Complementary and Alternative Therapies in Developmental Disabilities

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Objective:

Identify advances in clinical assessment and management of selected healthcare issues related to persons with developmental disabilities

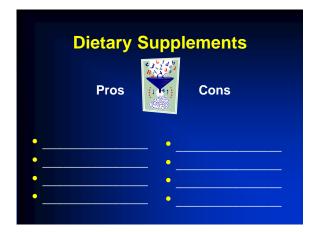
Notes:

Complementary and Alternative Therapies Developmental Disabilities Teresa Bailey, PharmD, BCACP, BCPS Professor Ferris State University College of Pharmacy 2016

Objectives • Explain the steps that should be taken when counseling a patient about a dietary supplements • Understand the general guidelines regarding dietary supplements • Recognize dietary supplements that are considered unsafe







Advantages Regarding Dietary Supplements Patient autonomy Patient use Cheaper than prescription medication Profit to be made?

2012 National Health Interview Survey National Institutes of Health National Center for Complementary and Alternative Medicine Report 33.2% adults reported using CAM in previous year 83 million adults spent \$33.9 billion out-ofpocket on CAM (1.5% of total) Conventional out-of-pocket = \$268.6 billion Total health care spending = \$2.2 trillion

\$14.8 billion on natural products vs \$47.6 billion

on Rx drugs

2012 National Health Interview Survey National Institutes of Health National Center for Complementary and Alternative Medicine Report No difference in gender, age More likely to be Caucasian, Asian Some college or college degree Private insurance

Children with Autism Spectrum Disorder

 30-95% of children have been provided with CAM

Limitations to Dietary Supplement

- Fear of legal liability
- Lack of reputable manufacturers
- Absence of FDA approval
- Difficulty identifying product content
- Reviewing hundreds of products and indications
- Health care provider concerns



























Top Dietary Supplements
Used in Developmental
Disabilities
Specific Information

According to Autism Speaks Vitamins Melatonin Omega 3 fatty acids Probiotics? Casein and Gluten free diets

Vitamins/Minerals

- Autism Speaks Autism Treatment Network
 - Found that supplements and special diets for children with autism
 - Unsafe levels of Vitamin A, folic acid and Zn
 - Low levels of Calcium and Vitamin D

Melatonin

Natural Medicine Comprehensive Database



- Orphan drug status
 - Treatment of circadian rhythm sleep disorders in blind people with no light perception
- Non-approved indications
 - Jet lag, insomnia, depression, and cancer

Melatonin

Natural Medicine Comprehensive Database

- Mechanism of action
 - Hormone made from serotonin and secreted by the pineal gland
 - Melatonin controls the periods of sleepiness and wakefulness
 - May possess antioxidant properties



The use of MElatonin in children with Neurodevelopmental Disorders and impaired Sleep: a randomised, double-blind, placebo-controlled, parallel study (MENDS).

Health Technol Assess 2012;16(40)

- 146 children with neurodevelopmental disabilities
 - aged from 3 years to 15 years 8 months
 - did not fall asleep within 1 hour of lights out or who had <6 hours of continuous sleep
 - Autism, epilepsy, developmental delays

MENDS

Health Technol Assess 2012;16(40)

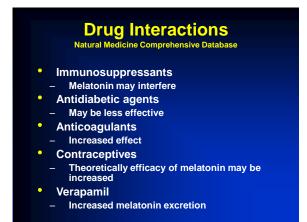
Melatonin or placebo capsules in doses of 0.5mg, 2mg, 6mg and 12mg for 12 weeks

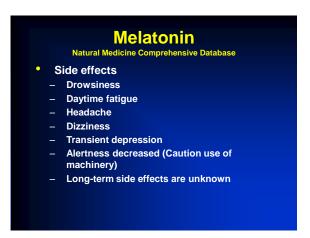
- Time to sleep onset 45.34 minutes sooner*
- Total sleep time 22.43 minutes longer*
- Total sleep time 9.5 hours*

Melatonin Dose Escalation 0.5 mg 2 mg 6 mg 12 mg 15% 20% 26% 39%



Drug Interactions Natural Medicine Comprehensive Database Selective serotonin reuptake inhibitors May increase melatonin serum concentrations Other sedatives may exacerbate the sedative effects of melatonin Alcohol Benzodiazepines Caffeine Theoretically, efficacy of melatonin may be decreased









Omega-3 Fatty Acids for

- Conflicting data on the effectiveness of omega-3 fatty acids in ADHD
 - Necessary for proper brain development and
 - When supplemented, results are clinically
 - No studies prove that fatty acids alone are an effective treatment for ADHD

Omega-3 Fatty Acids

- Likely safe in children when taken orally and appropriately
- Dose for pediatric patients for ADHD has not been established however there are many different sources
 - Breast milk, flaxseed oil, Docosahexanoeic Acid (DHA), Alpha linolenic acid (ALA)

Omega-3 Fatty Acids

- For Autism
- Small studies suggest omega-3 fatty
 - -reduces symptoms of repetitive behavior, hyperactivity
 - improves socialization
- Studied dose of 1.3 grams of omega-3 fatty acids/day for 12 weeks

Contraindications and Precautions

Natural Medicine Comprehensive Database

- Seafood allergy
- Bipolar disorder (possible hypomania)
- Bleeding
- Cardiac disease
- Depression (possible hypomania)
- Diabetes mellitus (possible BG worsens)
- Hypertension

CLUTTON CALIFORN CHILTON Immunodeficiency (possible suppression)

Drug Interactions

Natural Medicine Comprehensive Database

- Anticoagulants/Antiplatelets/Thrombolytics
 - Increase bleeding
- Antihypertensives
 - Additive blood pressure reduction
- Xenical, Alli, Orlistat
 - Decreased fish oil absorption
 - » Separate by 2 hours



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Adverse Reactions

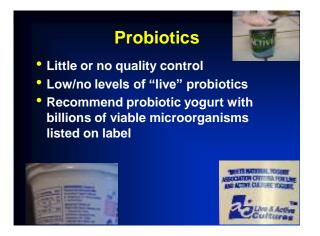
Natural Medicine Comprehensive Database

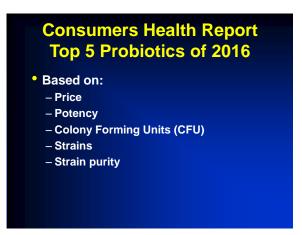
- Bleeding
- Ecchymosis (bruising)
- Epistaxis (nosebleeds)
- Hypervitaminosis A
- Hypervitaminosis D
- Rash

- Dyspepsia
- Eructation (burping)
 - Nausea/Vomiting
- Diarrhea
- Halitosis
- Dysgeusia (taste perversion)
- Freeze capsules???
- Enteric coated capsules













Vitamin B6

- Drug Interactions:
 - Isoniazid, cycloserine, hydralazine antagonize pyridoxine.
 - Levodopa is antagonized
- Side effects: neuropathy

Vitamin B6

- Dietary Sources
 - -****Protein rich foods---extra-lean meat, chicken, fish, soybeans, cooked dried beans and peas, wheat germ, brewer's yeast, and peanuts
 - Avocados, bananas, cabbage, cauliflower, potatoes, whole grain breads and cereals

Magnesium

- Essential macromineral for enzymecatalyzed metabolic reactions
- When combined with vitamin B6, increased B6 efficacy
- Doses studied:
 - 100 mg/70 kg
 - 10 mg/kg; max 350 mg/day



Magnesium

- Side Effects
 - Diarrhea
 - Abdominal cramping
- Toxicity increases with kidney impairment

Magnesium

- Contraindications
 - Heart block
 - Kidney failure
- Safety
 - Large doses unsafe
 - Irregular heart beat, low BP, confusion, coma, and death

Drug Interactions

- Decrease effectiveness
 - Quinolones and tetracyclines
 - » Separate by 2 hrs before or 6 hrs after the antibiotic
 - Levothyroxine
 - » Separate by 4 hrs.

Selected Food Sources of Magnesium http://ods.od.nih.gov/factsheets/Magne			
FOOD	sium_pf.asp	Milligrams (mg)	%DV*
Halibut, cooked, 3 ounces		90	20
Almonds, dry roasted, 1 ounce		80	20
Cashews, dry roasted, 1 ounce		75	20
Soybeans, mature, cooked, ½ cup		75	20
Spinach, frozen, cooked, ½ cup		75	20
Nuts, mixed, dry roasted, 1 ounce		65	15
Cereal, shredded wheat, 2 rectangular biscuits		55	15
Oatmeal, instant, fortified, prepared w/ water, 1 cup		55	15
Potato, baked w/ skin, 1 medium		50	15
Peanuts, dry roasted, 1 ounce		50	15
Peanut butter, smooth, 2 Tablespoons		50	15

Carnitine • Helps intracellular transport of long chain fatty acids and energy generation • Improves expressive and receptive vocabulary • Improves Gilliam Autism Rating Scale • Dose 800 mg/day for 8 weeks

Carnitine

- Side Effects: nausea, vomiting, diarrhea
 - Breath, urine may have a fishy odor
- Drug interactions: warfarin, levothyroxine
- Disease interactions: seizure disorder, hypothyroidism worsens

Down Syndrome

 American College of Medical Genetics states no scientific evidence that supplements can improve mental functioning

Cerebral Palsy

- WebMD
 - GABA (Insufficient evidence)
 - » Might improve mental development, learning, vocabulary, and physical function
 - Magnesium (Possibly effective)
 - » Given in utero may decrease risk of cerebral palsy in infant

Valerian (Valeriana officinalis)

- Indications
 - Restlessness
 - Nervous disturbance of sleep
- Pharmacology
 - Central depressant action
 - Inhibition of GABA enzyme
 - Spasmolytic effect

Valerian (Valeriana officinalis)

- Contraindications/Precautions
 - Similar: benzodiazepines, barbiturates, opiates
- Drug Interactions
 - Sedatives
 - Anxiolytics
 - Monoamine oxidase inhibitors
 - Alcohol
 - Antidepressants

Valerian (Valeriana officinalis)

- Side effects
 - Headache, hangover, insomnia, cardiac disturbances
 - Toxicity: Ataxia, hypothermia, hallucinations, increase muscle relaxation
 - No effect on reaction time, alertness, concentration in the morning
- » (Pharmacopsychiatry 1999;32(6):235-41.)
 Dosage: 2-3 grams QD-TID

General Guidelines Regarding Dietary Supplements

- "First do no harm."
- Pregnancy, lactation
- Children
- Medications
 - Warfarin
 - Cytochrome P450
- Immunocompromised states
 - Cancer, HIV, transplant patients
- Anti-obesity herbs
 - Laxatives, diuretics, ma huang, thyroid herbs

Patient Counseling

- "What remedies are you using in addition to your medications?"
- Any OTC medications, any herbs, vitamins, or other dietary supplements?"
- Nonjudgmental

Patient Counseling

- Inform patients
 - FDA does not regulate
 - » Standardization
 - » Efficacy
 - » Safety
 - » Drug interactions
 - What is actually known of the product
 - » Textbooks
 - » Literature searches
 - » Internet

Patient Counseling

- - Potential liability
- Patient follow-up
 - Report Adverse Drug Reactions
 - » FDA's MedWatch hotline at 1-800-FDA-1088
 - » Fax a report to 1-800-FDA-0178
 - » http://www.fda.gov/medwatch/report/hcp.htm
 - Drug Interactions

