Your participation may help us to learn how certain kinds of mental health problems begin how to identify those most at risk and in need of early treatment.



To discuss participation or to receive more information, contact:

Corin 617.754.1224 cpilo@bidmc.harvard.edu

Participation is Confidential

It is important to us that you understand everything involved in your participation, and the potential benefits and risks of your participation.

Key Study Staff:

Principal Investigator: Larry Seidman, Ph.D. Project director: Kristen Woodberry MSW, Ph.D. Recruiter: Corin Pilo, L.M.H.C. Study Coordinators: Chelsea Wakeham, B.A. & Rachael Serur, B.S.

> Study Clinicians: Ann Cousins, A.P.R.N, Ph.D. Janine Rodenhiser-Hill, Ph.D. Michelle Friedman-Yakoobian, Ph.D. Andrea Gnong Granato, L.C.S.W. Raquelle Mesholam-Gately Ph.D. Joanne D. Wojcik, A.P.R.N., Ph.D. Bill Stone, Ph.D. Kyle Minor, Ph.D. Tory Choate, M.A.



HARVARD MEDICAL SCHOOL

Mental Health, Brain Development & Omega-3 in Youth and Young Adults





Monitoring and Treatment studies of adolescents and young adults experiencing recent changes in their thoughts, feelings and/or behavior.

Contact: 617.754.1224

Version 10.17.12

This clinical research study is dedicated to addressing the earliest signs of mental and emotional problems in youth and young adults. Could you or someone you know be at risk?

Who can Participate?

Adolescents or Young Adults (ages 12-35) with some of the following difficulties that have *begun or worsened in the past year*

- Worrisome drop in grades or work performance
- Having trouble thinking clearly, focusing, or concentrating
- Suspiciousness or uneasiness with others
- Decline in self-care or personal hygiene
- Withdrawal from friends or family —spending a lot of time alone
- Increased sensitivity to sights or sounds, or mistaking noise for voices or messages
- Having ideas that others may find unusual or too intense
- Having strange feelings or no feelings at all
- Feeling like your mind is playing tricks on you
- * Especially if there is a family member with mental illness or psychosis.



What's Involved?

An initial screening evaluation with a clinician to discuss your history & any changes in your thinking, feelings & behavior

Eligible participants will be asked to enroll in **two** related studies::

- 1) The Monitoring Study involves Baseline, 6- & 12month assessments which include:
- Personal Interviews about your history & experiences
- An interview with a family member to understand your family history (with your permission)
- Paper & Pencil and computerized tests of your attention & memory
- Collection of saliva & blood
- Brain Magnetic Resonance Imaging (MRI) scan
- Electroencephalogram (EEG) of your brain
- The goal of the Treatment Study is to see if Omega-3 improves symptoms & functional outcomes in youth with new changes in thinking, feeling, or functioning

Eligible participants will be randomized to 6-months of Omega-3 or placebo (sugar) pills.

Monthly assessments will include:

- Personal interviews about your history & experiences
- Symptom and side effect monitoring
- Vital signs, heart rate, weight & waist measurements

The 6-Month Assessment of the Treatment study will also include additional MRI, EEG and Paper & Pencil testing.

There is no cost to participate. In addition to the study medication, all participants can receive up to 6 months of case management, as needed.

<u>Payment</u>

If all assessments are completed for both studies, you will be paid up to a total of \$1,045 for your participation.

Will I get feedback?

Study staff will provide feedback to participants, their families and, with your permission, to doctors, clinicians, or school personnel. Our study team will evaluate each participant's clinical status at each assessment and, when indicated, make recommendations and referrals for treatment, including to our affiliated CEDAR clinic, which offers a range of services (www.cedarclinic.org).



You may not be able to participate if...

- You have a seafood or soy allergy
- You have taken Omega-3 supplements *regularly* in that past 3 months
- You have been on certain prescription medications in the past 1 month

