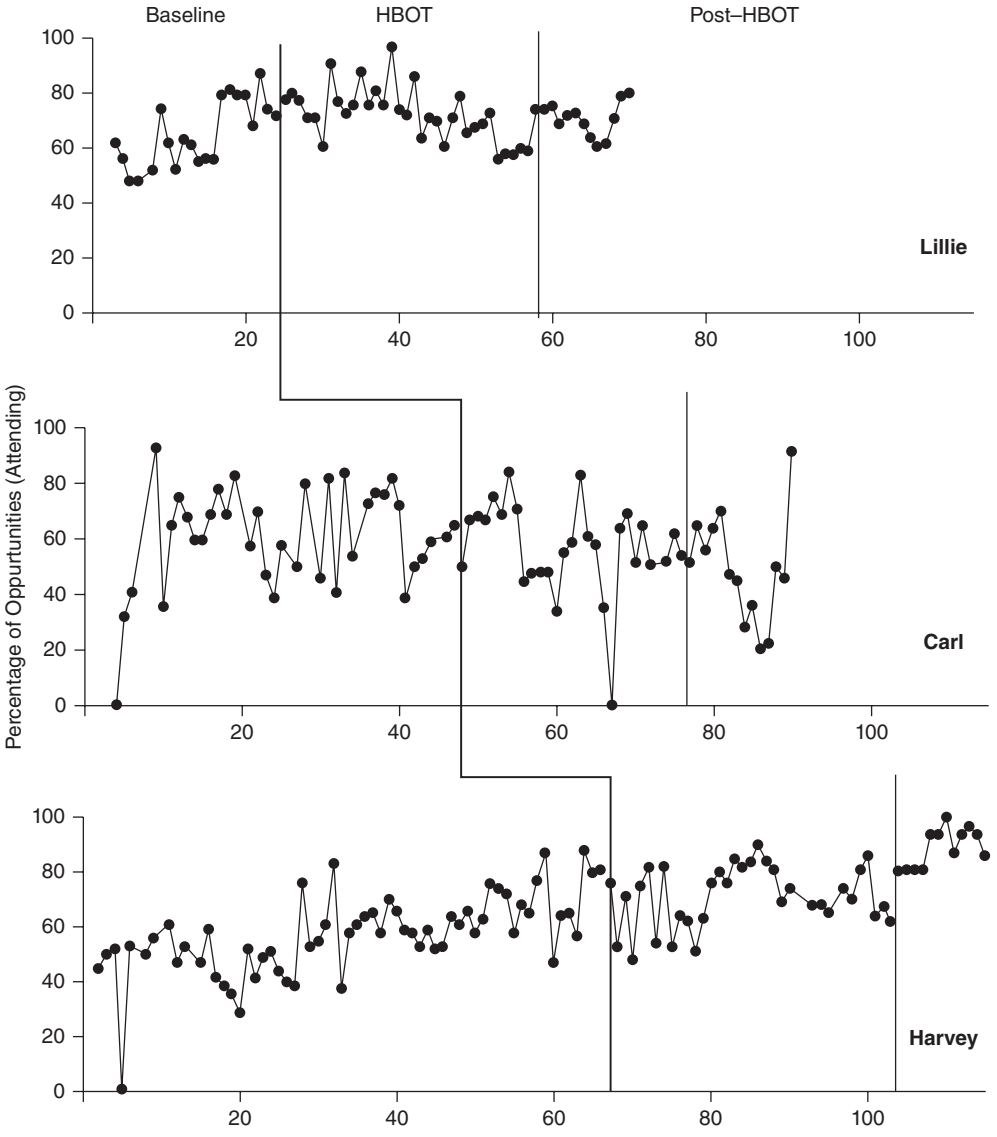

Figure 46.3 Percentage of task engagement across baseline, HBOT, and post-HBOT conditions for Lillie, Carl, and Harvey (calendar dates appear below the session numbers).

Source: Reprinted from Lerman et al. (2008). Copyright © 2008 by the Association for Behavior Analysis International. Reprinted with permission.

DISCUSSION

CAM and AAH treatments for individuals with ASD are many, varied, and popular. This chapter has described several strategies that show promise in helping families and practitioners evaluate such treatments. First, in some (though not all) cases, research on the safety and efficacy of alternative treatments has appeared to have an impact. For example, negative findings from multiple clinical trials of secretin seems to have dampened enthusiasm for this treatment (Smith & Wick, 2008). As discussed in "Challenges in Studying Alternative Treatments," investigators may need to consider creative research strategies such as conducting pragmatic trials that evaluate these treatments as they are usually delivered in practice, rather than attempting to study components of the treatments in isolation. Second, professional organizations and individual authors have offered practical suggestions for facilitating open communication and shared decision making between practitioners and families regarding alternative treatments. They have also identified approaches for assessing such treatments rigorously on a case-by-case basis in applied settings.

Looking to the future, several new developments also may be beneficial to practitioners and families. Careful research is beginning to accumulate on features of ASD that are targeted in many alternative treatments, such as unusual sensory processing (Bennetto, Kuschner, & Hyman, 2007) and difficulties with feeding (Seiverling et al., 2011) or sleeping (Richdale & Schreck, 2009). This research has the potential to increase understanding of these problems and lead to more effective treatments.

Also, efforts are underway to increase access to and quality of conventional care, which may reduce the impetus for families to seek alternative treatments. Notably, ASD specialists have developed supports for primary care providers to maintain a medical home that coordinates care for children with ASD (Hyman & Johnson, 2012). These supports include guidelines for establishing a medical home (Waisman Center, 2008), a resource toolkit for primary care providers (American Academy of Pediatrics, 2012), and training courses on early identification and ongoing management of ASD (CDC, 2011). In addition, Golnik and colleagues (Golnik, Scal, Wey, & Gaillard, 2012) described a short-term intervention to help pediatricians improve the medical home for children with ASD.

At the same time, a number of states have passed legislation mandating insurance coverage for treatment of individuals with ASD. This legislation may increase access to services while reducing financial burdens on families (Parish, Thomas, Rose, Kilany & McConville, 2012). In addition, resources are becoming available to help families make informed decisions about care for their children. For example, the private foundation Autism Speaks maintains an online library of toolkits for parents. These toolkits address topics such as what caregivers can do in the first few months after their child is diagnosed with ASD, how to work with educators and healthcare providers, what the pros and cons of placing children with ASD on psychotropic medication might be, and how to deal with situations that are often stressful for individuals with ASD such as going to the dentist. Other private foundations such as the Organization for Autism Research and the Autism Science Foundation have also created valuable online guides for families. These enhancements in service systems and resources show promise for increasing the availability of comprehensive care that meets the needs of individuals with ASD and their families.

CROSS-REFERENCES

Evidence-based treatments are the focus of Chapter 42. Cultural aspects of autism are addressed in Chapter 43.

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