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# Educating pharmacists and the public about the role of over-the-counter medications in the management of Autism Spectrum Disorders

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# Educating pharmacists and the public about the role of over-the-counter medications in the management of Autism Spectrum Disorders

## **Abstract**

Over-the-counter (OTC) medications are used by various populations as an adjunct to help improve various aspects of life, such as sleep cycles, disease prevention, and mood. The purpose of this study is to compile all of the available data from human trials of over-the-counter medications used in patients with Autism Spectrum Disorders (ASD). OTCs have been used in the treatment of ASD to minimize social impairments, suppress repetitive behaviors, and enhance quality of sleep to improve daytime behaviors. Ultimately, the main objectives of this project are to educate pharmacists and the public (both patients and their families) about the role of over-the-counter medications in the treatment and management of ASD.

## **Disciplines**

Pharmacy and Pharmaceutical Sciences

## **Comments**

Poster presented at the American Society of Health Systems Pharmacy Midyear Clinical Meeting in Anaheim, California, December 2014.

## Objective

Over-the-counter (OTC) medications are used by various populations as an adjunct to help improve various aspects of life, such as sleep cycles, disease prevention, and mood. The purpose of this study is to compile all of the available data from human trials of over-the-counter medications used in patients with Autism Spectrum Disorders (ASD). OTCs have been used in the treatment of ASD to minimize social impairments, suppress repetitive behaviors, and enhance quality of sleep to improve daytime behaviors. Ultimately, the main objectives of this project are to educate pharmacists and the public (both patients and their families) about the role of over-the-counter medications in the treatment and management of ASD.

## Methods

All clinical trials regarding the use of OTC medications in ASD were found using PubMed, MedlinePlus, and primary literature sources found in a public library. From these trials, data was recorded based on the type of study, objective, sample size, the behavior that was measured, and final results and conclusions. After data collection and compilation, materials will be developed for dissemination to pharmacists and the public. This study includes preparing informational pamphlets for parents and care-takers of children with ASD. General information on individual products as well as the clinical data will be included. This information will be disseminated through local ASD organizations and medical providers. Additionally, the collected data will be used to develop a Continuing Education course (CE) for pharmacists.

## Results

### Melatonin

- Hypothesized MOA for ASD:
  - Reduces the amount of time it takes to fall asleep and increases duration of sleep leading to better daytime behavior
- Side effects include:
  - Nightmares and sleep walking
- Studied dose ranges:
  - 0.75mg-25mg

### Vitamin C

- Hypothesized MOA for ASD:
  - Improvements in stereotypical behaviors including rocking, pacing, flapping, and whirling
- Side effects include:
  - Diarrhea, nausea, cramping, and nephrolithiasis
- Studied dose:
  - 114mg/kg/day

### Over-the-Counter Medications used in ASD\*

### Vitamin B<sub>6</sub> & Magnesium

- Hypothesized MOA for ASD:
  - Improvements in speech and language and reduction in hyperexcitability
- Side effects include:
  - Nausea, photosensitivity, peripheral neuropathy (Vitamin B<sub>6</sub>), and diarrhea (Magnesium)
- Studied dose ranges:
  - 2.9-30mg/kg (Vitamin B<sub>6</sub>)
  - 1.4-10mg/kg (Magnesium)

### Omega-3 Fatty Acids

- Hypothesized MOA for ASD:
  - Reduce hyperactivity and mitigate social impairments
- Side effects include:
  - Belching, indigestion, and diarrhea
- Studied dose ranges:
  - 200mg-1.3 g/day

Figure 1: Compiled results of primary literature with OTC use in ASD.

\*Note: this is not a comprehensive list of the OTCs studied in the treatment of ASD.

OTC/Herbal	Number of Studies	Number of Participants	Outcome
Melatonin	39	879	21 out of 39 studies showed improved sleep duration.
Vitamin C	3	37	All studies showed positive result by reducing severity of repetitive behaviors.
Vitamin B <sub>6</sub> and Magnesium	21	493	17 of 21 studies showed some improvement, whereas 4 showed no significant difference
Omega-3 Fatty Acids	11	339	4 studies showed insignificance; all other studies were inconclusive and require larger sample sizes.

Table 1: Summary table of trials studying OTC use in ASD.

## Conclusions

- Data is incomplete based on the number of trials available and the number of ASD participants. Further studies are required prior to any definitive conclusions.
- Future directions:
  - Summaries and informational pamphlets will be distributed to caregivers of children with ASD.
  - Further research will be conducted on the following herbals/OTCs: Vitamin B<sub>12</sub>, Tetrahydrobiopterin, Carnitine, and Vitamin A
  - A CE for pharmacists will be created.

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