The Use of a Dietary Supplement Combination and an Essential Fatty Acid as an Alternative and Complementary Treatment for Children with Attention-Deficit/Hyperactivity Disorder

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Abstract. ***Background:*** We investigated the efficacy of a dietary supplement combination (Ginkgo biloba, Melissa officinalis, Grapine, dimethylaminoethanol, and l-glutamine) and an essential fatty acid (flaxseed) as a treatment for inattentiveness and hyperactivity-impulsivity. The purpose of this study was to provide empirical evidence regarding their effectiveness in reducing ADHD-related behaviors in children diagnosed with this disorder.

Methods: Sixty participants initially were chosen to participate in 2 12-week trials. Thirty participants were chosen randomly from those not taking Ritalin, and 30 participants were chosen randomly from those taking Ritalin. After attrition, the same 51 children completed each trial.

Results: During trial 1, the dietary supplement combination was not more effective than a placebo at ameliorating children's inattentiveness and hyperactivity-impulsivity among children taking and not taking Ritalin. Results from trial 2 were mixed. Among children taking Ritalin, teachers reported those who received the double dietary supplement combination displayed less inattentive behavior than those who received the double dietary supplement combination plus an essential fatty acid. Also, among children not taking Ritalin, parents reported those who received the double dietary supplement combination plus an essential fatty acid displayed less hyperactive-impulsive behavior than those who received the double dietary supplement combination. However, teachers reported those who received the double dietary supplement combination displayed less hyperactive-impulsive behavior than those who received the double dietary supplement combination plus an essential fatty acid.

Conclusions: Given the mixed results from this study, the ingredients in the dietary supplement combination and an essential fatty acid taken either individually or in combination with Ritalin may not be a reliable and effective alternative or complementary treatment of ADHD.

Introduction

Most children are active and energetic, moving quickly from one activity to the next. Although they may become bored with tasks offering few rewards, they typically are able to display self-discipline while attending to tasks, concentrating, and sitting still. Other children's behaviors appear disorganized and frenzied, showing inability to sustain interest and persistence. Their intellectual ability may also be diminished. Many of these children have been diagnosed with an attention-deficit/hyperactivity disorder (ADHD).

Children with ADHD daydream, lack concentration, and change activities more than others. They show

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less-sustained concentration for dull and repetitive tasks (e.g., schoolwork, homework, chores).[1,2,3] Children with ADHD act impulsively and show lower regard for the consequences of their actions, not allowing sufficient time between presentation of the stimulus and their response.[4] They often fidget, create noise, and engage in nervous habits (e.g., finger tapping, hair twirling). They become overexcited more easily when overstimulated. Although many children exhibit hyperactive symptoms on occasion, those with ADHD show increased frequency, duration, and intensity of these symptoms. Impulsiveness in school can lead to deficient academic attainment and impaired social relationships.

The prevalence of ADHD, the proportion of the population affected, is estimated to be from between 6 and 8% to as much as 10% of school-aged children.[5,6] Differences in estimates are due, in part, to lack of agreement as to which dysfunctions characterize the syndrome.[7]

The total number of school-aged children in the United States with ADHD is approximately 2 to 3 million.[8] U.S. classrooms from kindergarten through 12th grade average 1 or 2 students with the disorder.[9] While some claim ADHD is overdiagnosed,[10] other research suggests it is not.[11] Although some children are diagnosed with ADHD without a sufficient evaluation, researchers generally report little evidence of widespread overdiagnosis of this disorder.

Pharmacological intervention

Stimulant medication, proposed as a treatment for hyperactivity in the 1930s, is one of the most common and successful treatments for ADHD.[12,13] Positive response rates to stimulant medications, usually Ritalin, reportedly vary from 70 to 96%.[14]

About three fourths of the 2.6 million consumers of Ritalin are children aged 5 to 12.[15] It is prescribed for more than 90% of children with ADHD who receive stimulant medication.[11,16] The number of U.S. children taking stimulant medications has doubled every 2 years since 1988 and was expected to reach 8 million by the year 2000.[17]

The majority of children treated with stimulant medications experience some adverse reactions, ranging from mild to severe.[18] Milder symptoms include insomnia, decreased appetite, irritability, anxiety, headaches, and stomachaches in 20 to 50% of children.[19] More severe adverse reactions include liver dysfunction,[6,20,21] glaucoma,[22] symptoms of psychosis,[23] anorexia,[24] heart problems leading to sudden death,[22] leukopenia,[25] depression,[26] motor and vocal tics,[27] and permanent facial tics.[6,28,29]

"Alternative" treatments

Some believe that alternatives to stimulant medications, or "natural" approaches, should be explored before beginning drug therapy.[30,31] A number of these methods include Ginkgo biloba, Melissa officinalis, Grapine, dimethylaminoethanol, l-glutamine, and essential fatty acids (e.g., flaxseed).

Ginkgo biloba is one of the oldest living tree species, dating back more than 200 000 years. It is claimed to improve mental clarity and alertness.[32] A review of 40 controlled trials found most trials reported at least a partially positive outcome in patients with cerebral insufficiency (i.e., difficulties with concentration and memory, absentmindedness, confusion, lack of energy, depressive mood, anxiety, dizziness, tinnitus, and headache).[33]

Melissa officinalis (lemon balm) contains nervine principles that are claimed by some to help restore the function of brain and nerve cells. It has a mild relaxing effect,[34,35] making it a candidate drug, but with effects acting opposite from stimulatory drugs.[36]

Grapine is derived from both the bark of the French maritime pine tree and grape seed.[37] Some have reported grapine to decrease ADHD symptoms.[38,39] It is an antioxidant known to cross the blood-brain barrier. Some claim it improves memory, recall, and concentration[36] as well as attentiveness and self-regulated activity levels.[40] Often used in France to control symptoms of ADHD, it is used by some in the United States as an alternative to Ritalin.[41]

Dimethylaminoethanol (DMAE) is a choline precursor that crosses the blood-brain barrier. It is normally present in small quantities and is claimed to improve memory, learning, and intelligence, and to elevate moods.[39] DMAE is naturally abundant in seafood (e.g., sardines, anchovies). The rationale for its use is based on its being a precursor to the neurotransmitter acetylcholine.

L-glutamine, an amino acid, penetrates the blood barrier. It is claimed to provide improved mental alertness and clarity[42] and to be deficient in children with ADHD.[36] Supplementation is claimed to improve concentration, alertness, memory, and recall.[43] Some believe glutamine and Ginkgo biloba are effective in combination, promoting concentration, memory, and on-task behavior.[43]

Flaxseed is rich in omega-3 essential fatty acids (EFAs).[44] One study found that children with ADHD cannot metabolize or absorb EFAs normally.[45] EFAs are claimed to have been found in lower concentrations in the plasma polar lipids and red blood cell lipids among persons with ADHD.[46] Essential fatty acid supplemen-

Table 1. Treatment During Trials 1 and 2

Trial & Group	Treatment	Treatment Ingredients and Dosages
Trial 1, Group 1A (Treatment)	Dietary supplement combination	Ginkgo biloba 10 mg; Melissa officinalis 200 mg; Grapine 30 mg; dimethylaminoethanol 35 mg; l-glutamine 100 mg
Trial 1, Group 1B (Control)	Placebo	Slippery elm supplement 220 mg
Trial 1, Group 2A (Treatment)	Ritalin plus dietary supplement combination	Ginkgo biloba 10 mg; Melissa officinalis 200 mg; Grapine 30 mg; dimethylaminoethanol 35 mg; l-glutamine 100 mg
Trial 1, Group 2B (Control)	Ritalin plus placebo	Slippery elm supplement 220 mg
Trial 2, Group 1A (Control)	Double dietary supplement combination	Ginkgo biloba 20 mg; Melissa officinalis 400 mg; Grapine 60 mg; dimethylaminoethanol 70 mg; l-glutamine 200 mg
Trial 2, Group 1B (Treatment)	Double dietary supplement combination with an essential fatty acid	Ginkgo biloba 20 mg; Melissa officinalis 400 mg; Grapine 60 mg; dimethylaminoethanol 70 mg; l-glutamine 200 mg; flaxseed 1000 mg
Trial 2, Group 2A (Control)	Ritalin plus double dietary supplement combination	Ginkgo biloba 20 mg; Melissa officinalis 400 mg; Grapine 60 mg; dimethylaminoethanol 70 mg; l-glutamine 200 mg
Trial 2, Group 2B (Treatment)	Ritalin plus double dietary supplement combination with an essential fatty acid	Ginkgo biloba 20 mg; Melissa officinalis 400 mg; Grapine 60 mg; dimethylaminoethanol 70 mg; l-glutamine 200 mg; flaxseed 1000 mg

tation in one study was shown to improve problems with attention and motor excess.[47]

This study investigated the efficacy of the use of a dietary supplement combination of Ginkgo biloba, Melissa officinalis, Grapine, dimethylaminoethanol, and l-glutamine with essential fatty acid (i.e., flaxseed) as treatments for ADHD in children taking and not taking Ritalin.

Methods

Participants

Participants were referred by parents, pediatricians, psychologists, psychiatrists, and educators. They met the criteria of the *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (*DSM-IV*) for a diagnosis of ADHD, Combined Type. The disorder was diagnosed by a physician or psychologist. Those with serious and preexisting medical or psychological conditions (e.g., asthma, depression) and those taking a stimulant medication other than Ritalin were not included in this study. Fifty-one (44 males and 7 females) of the 60 children originally selected to participate remained throughout the study. They ranged in age from 4 to 12, with an average age of 8.4 years. Twenty-six (51%) of these children, 23 males and 3 females, were taking the stimulant medication Ritalin.

Procedures

The study consisted of 2 12-week trials, hereafter called trial 1 and trial 2. Within each trial were 2 experimental and 2 control groups (Table 1). As previously noted, 60 candidates were initially chosen to participate. Thirty participants were chosen from those not taking Ritalin, and 30 participants were chosen from those taking Ritalin. Participants were assigned randomly to either a treatment group or a control group prior to trial 1, resulting in 15 participants in each of 4 groups. Participants who were not taking Ritalin were assigned to either

the non-Ritalin treatment group or the non-Ritalin control group. Participants who were taking Ritalin were assigned to either the Ritalin treatment group or the Ritalin control group.

The Conners' Rating Scales–Revised: Long Form (CRS–R:L) were used to assess qualities relevant to ADHD. These scales were administered prior to commencement of the study and at the conclusions of trials 1 and 2 to assess treatment effects. Information regarding each participant's inattentive, hyperactive, and impulsive behaviors was collected from both parents and teachers using this measure. Participants' parents were asked to complete a Conners' Parent Rating Scale–Revised: Long Form.[47] The teacher with whom each participant spent most of his or her school day was asked to complete a Conners' Teacher Rating Scale–Revised: Long Form.[47] The CRS–R:L were chosen over other instruments such as the Child Behavior Checklist[48] and the Teacher's Report Form[49] because items from the Conners' DSM-IV: Inattentive and DSM-IV: Hyperactive-Impulsive symptoms subscales parallel *DSM-IV* criteria for a diagnosis of ADHD. Thus, its items match the core behaviors of the disorder.

Treatments

This was a double- to triple-blind study wherein parents, teachers, and data collectors did not know what substances the participants were taking until the study was completed. Only the study physician had access to this information.

Upon commencement of trial 1, participants in the treatment groups began taking their dietary supplement combination (Table 1). This dietary supplement combination consisted of Ginkgo biloba 10 mg, Melissa officinalis 200 mg, Grapine 30 mg, dimethylaminoethanol 35 mg, and l-glutamine 100 mg. For those not taking Ritalin, participants in group 1A received this dietary supplement combination while participants in group 1B received a placebo. Participants already taking Ritalin were instructed to take it in addition to their study medication. Participants in group 2A received the dietary supplement combination in addition to their Ritalin while participants in group 2B received a placebo in addition to their Ritalin. Participants were instructed to take their treatment medication twice daily, once with breakfast and again with an afternoon snack or with dinner.

Trial 2 was implemented following the completion of trial 1 (i.e., after 12 weeks), using the same subjects from the first trial. Subjects remained in their cohort groups; only the treatment changed. All participants received a dietary supplement combination whose concentration was doubled (i.e., the dosage of each ingredient was doubled). The initial lower concentration was used during trial 1 since professionals often believe it best to begin on a lower herbal dose and increase it only if improvements are not demonstrated.[50] Moreover, we wanted to determine if changes become apparent with the use of lower doses. Anecdotal reports from parents to the study physician led to a decision to double the concentration of each ingredient in the dietary supplement during trial 2. The 2 treatment groups received an essential fatty acid with their combination. Participants again were instructed to take their treatment medication twice daily, once with breakfast and again with an afternoon snack or with dinner.

Upon commencement of trial 2, participants in the treatment and control groups began taking their dietary supplement combination (Table 1). Those in the control group received a double dietary supplement combination consisting of Ginkgo biloba 20 mg, Melissa officinalis 400 mg, Grapine 60 mg, dimethylaminoethanol 70 mg, and L-Glutamine 200 mg. Those in the treatment group received a double dietary supplement combination consisting of Ginkgo biloba 20 mg, Melissa officinalis 400 mg, Grapine 60 mg, dimethylaminoethanol 70 mg, l-glutamine 200 mg, and flaxseed 1000 mg.

For those not taking Ritalin, participants in group 1A (who first received the dietary supplement combination) received the double dietary supplement combination. Participants in Group 1B (who first received a placebo) received the double dietary supplement combination as well as an essential fatty acid. For those already taking Ritalin, participants in group 2A (who first received the dietary supplement combination) received the double dietary supplement combination. Participants in Group 2B (who first received a placebo) received the double dietary supplement combination as well as an essential fatty acid.

A slippery elm supplement was used as the placebo. It has a long history of use as a food supplement, especially by pioneers who considered it "survival food."[51] It was chosen for this study since it has been declared safe by the Food and Drug Administration.[52]

Data analysis procedures

The data were analyzed using analysis of covariance (ANCOVA). The method is used to compare data from 2 or more time periods when data from the first period may display group differences and be correlated with data from a second time period. ANCOVA adjusts data

at time 2 based on data from time 1. Thus, ANCOVA helps to eliminate initial group differences on the covariate and increases precision. Pretest raw scores from the Conners' Rating Scales–Revised, children's age groups from the Conners' Rating Scales–Revised, and gender were used as covariates. The rating scale does not use a child's actual age when calculating a raw score; rather, it clusters children into one of five age groups (i.e., ages 3 to 5, ages 6 to 8, ages 9 to 11, ages 12 to 14, and ages 15 to 17) depending on gender. The 3 covariates are appropriate because their values are indicators of a characteristic of the experimental units (i.e., posttest raw score) and the treatments have no influence on the value of these covariates when measured prior to the intervention. Separate analyses were performed on trial 1 and trial 2 data. Data acquired before the initiation of the study were used as covariates for trial 1 data. Data acquired at the end of trial 1 were used as the covariate for trial 2 data. An alpha level of .05 was used to determine whether group differences were significant.

RESULTS

Trial 1 hypotheses and results

Participants receiving the dietary supplement combination (group 1A) were expected to display less inattentiveness than those receiving the placebo (group 1B), based on parent and teacher reports. Differences in parent ($p = .89$) and teacher ($p = .12$) reports of attentiveness were not significant.

Participants receiving Ritalin plus the dietary supplement combination (group 2A) were expected to display less inattentiveness than those receiving Ritalin plus the placebo (group 2B), based on parent and teacher reports. Differences in parent ($p = .40$) and teacher ($p = .29$) reports were not significant.

Participants receiving the dietary supplement combination (group 1A) were expected to display less hyperactivity-impulsivity than those receiving the placebo (group 1B), based on parent and teacher reports. Differences in parent ($p = .27$) and teacher ($p = .63$) reports were not significant.

Participants receiving Ritalin plus the dietary supplement combination (group 2A) were expected to display less hyperactivity-impulsivity than those receiving Ritalin plus the placebo (group 2B), based on parent and teacher reports. Differences in parent ($p = .93$) and teacher ($p = .71$) reports were not significant.

Trial 2 hypotheses and results

Participants receiving the double dietary supplement combination with an essential fatty acid (group 1B) were expected to display less inattentiveness than those receiving the double dietary supplement combination (group 1A), based on parent and teacher reports. Differences in parent ($p = .39$) and teacher ($p = .06$) reports were not significant.

Participants receiving Ritalin plus the double dietary supplement combination with an essential fatty acid (group 2B) were expected to display less inattentiveness than those receiving Ritalin plus the double dietary supplement combination (group 2A), based on parent and teacher reports. Differences in parent reports were not significant ($p = .60$); differences in teacher reports ($p = .04$) were significant (Table 2). Teachers reported children taking Ritalin plus the double dietary supplement combination with an essential fatty acid displayed less inattentiveness than those taking Ritalin plus the double dietary supplement combination.

Participants receiving the double dietary supplement combination with an essential fatty acid (group 1B) were expected to display less hyperactivity-impulsivity than those receiving the double dietary supplement combination (group 1A), based on parent and teacher reports. Differences in parent reports were significant ($p = .03$) (Table 2). Parents reported children taking the double dietary supplement combination with an essential fatty acid displayed significantly less hyperactivity-impulsivity than those taking a double dietary supplement combination. Differences in teacher reports of hyperactivity-impulsivity also were significant ($p = .04$) (Table 2). Teachers reported children taking the double dietary supplement combination displayed significantly less hyperactivity-impulsivity than those taking a double dietary supplement combination with an essential fatty acid.

Participants receiving Ritalin plus the double dietary supplement combination with an essential fatty acid (i.e., group 2B) were expected to display less hyperactivity-impulsivity than those receiving Ritalin plus the double dietary supplement combination (i.e., group 2A), based on parent and teacher reports. Differences in parent ($p = .87$) and teacher ($p = .50$) reports were not significant.

DISCUSSION

The dietary supplement combination (Ginkgo biloba, Melissa officinalis, Grapine, dimethylaminoethanol, and

Table 2. Conners' Rating Scales–Revised Scores of Inattentiveness and Hyperactivity-Impulsivity from Parents and Teachers

DSM-IV: Inattentive Subscale

		Parents		Teachers	
	Group	Mean	SD	Mean	SD
Trial 1	Non-Ritalin treatment	17.2	1.8	13.8	2.0
	Non-Ritalin control	16.9	1.7	17.7	1.9
	Ritalin treatment	17.2	1.7	16.9	2.1
	Ritalin control	15.3	1.8	14.2	2.0
Trial 2	Non-Ritalin treatment	12.0	1.5	19.1	1.5
	Non-Ritalin control	13.7	1.6	15.3	1.6
	Ritalin treatment	15.6	1.5	16.3*	1.5
	Ritalin control	14.6	1.4	12.2*	1.7

DSM-IV: Hyperactive-Impulsive Subscale

		Parents		Teachers	
	Group	Mean	SD	Mean	SD
Trial 1	Non-Ritalin treatment	13.8	1.5	11.2	2.1
	Non-Ritalin control	15.8	1.5	12.4	2.0
	Ritalin treatment	13.5	1.4	13.8	2.2
	Ritalin control	13.3	1.5	14.8	2.0
Trial 2	Non-Ritalin treatment	9.4†	1.3	17.9‡	1.7
	Non-Ritalin control	13.1†	1.3	13.4‡	1.8
	Ritalin treatment	13.7	1.3	10.8	1.7
	Ritalin control	13.5	1.3	12.3	1.9

*Significant difference $p = .04$
†Significant difference $p = .03$
‡Significant difference $p = .04$

L-Glutamine) was hypothesized to ameliorate the inattentive and hyperactive-impulsive behaviors exhibited by participants and thus was evaluated during trial 1 based on previous research.[32,35,41] Results indicate this dietary supplement combination had no significant effect on children's inattentiveness or hyperactivity-impulsivity when taking or not taking Ritalin.

During trial 2, the double nutritional combination was hypothesized to ameliorate inattentive and hyperactive-impulsive behaviors exhibited by participants based on previous research.[32,33,41,46] Results from trial 2 were mixed. For children not taking Ritalin, differences in attentiveness between those receiving the double nutritional combination with an essential fatty acid and those receiving the double nutritional combination were not significant. This is consistent with the results from trial 1. For children taking Ritalin, differences in attentiveness based on parent reports were not significant, but were significant based on teacher reports. They reported children who received a double dietary supplement combination displayed less inattentiveness than those who received a double dietary supplement with an essential fatty acid.

Among children not taking Ritalin, measurable dif-

ference in hyperactivity-impulsivity was noted from both parent and teacher reports. However, the results are contradictory. Parents reported children who received the double dietary supplement combination with an essential fatty acid displayed significantly less hyperactive-impulsive behavior than those receiving the double dietary supplement combination. Meanwhile, teachers reported children who received the double dietary supplement combination with an essential fatty acid displayed more hyperactive-impulsive behavior than those receiving the double dietary supplement combination.

Several reasons are offered to explain differences between the findings from this study and those reported by others. For example, anecdotal reports may not have used objective criteria when determining whether improvements exist in children's behaviors.

The dosages used in other studies[36,38,39] reporting significant changes in inattentiveness often are unknown. The choice of dosage of herbal supplements and dietary supplements remains somewhat arbitrary, especially for children. Lack of information regarding dosages used in studies with children with ADHD makes it difficult to compare dosages and interpret research findings.

Also, not all essential fatty acids may work alike. It is possible that flaxseed, while high in omega-3 essential fatty acids, works differently than other essential fatty acids. Reports of positive responses to essential fatty acids often do not indicate which kind was used. Instead, the generic term "essential fatty acid" typically is reported, leaving the reader without knowledge regarding the type of supplement.

Conclusions

The use of a double dietary supplement combination with an essential fatty acid may not be a reliable treatment for ADHD. In other words, the use of these supplements with the dosages used in our study should not be expected to reduce behaviors associated with ADHD. More empirical research is necessary to determine if higher dosages of these supplements have the ability to improve inattentiveness and hyperactivity-impulsivity before they can be replied upon as a viable alternative to Ritalin for the treatment of children with ADHD.

Mixed results from trial 2 suggest further study of essential fatty acids as a potentially effective alternative or complementary treatment is necessary. Essential fatty acids should be studied independently of any other treatment to test for possible treatment effects.

The double dietary supplement combination also should be studied independently of other treatments. This combination functioned as a uniform intervention to detect any significant differences in the groups receiving the essential fatty acid. Although the single dietary supplement was shown to be ineffective at ameliorating children's inattentiveness and hyperactivity-impulsivity, the double dose may potentially offer some benefit.

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