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FRAGILE X CLINICAL &
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Integrative Health Recommendations for the Treatment of Fragile X Syndrome

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Integrative health[1] combines the Western biomedical model of medicine with complementary and alternative therapies. While the biomedical approach focuses on treating the individual's disease with traditional medications and non-pharmacological therapies, integrative health emphasizes a broader communication between healthcare providers and patients to determine the best combination of traditional and non-traditional therapies. This collaboration between patients and providers fosters a more holistic outlook on a patient's well-being.

Integrative health, complementary therapies, and alternative therapies are terms that sound very similar, but should not be confused with one another.

- When non-traditional therapies are used to *replace* traditional therapies, these are alternative therapies.
- When non-traditional therapies are used *together* with traditional therapies, these are complementary therapies.
- Integrative health is the combination of non-traditional complementary therapies and traditional therapies in a *coordinated* way.[2]

This document focuses on consensus and evidence-based therapies within the category of integrative health. For more information about melatonin and integration therapies, including Ayres Sensory Integration therapy, please see:

- **Sleep in Children with Fragile X Syndrome**[3]
- **Sensory Processing and Integration Issues in Fragile X Syndrome**[4]

Families often choose integrative health because traditional biomedical interventions have not resolved their concerns.[5] According to the **2012 National Health Interview Survey**,[6] more than 30% of US adults use some form of integrative health (mostly natural products, followed by deep breathing and yoga), but this rate is estimated to be anywhere between 28% and 95% in children with autism spectrum disorder (ASD).

Seeing that Fragile X syndrome (FXS) is the leading single-gene cause of autism, and often overlaps in presentation for many of the symptoms,[7] many families turn to non-traditional therapies to decrease the symptoms of autism that the biomedical model currently fails to treat. Integrative health therapies fall into a few basic categories:

- **Mind-body practices**: Yoga, qigong, hypnosis, neurofeedback, and meditation.
- **Nutritional approaches**: Special diets, vitamins, and supplements.
- **Whole body medicine**: Acupuncture, Traditional Chinese Medicine (TCM), and Ayurveda.
- **Manual therapies:** Massages, craniosacral therapy, reflexology, and the **Alexander Technique**.[8]
- **Homeopathy and energy therapies**: Reiki, crystal, and magnetic therapy.[9]

These health modalities each consist of varying degrees of evidence as to their benefits or harms. However, there is much more evidence for integrative health in patients with autism than there is in patients with FXS. Therefore, most of the evidence in this

document is extrapolated from studies involving patients with autism. However, initial unpublished data from the FORWARD study suggest some families living with FXS are using some form of alternative or complementary therapy. Some examples from the data include vitamins of any kind, fish oil, and probiotics.

Introduction

Currently, treatment guidelines for FXS do not specifically advocate for any form of integrative health therapy. That being said, as long as a treatment is safe and appears to benefit the patient, families should feel empowered to collaborate with their doctor to discuss different integrative health therapies. We strongly recommend that families discuss the treatment with the physician responsible for managing FXS symptoms to avoid adverse effects or harmful interactions with the treatment plan.

In addition, knowing a family is interested in pursuing these approaches allows the physician to guide the family away from potentially dangerous interventions and discuss alternatives.[10] Other things to consider when choosing to pursue integrative health include the financial burden of the therapy[11] and the emotional toll of the treatment, including any discomfort for the patient and the time required to administer the therapy.

Nontraditional Therapies with Potential Benefits

The therapies that have clear benefits include hippotherapy (horseback riding), instruction-based exercise, and melatonin.

Hippotherapy has been shown to definitively provide positive benefits for children with autism, especially in terms of improving social and communication skills, decreasing aberrant behaviors, and improving their postural control patterns. Nevertheless, these deficits are not cured with hippotherapy, so it should still be used in conjunction with other standard treatments such as behavioral and occupational therapies.[12]

Different forms of **instruction-based exercise** have also been shown to improve the lives of those with autism via multiple different avenues. Swimming was associated with increased social skills, while hydrotherapy uses hydrostatic pressure to decrease sensory overload. Cycling improved motor function, aerobic endurance, and strength in children aged 7-18. Neuromuscular training resulted in increased endurance, strength, and balance. Yoga improved balance, but requires more research to determine whether it has cognitive benefits for those with autism. Team sports improve social skills. Exergaming (video games for exercise) improved memory and focus.[13]

Melatonin has been shown to be safe and effective, though long-term safety data remain limited for those with **insomnia**.[14,15,16,17]

Therapies with Possible Benefits

There are many types of therapies with ongoing research for their potential benefits. These include different types of physical therapies (music, dance, massage, acupuncture) and certain supplements (omega-3, folic acid, magnesium, cannabidiol or CBD, and sulforaphane).

Acupuncture has conflicting research as to its efficacy and requires further research, but it is generally safe, with the caveat that initially, the children may be fearful or irritable when starting the therapy.[18]

Massages appear to improve sleep and pain symptoms in patients with autism, thereby positively affecting their adaptive behaviors.

Music therapy has been shown to have short-to-medium term benefits for social interactions and global functioning for patients with autism.

Dance movement therapy (based on the mirroring technique) was researched on adults with autism[19] and has moderate benefits on mental health, such as reducing anxiety and depression.[20]

Omega-3 fatty acids alone appear to have inconclusive evidence of efficacy in improving autism symptoms and have no effects on ADHD. But when **Mazahery et al**[21] looked at inflammation in autism, they found that the combination of omega-3 and vitamin D showed positive benefits for social awareness, communication, irritability, hyperactivity, and lethargy.

Another **case study from Italy**[22] that administered a combination of omega-3 and vitamin D showed similar significant improvements in agitation, self-injury, and social skills.[23] One caveat is that most studies have uncovered some adverse effects of omega-3 fatty acids, such as diarrhea, vomiting, or rash.[24] That being said, a Canadian survey found that 75% of autistic children use supplements, and of those, 42.5% use omega-3.[25] Despite the adverse effects, the popularity of omega-3 hints at a minimal overall side-effect profile and should not deter parents from attempting omega-3 supplementation.

Clinical research on folic acid has shown that taking it orally does not improve symptoms of FXS.[26] Folinic acid, which is derived from folate in the body, has been proposed as a treatment for autism under the presumption that there are antibodies that inactivate the enzyme converting folate to folinic acid and, therefore, low levels of folinic acid that need to be replaced.

The data on this are at best mixed, and there is no evidence for a deficit in the pathway for converting folate to folinic acid in FXS. In fact, a randomized controlled clinical trial of folinic acid (leucovorin) in FXS did not show benefit in any area among those receiving folinic acid versus placebo.[27]

Studies using a combination of magnesium with vitamin B6 do not have enough evidence to support an improvement in symptoms of autism. A **2005 Cochrane Review**[28] showed that there wasn't enough evidence supporting the use of magnesium with vitamin B6 in patients with autism.[29] However, **a Canadian survey**[30] found that 75% of children with autism used supplements, and of that population, 28.1% used magnesium, showing it is commonly used in patients with ASD Additionally, emerging evidence shows that magnesium is inversely correlated with hostility,[31] can help improve sleep quality and anxiety,[32] and is beneficial for depression.[33] It is important when supplementing with B6 and some other vitamins, particularly the fat-soluble ones, to avoid overdosing, as toxicity can result.

Cannabidiol (CBD) supplements, consisting of the non-intoxicating agent derived from cannabis plants, have also started to be investigated for their effects on individuals with FXS. While an initial registration trial for CBD gel appeared to show promising results in fully methylated individuals with FXS,[34] a recent phase 3 randomized, double-blind, placebo-controlled, multi-center study did not show significant improvement in social avoidance due to a higher-than-expected placebo response rate, and more studies are needed.[35] There are also accounts of patients trying various CBD supplements, some of which contain THC, the intoxicating agent from the cannabis plant. Any of these CBD supplements comes in various forms, such as oil, gummies, pills, or topical products. Despite a large variety of forms, dosages, and frequencies as to when CBD supplements were administered, the majority of respondents reported improvement in patient symptoms, especially anxiety.[36]

Sulforaphane (a compound found in cruciferous vegetables) is well-tolerated but has shown mixed results in the autism and Fragile X populations. Some studies suggest that sulforaphane supplementation improves aberrant behavior and verbal

communication skills, whereas others show no significant difference. This suggests that external factors, such as age and study methodology, are affecting the results, and that further studies are needed.[37,38,39,40]

Therapies of Unknown Efficacy

Many therapies do not have enough data on whether they are beneficial or harmful for patients with autism, including traditional Chinese and Ayurvedic therapies, curcumin, and some supplements (zinc, iron, vitamin A, prebiotics, probiotics).

Therapies such as **traditional Chinese and Ayurvedic therapies** have not been studied to a sufficient degree or in a manner that allows for risk-benefit assessment at this time. A meta-analysis of East Asian herbal medicines found that most human trials had a high risk of bias, showing only the advantages of herbal medicines while disregarding the disadvantages. Furthermore, ingredients used in these therapies have been reported to interact with medications commonly used in autism treatment. For example, the Ginkgo biloba herb was found to increase the negative side effects of risperidone, but when used alone, Ginkgo biloba didn't improve symptoms of autism.[41]

Curcumin, the main active compound found in turmeric, has gained wide interest for its anti-inflammatory properties.[42] Curcumin has been shown to regulate the RNA structure of the CGG expansion in controlled laboratory experiments, which could be used to treat Fragile X-associated tremor/ataxia syndrome (FXTAS), but no human clinical trials for FXS or autism have been performed yet.[43] It's important to note that although these lab experiments are exciting advances towards a treatment, they do not necessarily mean they will work when given to a patient. Without evidence from clinical trials, we cannot determine whether curcumin will treat the symptoms of any Fragile X-associated condition.

Caution should also be given to **supplements such as zinc and iron**, which can cause gastrointestinal issues. Furthermore, overconsumption of iron and vitamin A can lead to toxicity. Prebiotics and probiotics require more evidence as to their efficacy.

Some supplements may have positive benefits for those with autism. However, families should proceed with caution, as the supplement industry is unregulated by the FDA and often faces problems with contaminants, unknown dosages, and unfounded claims made by supplement companies.[44] Similarly, herbal medicines have been reported to have contaminants such as heavy metals, mycotoxins, pesticides, and fungi.[45]

Therapies with No Benefits

There are numerous therapies that have no evidence supporting their use for symptoms related to FXS. These include homeopathy, crystal therapy, Reiki, some supplements (acetyl-L-carnitine), and special diets.

There are two small clinical studies in children with FXS that show acetyl-L-carnitine 20-50 mg/kg daily for one year does not improve intellectual function compared with placebo. Also, while it may reduce hyperactive behavior in these patients as assessed by parents, it does not appear to reduce it as assessed by teachers.[46,47]

Although previous studies indicated a possible benefit from a casein and gluten-free diet, the controlled trial looking at a gluten-free casein-free diet did not show any benefit for individuals with autism who did not have a gluten or casein-related disorder.[48,49] Additionally, adherence to this diet clearly increases the risk of calcium, vitamin D, and protein deficiencies;[11] and maintaining such a strict diet can place significant financial and social burdens on the family. Families who choose elimination of diets may find referral to a dietitian to discuss the potential benefits and risks helpful.[50]

Dangerous Therapies

The following therapies should never be used as they are dangerous and have no benefit: Raw camel milk,[51] chelation therapy, and severe dietary restrictions.

In addition, hyperbaric oxygen therapy[52] and holding therapies involving physical restraint or interventions were found to be harmful with no efficacy. It is also important to bear in mind that avoidant therapies, such as withholding vaccines, have no evidence to support their efficacy in minimizing developmental or autistic symptoms in children with or without FXS.[53]

Many online sources and products claim that an "autism detox" will cure a patient's autism symptoms by removing toxins from the bloodstream. However, autism spectrum disorder cannot be cured. Some of these therapies are dangerous and should not be used, such as chelation therapy, Miracle Mineral Solution (chlorine dioxide),[54] zeolite-containing products,[55] or colonic irrigations.[56] The IonCleanse Footbath has been marketed as a product that removes toxins via the feet, but that claim is unfounded.[57] Glutathione has also been marketed as a "detox" cure, but has not been found to have any benefits in behavior or biological markers of glutathione.[58] If you have any questions about starting a new therapy, please consult your doctor first.

The Bottom Line

If you are interested in using integrative health to help someone with FXS, your doctor should help you and support your decision. Both traditional and non-traditional practitioners should work together to help the patient with FXS get the personalized care they need. Together, the patient, caregivers, and team can decide on the best treatment regimen based on research evidence, cost, and risk-benefit analysis. If there are any questions about a new therapy, please contact your doctor first.

Frequently Asked Questions

Q: What to do in an acute situation?

A: If the child is acutely ill, the family should contact their physician or take the child to the emergency room. The **Poison Control Center**[59] may be able to assist physicians dealing with unknown agents.

Q: Are there therapies other than those discussed here?

A: Yes, the therapies mentioned in this article are by no means comprehensive. The **National Center for Complementary and Integrative Health (NCCIH)**[60] has further information. No list, however, is exhaustive. Even greater care should be taken when pursuing newer options, as there will be fewer known side effects than in the more well-known options.

Author's Note

This guideline was authored by Emie Ung, Rena Pressman, LCGC, and Deborah Barbouth, MD. The original guidelines were written by Jonathan Picker, MD, PhD, who also reviewed and edited this updated version. The revised guidelines were additionally reviewed and edited by members of the National Fragile X Foundation's Fragile X Clinical & Research Consortium. They have been approved by the Consortium and represent the current consensus of its members.

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