

Why is this study important?

This study will generate new knowledge about a safe and potentially effective treatment for core symptoms of autism. This may benefit the autism community because current treatment options are limited.



How will privacy be protected?

Records of participation in this research project will be kept and will not be released without prior authorization.

All information obtained during this study, including identity, will be safe guarded. A research number will be assigned to each participant, and names will not be used. We will store all records in locked files in a locked room that only the research team has access to. Any information kept on a computer will be kept in password protected files which are accessible only to authorized staff members.

If you or someone you know may be interested in participating in this study, please contact:

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BENEFITS OF BROCCOLI EXTRACT IN YOUNG MEN WITH AUTISM



**Funded by the
Nutrition Research
Institute**



The Purpose of This Study

The purpose of this research study is to explore possible benefits of a broccoli extract supplement (sulforaphane) for young men with autism. Young broccoli plants contain high levels of something called sulforaphane, which has health protective benefits, like reducing inflammation and increasing the body's natural antioxidants. In other studies, sulforaphane has been found to be very safe with few side effects.

In this study, our goal is to see if taking the supplement could improve social communication and behaviors in people with autism. Participation entails "blinded" assignment to receive either a daily broccoli extract supplement or a sugar pill (i.e., placebo) over approximately 5 months.

Participants Needed

- Young men between 13 and 30
- Diagnosed with autism
- Primarily English speaking
- A parent/caregiver who can participate

What will happen in this study?

A Pre-Screen Phone Call:

Duration: approx. 30 mins

This is to determine that basic eligibility requirements are met. Eligible families will be sent a caregiver informed consent document to review prior to the screening visit.

All appointment visits will be held at the CIDD.

Screening Visit:

Duration: approx. 3 hrs.

The visit will include informed consent, diagnostic assessments, questionnaires, baseline vitals and lab work collection, and a physical exam performed by the study physician. Interviews will be conducted with participants and their caregivers.

Week 0 Baseline Visit:

Duration: approx. 1.5 hrs.

The visit will take place 2 weeks after the screening visit. It will include informant questionnaires and vitals. Participants will be randomly assigned the sulforaphane supplement or the identical placebo tablets during this visit.

Week 2 Telephone Call:

Duration: approx. 20 mins

This call will be conducted by the study physician to assess tolerability and general response.

Weeks 4 and 8 Follow-Up Visits:

Duration: approx. 1 hr.

Each of these visits includes a physician interview, informant questionnaires, and vitals.

Week 12 Follow-Up Visit:

Duration: approx. 1.5 hrs.

This visit will mark the end of the active treatment phase of the study. It will include lab work, a physician interview, informant questionnaires, and vitals.

Week 16 Final Study Visit:

Duration: approx. 1 hr.

This follow up visit will occur 4 weeks after discontinuing the investigational treatment. This visit will include a physician interview, informant questionnaires, and vitals.

Are there benefits offered for participation?

Caregivers will receive \$30 per visit to assist with travel expenses, and participants will receive \$20 per visit as a token of appreciation.



We will also offer an opportunity to register to receive the Carolina Institute for Developmental Disabilities quarterly newsletter. This publication keeps families up to date on clinical services, research developments, and educational opportunities being offered at the CIDD.

Whom should I contact?

For more information, please contact Jessica Blanks at 919-962-8462 or by email: Jessica.Blanks@cidd.unc.edu